PUBLIC VERSION

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Paper 19
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UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

BIONTECH SE AND PFIZER INC.,
Petitioners,

v.

MODERNA TX INC.,
Patent Owner.

IPR2023-01358
Patent 10,702,600 B1

Before SHERIDAN K. SNEDDEN, TIMOTHY G. MAJORS, and DAVID COTTA, *Administrative Patent Judges.*

COTTA, *Administrative Patent Judge*

DECISION
Granting Institution of *Inter Partes* Review and
Granting the Parties' Respective Motions to Seal
Granting Request to Enter Protective Order
35 U.S.C. § 314; 37 C.F.R. § 42.14, 42.54

I. INTRODUCTION

BioNTech SE and Pfizer Inc. (collectively "Petitioner") filed a Petition to institute an *inter partes* review ("IPR") of claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 (the "challenged claims") of U.S. Patent No. 10,702,600 B1 ("the '600 patent"). Paper 3 ("Petition" or "Pet."). Moderna Tx, Inc. ("Patent Owner") filed a Preliminary Response. Paper 8 ("Prelim. Resp."). With our prior authorization, Petitioner filed a Reply to Patent Owner's Preliminary Response (Paper 9, "Prelim. Reply") and Patent Owner filed a Sur-reply (Paper 14, "Prelim. Sur-reply"). Also with our prior authorization, Patent Owner and Petitioner filed statements regarding Patent Owner's allegedly inconsistent positions (Papers 10 and 13).

Under 35 U.S.C. § 314(a), *inter partes* review may not be instituted unless the Petition "shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." Petitioner has established a reasonable likelihood of prevailing on its assertion that the challenged claims are unpatentable based on the grounds advanced here. We decline to deny the Petition on a discretionary basis as requested by Patent Owner. Thus, for reasons explained below, we institute *inter partes* review of claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 of the '600 patent.

Findings and conclusions at this stage are preliminary and based on the current record. Any final decision will be based on a full trial record.

A. Real Parties-in-Interest

Petitioner identifies BioNTech SE, BioNTech US Inc., BioNTech Manufacturing GmbH, and Pfizer Inc. as the real parties-in-interest. Pet. 3.

Patent Owner identifies itself and Moderna US, Inc. as the real parties-in-interest. Paper 6, 1.

B. Related Matters

The parties identify as a related matter the following lawsuit involving the '600 patent (and other patents): *ModernaTX, Inc. et al. v. Pfizer Inc., BioNTech SE, et al.*, 1:22-cv-11378-RGS (D. Mass) (hereafter "Massachusetts Litigation"); Pet. 3; Paper 6, 1.

Petitioner also identifies U.S. Application No. 16/880,829, which application issued in 2021 as U.S. Patent No. 10,933,127 ("the '127 patent"). Pet. 3. Patent Owner states that the '127 patent is also asserted in the Massachusetts Litigation. Paper 6, 1–2 (listing, as related, several other patents and applications). Claims of the '127 patent are challenged in IPR2023-01359 (Paper 6, 1; Pet. 3), in which we institute trial concurrent with this decision.

C. The '600 Patent

The '600 patent is titled "Betacoronavirus mRNA Vaccine." Ex. 1001, code (54) (capitalization omitted). The '600 issued from an application filed February 28, 2020. *Id.* at code (22). The '600 patent further claims priority to several other, earlier-filed applications, including non-provisional applications filed in 2017 and 2018 that issued as U.S. Patent Nos. 10,272,150 ("the '150 patent") and 10,064,934 ("the '934 patent"). *Id.* at code (63). The '600 patent also claims priority to nine provisional applications, the earliest of which were filed October 22, 2015. *Id.* at code (60).

According to the '600 patent, "[r]espiratory disease is a medical term that encompasses pathological conditions affecting the organs and tissues that makes gas exchange possible in higher organisms." *Id.* at 1:27–32 (explaining that such disease includes, for example, conditions of the upper respiratory tract, bronchi, alveoli, and the nerves and muscles that affect breathing). Further, the patent explains, "[r]espiratory disease is a common and significant cause of illness and death around the world." *Id.* at 1:35–37.

The '600 patent provides, as background, an overview of various viruses and the respiratory diseases that such viruses may cause. *Id.* at 1:27–3:9. The '600 patent identifies, among other viruses, Parinfluenza virus type 3 (PIV3), Respiratory Syncytial Virus (RSV), and Betacoronaviruses (BetaCoVs). *Id.* (explaining that PIV3 and RSV are negative-sense, single-stranded RNA viruses of the *Pneumovirinae* genus). Regarding Betacoronaviruses, the '600 patent states:

> Betacoronviruses (BetaCoVs) are one of four genera of coronaviruses of the subfamily Coronavirinae in the family Coronaviridae . . . . They are enveloped, positive-sense, single-stranded RNA viruses of zoonotic origin. . . . The BetaCoVs of the greatest clinical importance concerning humans are OC43 and HKU1 of the A lineage, SARS-CoV of the B lineage, and MERS-CoV of the C lineage.

Id. at 2:47–57. The '600 patent notes the prior reported outbreaks of MERS-CoV between 2012 and 2015. *Id.* at 2:60–35. Further, the '600 patent reports that SARS "emerged in China in 2002 and spread to other countries before [being] brought under control." *Id.* at 3:4–6. However, "[b]ecause of a concern for reemergence or a deliberate release of the SARS coronavirus, vaccine development was initiated." *Id.* at 3:6–8.

In summarizing the invention, the '600 patent states:

> Provided herein are ribonucleic acid (RNA) vaccines that build on the knowledge that RNA (e.g., messenger RNA (mRNA)) can safely direct the body's cellular machinery to produce nearly any protein of interest, from native proteins to antibodies and other entirely novel protein constructs that can have therapeutic activity inside and outside of cells. The RNA (e.g., mRNA) vaccines of the present disclosure may be used to induce a balanced immune response against hMPV, PIV, RSV, MeV, and/or BetaCoV (e.g., MERS-CoV, SARS-CoV, HCoV-OC43, HCoV-229E, HCoV-NL63, HCoV-NL, HCoV-NH and/or HCoV-HKUl), or any combination of two or more of the foregoing viruses, comprising both cellular and humoral immunity, without risking the possibility of insertional mutagenesis[.]

Id. at 3:24–37. According to the '600 patent, "[t]he RNA (e.g., mRNA) vaccines have superior properties in that they produce much larger antibody titers and produce responses earlier than commercially available anti-viral therapeutic treatments." *Id.* at 3:56–59. Moreover, the '600 patent explains, "[u]nlike traditional vaccines, which are manufactured ex vivo and may trigger unwanted cellular responses, RNA (e.g., mRNA) vaccines are presented to the cellular system in a more native fashion." *Id.* at 3:64–3:67.

More specifically, the '600 patent states that, in embodiments, the BetaCoV is, for example, MERS-CoV or SARS-CoV, and the vaccine comprises at least one mRNA polynucleotide that encodes a BetaCoV antigenic polypeptide. *Id.* at 7:15–23. The encoded BetaCoV polypeptide may be a structural protein such as a spike protein (S) or a subunit or immunogenic fragment thereof. *Id.* at 7:25–28; *see also id.* at 213:57–214:10 (Example 23, mouse study using an mRNA vaccine encoding

MERS-CoV spike protein and subunit), 214:11–214:66 (Example 24, rabbit study using mRNA vaccine encoding MERS-CoV spike protein). The '600 patent also discloses that the vaccine may comprise the mRNA polynucleotide formulated in a cationic lipid nanoparticle. *Id.* at 4:1–5.

D. Challenged Claims

The '600 patent includes 26 claims, of which claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 are challenged here. Claim 1 is illustrative of the subject matter of the challenged claims and is reproduced below.

> 1. A composition, comprising: a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle.

Ex. 1001, 737:26–29.

E. Asserted Grounds of Unpatentability

Petitioner asserts that claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 would have been unpatentable on the following grounds:

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1, 2, 4–6, 8–12, 16, 17, 20, 21, 26	102(a)	Schrum[2]

[1] The Leahy-Smith America Invents Act ("AIA"), Pub. L. No. 112–29, 125 Stat. 284, 285–88 (2011), revised 35 U.S.C. §§ 102, 103 effective March 16, 2013. Petitioner asserts that the earliest date to which '600 patent claims priority is October 22, 2015. Pet. 2–3. Because that date falls after the effective date of the applicable AIA amendments, we apply the AIA versions of §§ 102 and 103 here.

[2] de Fougerolles et al., US 2013/0266640 A1, publ. Oct. 10, 2013 (Ex. 1009 ("Schrum")). Because the parties refer to this reference as "Schrum" rather than by the name of the first listed author, we do the same.

Claim(s) Challenged	35 U.S.C. §[1]	Reference(s)/Basis
1, 2, 4–6, 8–12, 16, 17, 20, 21, 26	103	Schrum, Geall[3]
1, 2, 4–6, 8–12, 16, 17, 20, 21, 26	103	Schrum, Yang[4]
1, 2, 4–6, 8–12, 16, 17, 20, 21, 26	103	Schrum, Altmeyer[5]

Petitioner relies on the declarations of Dr. Daniel O. Griffin (Ex. 1002) and Dr. James J. Moon (Ex. 1004).

II. EXERCISE OF DISCRETION

Patent Owner contends that we should exercise our discretion to deny institution because "Petitioner presents the same invalidity positions in parallel litigation between the same parties, in which trial is likely to be completed months before a Final Written Decision in this proceeding." Prelim. Resp. 16. Additionally, Patent Owner argues that Petitioner relies on substantially the same prior art as was considered during patent prosecution with no showing that the Examiner materially erred in granting the '600 patent. *Id.* at 25. We address these issues below.

A. Discretion under 35 U.S.C. § 325(d)

The Board has discretion under 35 U.S.C. § 325(d) to reject a petition when the same or substantially the same prior art or arguments were

[3] Geall, WO 2012/006369 A2, publ. Jan. 12, 2012 (Ex. 1010 ("Geall")).
[4] Zhi-yong Yang et al., *A DNA vaccine induces SARS coronavirus neutralization and protective immunity in mice*, 428 Nature 561–564 (Apr. 1, 2004) (Ex. 1011 ("Yang")).
[5] Altmeyer et al., WO 2005/118813 A2, publ. Dec. 15, 2005 (Ex. 1012 ("Altmeyer")).

presented previously in another proceeding before the Office. The relevant portion of that statute reads:

> In determining whether to institute or order a proceeding . . . , the Director may take into account whether, and reject the petition or request because, the same or substantially the same prior art or arguments previously were presented to the Office.

35 U.S.C. § 325(d). In evaluating whether to deny institution under 325(d), the Board has considered several non-exclusive factors: (a) the similarities and material differences between the asserted art and the prior art involved during examination; (b) the cumulative nature of the asserted art and the prior art evaluated during examination; (c) the extent to which the asserted art was evaluated during examination; (d) the extent of the overlap between the arguments made during examination and the manner in which a petitioner relies on the prior art or a patent owner distinguishes the prior art; (e) whether a petitioner has pointed out sufficiently how the Office erred in evaluating the asserted prior art; and (f) the extent to which additional evidence and facts presented in the petition warrant reconsideration of the prior art or arguments. *See Becton, Dickinson & Co. v. B. Braun Melsungen AG*, IPR2017-01586, Paper 8 at 17–18 (PTAB Dec. 15, 2017) (precedential as to § III.C.5, first para.).

Factors (a), (b), and (d) relate to whether the art or arguments in the Petition are the same or substantially the same as those previously presented to the Office. *Advanced Bionics, LLC v. MED-EL Elektromedizinische Geräte GmbH*, IPR2019-01469, Paper 6 at 10 (PTAB Feb. 13, 2020) (precedential) ("*Advanced Bionics*"). Factors (c), (e), and (f) "relate to

whether the petitioner has demonstrated a material error by the Office" in the Office's prior consideration of that art or arguments. *Id.*

Under *Advanced Bionics*'s two-part framework, we first determine whether the same or substantially the same art or arguments previously were presented to the Office. *Id.* at 8, 10. If "either condition of [the] first part of the framework is satisfied," we then determine whether material error by the Office has been shown. *Id.* at 8, 10.

Patent Owner argues that the first part of the *Advanced Bionics* framework is met because Petitioner's prior art and arguments are the same as, or cumulative to, the art and argument that were considered during prosecution of the '600 patent or related patents. Prelim. Resp. 25–35; Prelim. Sur-reply 6–8.

Patent Owner contends that Schrum was submitted during prosecution of the '600 patent in an Information Disclosure Statement ("IDS") and that Schrum and Geall were cited in IDSs during prosecution of the '127 patent. Prelim. Resp. 25 (citing Ex. 1008, 488), 26 (citing Ex. 2016, 468, 536). And, Patent Owner contends that Yang is cumulative to another reference (Nabel, Ex. 2020) also cited in an IDS during prosecution of the '127 patent. *Id.* at 26 (citing Ex. 1008, 536).

Patent Owner contends that, during prosecution of the related '934 and '599 patents, applicant traversed obviousness rejections over a combination of Haller (Ex. 2022), Geall 2012 (Ex. 2021), and the '482 Publication (Ex. 2019). Prelim. Resp. 26–27; Ex. 2017, 1137–1157 (Office Action), 1165–1170 (applicant's responsive remarks), 1202–1206 (Notice of Allowance); Ex. 2018, 431–447 (Office Action), 454–459 (applicant's

responsive remarks), 482–485 (Notice of Allowance). According to Patent Owner, Schrum (asserted by Petitioner in this proceeding) and the '482 Publication are both Moderna patent applications that include many overlapping disclosures and incorporate Geall in substantially the same way. Prelim. Resp. 29 ("Like Schrum, the '482 Publication focuses on mRNA for therapeutic proteins, not vaccines."); *compare* Ex. 1009 ¶ 342, *with* Ex. 2019 ¶ 929.[6] Patent Owner contends that the Examiner relied on Geall 2012 as teaching lipid nanoparticle formulations similar to how Petitioner relies on Geall here as teaching those limitations. Prelim. Resp. 30–31. And, Patent Owner contends, Petitioner's asserted Altmeyer reference teaches "viral vector vaccines" and is "substantially similar" to Haller, which was cited by the Examiner during prosecution of the '934 and '599 patents. *Id.* at 32–33.

Petitioner, for its part, argues that discretionary denial is not justified. Pet. 68–70; Prelim. Reply 5–8. Petitioner contends that Schrum and Geall, although identified in IDSs among hundreds of other references, were not substantively considered by the Examiner. Pet. 69. Petitioner contends that Yang and Altmeyer were not previously before the Office. *Id.* at 68–69. And, Petitioner argues that the Examiner erred, having raised no prior art rejections against the claims of the '600 patent, including no rejection based on Schrum and Geall. *Id.* at 69–70; Ex. 1008, 448–454 (enablement rejection); Prelim. Reply 5–8 (suggesting the Office erred in overlooking the art's material disclosures as cited in the Petition's grounds, and asserting that

[6] The '482 Application is also referred to as "Bancel" during the relevant prosecutions. *See, e.g.*, Ex. 2018, 440–441, 456–457.

the prosecution of related patents involved combinations of different references and different claims).

For purposes of our analysis and satisfaction of the first part of the *Advanced Bionics* framework, we will assume that the Office was previously presented with substantially the same or otherwise cumulative prior art.[7] There is no dispute here that Schrum, Geall, and Nabel (allegedly cumulative to Yang[8]) were identified on examiner-signed IDSs. That is sufficient to establish that such art was previously presented to the Office. *Advanced Bionics* at 7–8 ("Previously presented art includes art made of record by the Examiner, and art provided to the Office by an applicant, such as on an Information Disclosure Statement (IDS), in the prosecution history of the challenged patent").

Whether Altmeyer is cumulative is a closer call. Petitioner contends that Altmeyer is distinct from Haller because Altmeyer describes nucleic acid molecules that encode a SARS CoV spike protein, whereas Haller does not. Prelim. Reply. 7. Even if that is true, Patent Owner contends the key issue is not the immunogen targeted in Altmeyer or Haller but the

[7] We will also assume, for this analysis, that art and arguments raised during prosecution of the parent '599 and '934 patents can be considered in determining whether the challenge to the child '600 patent should be denied on the basis of discretion under § 325(d). *Cf. Apple, Inc. v. Seven Networks*, LLC, IPR2020-00266, Paper 12 at 23–24 (PTAB Aug. 14, 2020) (assuming the claims at issue were patentably indistinct from those of a related application and moving to the second part of *Advanced Bionics* based on art and arguments presented during prosecution of the child application).
[8] Petitioner provides no counterargument to Patent Owner's contention that Yang is cumulative to Nabel. *See generally* Prelim. Reply.

references' overlap in vaccine delivery—viral vector, not mRNA polynucleotides, in both references. Prelim. Sur-reply 8. Again, for purposes of this analysis, we will assume Patent Owner's assertion of cumulativeness is accurate.

If either condition (substantially the same art or arguments) of the first part of the *Advanced Bionics* framework is met, the Board generally proceeds to the second part of that framework and determines whether the Office erred. Before we do so, however, we note that, on balance, substantially the same arguments as raised by Petitioner here *were not* previously presented to the Office during prosecution of the related '599 and '934 patents. Schrum and Geall were never asserted by the Examiner in any rejection during those prosecutions. Inasmuch as Patent Owner contends that Schrum and the '482 Publication are cumulative in their teachings, the way Schrum is applied here versus how the '482 Publication was applied during prosecution differs materially. The '482 Publication was cited only for its teachings about RNA encoding 5′ terminal caps and modifications to the uracil content of mRNA, as recited in certain dependent claims of the related patents. *See, e.g.*, Ex. 2018, 440–442, 449 (claims 137–139[9]). The '482 Publication was not cited as an anticipatory reference, nor was it cited in any obviousness rejection as teaching or suggesting a use of mRNA vaccines, much less mRNA vaccines that encode viral immunogens, such as argued by Petitioner here with respect to the allegedly cumulative Schrum

[9] The rejected claims required an RNA polynucleotide and were amended, after the Examiner's rejection, to require, inter alia, an "(mRNA)" polynucleotide. *See, e.g.*, Ex. 2018, 449.

reference. *See, e.g.*, Pet. 22–42. In fact, during prosecution of the related patents, applicant sought to distinguish Haller, and Geall 2012 as related, respectively, to vaccines comprising chimeric PIV (parainfluenza) viruses, self-amplifying RNA, and siRNA—not, according to applicant, mRNA vaccines like claimed.[10] *See, e.g.*, Ex. 2018, 454–457 (arguing "none of the references of record teaches or suggests mRNA polynucleotides used as components of a vaccine" and arguing that the '482 Publication "does not make up for the deficiencies of" Haller, etc.). Neither Examiner nor applicant grappled during prosecution with Petitioner's argument in this case that Schrum (or the '482 Publication, if it is cumulative) discloses mRNA-based vaccines, contrary to what applicant suggested was missing in the references of record.

Patent Owner nonetheless contends that the arguments about the '482 Application are the same as Petitioner's arguments about Schrum. Prelim. Resp. 29–30. According to Patent Owner, "Moderna distinguished the '482 Publication because it relates to 'methods of protein production, ***not to viral vaccines***.'" *Id.* (quoting Ex. 2018, 456 (with Patent Owner's emphasis)). And, Patent Owner argues, "Petitioner likewise relies on Schrum as

[10] There are also differences in the claims at issue during prosecution of the '599 and '934 patents. For example, during prosecution of the '934 patent, the Examiner determined that "[t]he claims as written do not exclude mRNA that is within a viral particle." Ex. 2018, 466 (interview summary discussing applicant's arguments on Haller). This prompted applicant to amend the claims further to recite "an isolated messenger ribonucleic acid (mRNA)." *Id.* at 468; *see also* Ex. 2017, 1208 (similarly reciting "an isolated messenger ribonucleic acid (mRNA)"). The "isolated" language is missing in the challenged claims here.

purportedly teaching viral vaccines." *Id.* at 30 (citing, e.g., Pet. 21–23). Patent Owner is conflating different issues. "[V]iral vaccines," in the context that the term was used in the cited prosecution history was plainly referencing the vaccine delivery vehicle of Haller—engineered viral vaccines (and not mRNA), according to applicant. Ex. 2018, 454–456 (arguing that the "vaccine formulations of Haller et al., comprise chimeric PIV ***viruses***" and, in Haller, any cDNA or RNA constructs are "not components of a vaccine" and instead "are packaged with virus and amplified in Vero cells" before "[t]he engineered ***virus*** . . . [is] used as a vaccine against a viral infection"). Indeed, the quote in full related to whether a POSA would have been motivated to combine the '482 Application with the other references, which applicant argued a POSA would not, because the '482 Application "relates to methods of protein production, not to viral vaccines of Haller et al., self-replicating vaccines of Geall et al., or siRNA molecules of Heyes, et al." *Id.* at 456.[11] In contrast, Petitioner here is arguing that Schrum discloses mRNA vaccines that encode for immunogenic viral proteins. *See, e.g.*, Pet. 21–23.

Turning to the second part of the *Advanced Bionics* framework, based on the present evidentiary record, we determine that the Office materially erred in allowing the challenged claims. Even if the Office was previously presented with Schrum and Geall, there is no indication that the Examiner appreciated the full scope of their disclosure. Further, as explained in § III,

[11] Insofar as applicant's argument suggests that the '482 Application's relevant teachings were limited to "protein production" and not vaccines, the argument is also wrong, as we discuss below.

we find that the merits of Petitioner's showing at this stage for at least Ground 2 are compelling based on the alleged obviousness of the challenged claims over the combined teachings of Schrum and Geall. The strength of Petitioner's threshold showing on this ground supports a conclusion that the Office erred in overlooking those references' material teachings in route to allowing the claims of the '600 patent without a single prior art rejection being made.

In arguing the absence of any Office error, Patent Owner again relies heavily on the Office's consideration of allegedly cumulative art in earlier prosecution of related patents. Prelim. Resp. 34–35; Prelim. Sur-reply 6–8. This argument does not withstand scrutiny. Indeed, the Office's consideration of the cited art in related prosecutions (assuming the art is cumulative) supports a finding of material error. As we discussed above, during prosecution of the related patents, applicant suggested that the references of record, including Haller, Geall 2012, and the '482 Application did not teach mRNA polynucleotides used for vaccines. *See, e.g.*, Ex. 2018, 454–457. But that is not accurate. At least the '482 Application, similar to Schrum, *does disclose* mRNA vaccines—at least one section of the reference is devoted to this topic. Ex. 2019 ¶¶ 928–937 (disclosing, for example, mRNA that may encode an immunogen and be delivered in an amount sufficient to be immunogenic in a vertebrate, and may, for example, encode all or a part of a positive- or negative-sense stranded RNA virus genome).

Applicant's position was, thus, contradicted by disclosure in the '482 Application that the Examiner seemingly overlooked.[12]

Patent Owner argues that the Examiner's "silence is ***insufficient*** to show material error." Prelim. Resp. 34. That may be true under some circumstances, but is not always so. The Examiner's silence in response to an assertion from applicant that is plainly refuted by disclosure in the references of record suggests that the Examiner overlooked such disclosure and demonstrates error. As we discuss herein, we determine that Petitioner has established a reasonable likelihood of prevailing on the merits of at least Ground 2. Even if Schrum and Geall were before the Office (as having been cited in IDSs, but not applied in any rejection), we find that the Office erred in overlooking those references' relevant teachings. We also have expert testimony from Drs. Griffin and Moon on Ground 2 that is presently unrebutted—evidence that was not before the Office previously. This additional evidence further undermines the case for discretionary denial. Lastly, to the extent Patent Owner relies on the prosecution histories of related patents, as we explained above, those histories suggest that key

[12] Applicant also stated during prosecution of the '934 patent that the '482 Application "relates to methods of protein production" and not, "self-replicating vaccines of Geall [2012]." Ex. 2018, 456. This too is undermined by the '482 Application, which does not concern only generic "protein production" as asserted; the reference includes a section describing mRNA vaccines and further, in that section, cites approvingly to the vaccine formulations in Geall 2012. *See, e.g.*, Ex. 2019 ¶ 933. The notion that the '482 Application is unrelated to Geall 2012's vaccines or that Geall 2012 "teaches away" from mRNA vaccines (as argued during prosecution) is in tension with the '482 Application itself (an application filed and owned by Patent Owner). Ex. 2019, codes (71), (73); Ex. 2017, 1166–1167.

disclosures in the '482 Application (for which Schrum is allegedly cumulative) were overlooked, and that oversight likely carried forward into the '600 patent's prosecution.

For the reasons above and based on the record before us, we conclude that the Office materially erred in allowing the challenged claims. We, therefore, decline to deny the Petition under § 325(d).

B. Discretion Under 35 U.S.C. § 314(a)— Fintiv

Institution of an *inter partes* review is discretionary. *See* 35 U.S.C. § 314(a) (authorizing institution of an *inter partes* review under particular circumstances, but not requiring institution under any circumstances); *Cuozzo Speed Techs., LLC v. Lee*, 579 U.S. 261, 273 (2016) ("[T]he agency's decision to deny a petition is a matter committed to the Patent Office's discretion."); *SAS Inst. Inc. v. Iancu*, 138 S. Ct. 1348, 1356 (2018) ("[Section] 314(a) invests the Director with discretion on the question whether to institute review . . . ." (emphasis omitted)).

In the Preliminary Response, Patent Owner contends that we should exercise our discretion to deny the Petition because the Massachusetts Litigation will likely to be completed months before a Final Written Decision in this proceeding. Prelim. Resp. 16–25.

When determining whether to exercise discretion to deny institution in view of a parallel proceeding, we consider the following factors:

1. whether the court granted a stay or evidence exists that one may be granted if a proceeding is instituted;
2. proximity of the court's trial date to the Board's projected statutory deadline for a final written decision;

3. investment in the parallel proceeding by the court and the parties;
4. overlap between issues raised in the petition and in the parallel proceeding;
5. whether the petitioner and the defendant in the parallel proceeding are the same party; and
6. other circumstances that impact the Board's exercise of discretion, including the merits.

Apple Inc. v. Fintiv, Inc., IPR2020-00019, Paper 11 at 5–6 (PTAB Mar. 20, 2020) (precedential) ("*Fintiv*"). "These factors relate to whether efficiency, fairness, and the merits support the exercise of authority to deny institution in view of an earlier trial date in the parallel proceeding." *Id.* In evaluating these factors, we "take[] a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review." *Id.* at 6. We consider each of these factors below.

On June 21, 2022, the Director of the United States Patent and Trademark Office issued a Memorandum setting forth an "Interim Procedure for Discretionary Denials in AIA Post Grant Proceedings with Parallel District Court Litigation." ("Guidance Memo"). The Guidance Memo states that "to benefit the patent system and the public good, the PTAB will not rely on the *Fintiv* factors to discretionarily deny institution in view of parallel district court litigation where a petition presents compelling evidence of unpatentability." *Id.* at 2. "Compelling, meritorious challenges are those in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence." *Id.* at 4.

With these *Fintiv* factors and the Director's guidance in mind, we consider the parties' contentions.

In the analysis that follows, we first consider whether *Fintiv* factors 1–5 weigh in favor of exercising our discretion to deny institution. For the reasons discussed below, we conclude that *Fintiv* factors 1–5 weigh in favor of denying institution. Because *Fintiv* factors 1–5 favor denial of institution, we must also determine whether the Petition presents compelling merits. *See CommScope Techs. LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 4 (PTAB Feb. 27, 2023) (precedential) ("In circumstances where . . . the Board's analysis of *Fintiv* factors 1–5 favors denial of institution, the Board shall then assess compelling merits.").

1. *Likelihood of a Stay (Factor 1)*

Fintiv factor 1 recognizes that a stay of litigation pending resolution of the PTAB trial allays concerns about inefficiency and duplication of efforts, which strongly weighs against exercising the authority to deny institution. *Fintiv*, Paper 11 at 6.

Petitioner argues that this factor is neutral, asserting that "the Board need not speculate as to the likelihood of the district court entering a stay." Pet. 66. Patent Owner asserts that Petitioner has not requested a stay of the Massachusetts Litigation and there is no evidence that a stay would be granted. Prelim. Resp. 17–18. Patent Owner points to the advanced stage of the Massachusetts Litigation (*see infra* § II.B.3) and the fact that Petitioner did not file an IPR challenging one of the three patents asserted in that litigation as supporting that "[t]his factor favors denying institution, or is at least neutral." *Id.*

We decline to speculate on how the court may rule on a motion for a stay should one be filed. Accordingly, this factor is neutral. *Apple Inc. v.*

Fintiv, Inc., IPR2020-00019, Paper 15 at 12 (PTAB May 13, 2020) (informative) (explaining that factor 1 generally "does not weigh for or against discretionary denial" when neither party has requested a stay).

2. *Proximity of Trial Date to Projected Deadline (Factor 2)*

Fintiv factor 2 looks to the "proximity of the court's trial date to the Board's projected statutory deadline." *Fintiv*, Paper 11 at 9. The Board's projected statutory deadline for reaching a final written decision in this matter is early March 2025. The estimated date for trial before the district court is discussed further below.

As explained in *Fintiv*, "[i]f the court's trial date is earlier than the projected statutory deadline, the Board generally has weighed this fact in favor of exercising authority to deny institution." *Id.* The Guidance Memo recognizes that "[a] court's scheduled trial date . . . is not by itself a good indicator of whether the district court trial will occur before the statutory deadline for a final written decision." Guidance Memo, 8. The Guidance Memo thus authorizes the parties to "present evidence regarding the most recent statistics on median time-to-trial for civil actions in the district court in which the parallel litigation resides" and instructs the Board to consider such information along with "additional supporting factors such as the number of cases before the judge in the parallel litigation and the speed and availability of other case dispositions." *Id.* at 8–9 (footnote omitted).

Here, the Massachusetts Litigation was filed in August 2022, but a trial date has not been set because Judge Stearns's practice is not to set a trial date until dispositive and *Daubert* motions are decided. Prelim. Resp. 18–

19. Briefing on dispositive and *Daubert* motions is set to conclude in the Massachusetts Litigation on July 26, 2024. *Id.* at 19.

Petitioner argues that this factor is neutral "because trial is not yet scheduled." Pet. 67. In projecting when trial will occur, Petitioner directs us to the median time to trial statistics for the period from 2018–2023, which is 32.2 months. Prelim. Reply 3–4 (citing Ex. 2013). Petitioner also argues that Judge Stearns has had only two patent cases in the last ten years, and in those cases, the times between the filing and resolution of [dispositive pre-trial] motions were 294 days and 168 days. *Id.* at 4 n.3.

Patent Owner argues that this factor "strongly favors denying institution." Prelim. Resp. 18–19. As support, Patent Owner directs us to the median time for the 12-month period ending in June 2023—26.0 months—and argues that this would result in a trial date "around October 2024." *Id.* at 18–19 (citing Ex. 2013). In addition, Patent Owner argues that "Judge Stearns has expeditiously decided motions in the case, for example, issuing a *Markman* order just five days after the hearing." *Id.* As to the two patent cases Petitioner relies upon as predictive of how long it will take Judge Stearns to resolve dispositive motions, Patent Owner argues that one of those cases should be disregarded as "not representative because briefing concluded just before the pandemic." Prelim. Sur-reply 3–4. Patent Owner asserts that the other of Judge Stearns' patent cases is "[m]ore analogous" and, in that case, Judge Stearns issued orders "2.5 months after briefing ended." *Id.* at 4 (emphasis omitted). According to Patent Owner, assuming 2.5 months to resolve dispositive motions would result in trial date in late 2024.

We begin our analysis by considering the median time-to-trial statistics. Both parties rely on data from the table reproduced below.

U.S. District Court — Judicial Caseload Profile

MASSACHUSETTS

			12-Month Periods Ending					
			Jun 30 2018	Jun 30 2019	Jun 30 2020	Jun 30 2021	Jun 30 2022	Jun 30 2023
Median Time (Months)	From Filing to Disposition	Criminal Felony	14.0	12.9	12.7	16.9	21.8	26.1
		Civil [2]	19.4	27.2	11.0	12.2	10.0	10.0
	From Filing to Trial [2] (Civil Only)		34.8	30.7	32.0	35.6	34.5	26.0

Ex. 2013, 4. The table above is an excerpted version of a table entitled "U.S. District Court – Judicial Caseload Profile." The table includes a subheading indicating that the data in the table is for Massachusetts. Among other things, the table provides the median time, in months, from filing to trial for civil cases for the 12-month periods ending on June 30 for each year from 2018–2023. As discussed above, Patent Owner relies on the 26.0 months median time-to-trial for the most recent time period—the 12-month period ending June 30, 2023—and Petitioner relies on the 32.2-month average median time-to-trial for the entire period from 2018–2023.

Although the 26.0-month figure Patent Owner relies upon reflects the most current time-to-trial data, it appears to be somewhat of an outlier. The 5 years preceding the period ending June 30, 2023, had significantly higher median time-to-trial lengths ranging from 30.7 to 35.6 months. Patent Owner argues that the 32.2-month average time to trial that Petitioner relies upon includes data from 2018–2022 that are "outdated and artificially inflate time to trial by using statistics from years impacted by the COVID-19 pandemic." Prelim. Sur-reply 3. We agree that the 12-month periods ending June 30, 2020 and June 30, 2021 may have been impacted by the COVID-19

pandemic. But those years appear generally consistent with the time-to-trial lengths for unaffected years. Even excluding the COVID-19 affected years, the median time-to-trial for the periods ending June 30, 2018 and June 30, 2019 were 34.8 and 30.7 months and the median time-to-trial for the period ending June 30, 2022, was 34.5.

Absent explanation (such as a change in the rules or number of judges) for why median time-to-trial dropped in 2023, it is not clear that the data for 2023 is a more reliable indicator of how long it will take for the Massachusetts Litigation to reach trial than the average time-to-trial over the six-year period from 2018–2023. Conversely, we cannot simply ignore that the most recent year reflects a significantly lower time-to-trial than the six-year average. For purposes of this analysis, we start with the average time-to-trial of 32.2 months and reduce it to account for the reduction shown in the median time-to-trial for the most recent year for which we have data. More specifically, we assume an average time-to-trial of 30 months. This supports a trial date in February of 2025.

We next consider how quickly Judge Stearns is likely to resolve dispositive motions. The parties agree that Judge Stearns has only heard two patent cases in the last ten years. Prelim. Reply 4 n.3; Prelim. Sur-reply 3–4. We agree with Patent Owner that the time it took Judge Stearns to resolve dispositive motions for one of these cases is not representative because briefing concluded just before the pandemic. Prelim. Sur-reply 3. In the other of his patent cases, Judge Stearns issued orders on dispositive motions 2.5 months after briefing concluded. *Id.* at 4. If Judge Stearns resolves dispositive motions in a similar time frame in this case, the decision on

dispositive motions would come in mid-October 2024. Consistent with this expectation, Judge Stearns recently informed the parties that "they should be prepared to litigate this case in the fall or early winter of 2024." Ex. 2062. This supports a November/December 2024 trial date.

Although it is difficult to predict the trial date in this case with precision given the variance in median time-to-trial data and the limited number of dispositive motions Judge Stearns has decided in patent cases, it seems likely that the Massachusetts Litigation will be tried before the March 2025 deadline for our final written decision. Both the median time-to-trial and an estimate based on Judge Stearns' individual practices support a trial date a few months prior that date. Moreover, as noted above, Judge Stearns forecasted in his most recent order addressing trial timing, a "fall or early winter 2024" trial. Ex. 2062. Accordingly, this factor weighs somewhat in favor of discretionary denial. *Apple Inc. v. Fintiv, Inc.,* IPR2020-00019, Paper 15, 13 (PTAB May 13, 2020) (informative) ("Because the currently scheduled District Court trial is scheduled to begin two months before our deadline to reach a final decision, this factor weighs somewhat in favor of discretionary denial in this case.").

3. *Investment in the Parallel Proceeding (Factor 3)*

Fintiv factor 3 considers the "investment in the parallel proceeding by the court and parties," including "the amount and type of work already completed in the parallel litigation by the court and the parties at the time of the institution decision." *Fintiv,* Paper 11 at 9. For example, if, at the time of institution, the court in the parallel proceeding has issued "substantive

orders related to the patent at issue in the petition" or "claim construction orders" this favors denial. *Id.* at 9–10.

Petitioner asserts in its Petition that this factor "weighs against discretionary denial" because "[f]act discovery is still ongoing, with no witnesses having been deposed, and expert discovery has yet to begin." Pet. 67. In its Preliminary Reply, Petitioner acknowledged that "fact discovery will be closed by the institution deadline," but asserted that expert discovery and dispositive motions briefing will not be completed by institution. Prelim. Reply 5. Thus, Petitioner maintains that this factor is "neutral at best." *Id.*

Patent Owner responds that "at the time of the institution decision, the parties and court will have made substantial investment in the district court case." Prelim. Resp. 20. According to Patent Owner, Petitioner waited more than six months after receiving infringement contentions to file the Petition, and, as a result, "the district court already issued a *Markman* order," fact discovery is closed, and Petitioner's expert report on patent validity has been served. *Id.* at 20–21. Patent Owner asserts that the fact that "some litigation steps remain does not make Factor 3 neutral." Prelim. Sur-reply, 4 (internal citation omitted). To the contrary, Patent Owner contends that the "significant investment" in the Massachusetts Litigation to date, "strongly favors denial." *Id.*

We agree with Patent Owner that the existing investment by the parties and the court in the Massachusetts Litigation has been substantial. Judge Stearns has already construed the claims at issue, fact discovery has closed, and expert discovery is well underway, with opening expert reports

having been exchanged in mid-February and rebuttal expert reports due within one month from this decision. Ex. 2011, docket entries 62 (scheduling order) and 105 (claim construction order). Although work remains in the lead-up to trial before the district court, we find that this factor favors exercising our discretion to deny institution.

4. *Overlap of Issues (Factor 4)*

Fintiv Factor 4 considers whether "the petition includes the same or substantially the same claims, grounds, arguments, and evidence as presented in the parallel proceeding." *Fintiv*, Paper 11 at 12. If the issues in the Petition overlap substantially with those raised in the parallel proceeding, "this fact has favored denial." *Id.* "Conversely, if the petition includes materially different grounds, arguments, and/or evidence . . . this fact has tended to weigh against exercising discretion to deny institution." *Id.* at 12–13.

Together with its Preliminary Reply, Petitioner submits a stipulation that it contends "moots" the risk of duplicative efforts. Prelim. Reply 2, App'x. Petitioner's stipulation states that "Petitioner will not pursue in district court the four specific grounds that are raised in this IPR." *Id.* at App'x. The stipulation further states:

> For the avoidance of doubt, Petitioner will continue to be able present in the district court all arguments and grounds of patent invalidity that are not identical to the four above-listed grounds. For example, and without limitation, Petitioner will be able to raise in the district court any arguments or grounds involving Geall, Yang, and/or Altmeyer that are not identical to Grounds 2, 3, and 4 (*i.e.*, that are not obviousness based on Schrum in view of Geall, Schrum in view of Yang, or Schrum in view of Altmeyer).

Id. In view of this stipulation, Petitioner contends that *Fintiv* Factor 4 "weighs against exercising discretion to deny institution." *Id.* at 2.

Patent Owner argues that Petitioner's stipulation leaves "substantial overlap." Prelim. Sur-reply 2. Patent Owner explains that in the Massachusetts Litigation, Petitioner "asserts ***64*** grounds in district court that rely on the ***same references*** as the petition, and ***58*** more using art it could have raised here" but "only agrees not to pursue ***four***." *Id.* at 2–3. According to Patent Owner, "Petitioner's efforts to have the Board and the court analyze the ***same art*** would duplicate effort and potentially yield inconsistent results—precisely what *Fintiv* is meant to avoid." *Id.* at 3.

The Board's informative decision in *Sand Revolution II, LLC v. Continental Intermodal Group – Trucking LLC* expressed skepticism that stipulations like that at issue here achieve the goals of avoiding duplication and inconsistent decisions:

> Petitioner *could have stipulated* that it would not pursue any ground raised or that *could have been reasonably raised* in an IPR, i.e., any ground that could be raised under §§ 102 or 103 on the basis of prior art patents or printed publications. *A broader stipulation of that nature, not at issue here, might better address concerns regarding duplicative efforts and potentially conflicting decisions in a much more substantial way.* Likewise, such a stipulation might help ensure that an IPR functions as a true alternative to litigation in relation to grounds that could be at issue in an IPR. Further still, Petitioner could have expressly waived in the district court any overlapping patentability/invalidity defenses. Doing so might have tipped this factor more conclusively in its favor.

IPR2019-01393, Paper 24 at 12 n.5 (PTAB June 16, 2020) (informative) (emphasis added). The Board in *Sand Revolution* accorded a stipulation not

containing the "could have reasonably raised" provision "marginal[]" weight. *Id.* at 12.

Petitioner's stipulation does reduce somewhat the overlap relating to the challenge presented in the Petition, but not as fully as would a *Sotera-type* stipulation. *Sotera Wireless, Inc. v. Masimo Corp.*, IPR2020-01019, Paper 12 at 18–19 (PTAB Dec. 1, 2020) (precedential) (addressing a stipulation to not pursue in court any grounds raised or that reasonably could have been raised in the IPR); Guidance Memo, 7–8 (explaining that institution will not be discretionarily denied due to parallel litigation where a *Sotera*-type stipulation is made). If we grant institution in this and the related IPRs, the Board may well reconsider claims whose validity was previously tried before the district court and do so based on similar (though not "identical") grounds. Prelim. Reply, App'x. Thus, while the stipulation "mitigates to some degree the concerns of duplicative efforts between the district court and the Board, as well as concerns of potentially conflicting decisions" (*Sand Revolution*, Paper 24 at 12), it does not remove them. In addition, Petitioner's stipulation does not preclude Petitioner from relying on the same prior art in different combinations. Accordingly, consistent with the decision in *Sand Revolution* we find that Petitioner's stipulation weighs only marginally against discretionary denial. IPR2019-01393, Paper 24 at 12 (determining that stipulation similar to that here weighed "marginally" against discretionary denial).

Overall, we find that this factor weighs marginally against exercising our discretion to deny institution.

5. *Identity of Parties (Factor 5)*

Petitioner is the defendant in the Massachusetts Litigation. Pet. 3. To the extent that trial in the district court may precede the deadline for a final written decision in this proceeding, this factor favors exercising our discretion to deny institution. *Huawei Tech. Co. v. WSOU Inv., LLC*, IPR2021-00225, Paper 11 at 14 (PTAB June 14, 2021) (finding that "this factor favors denial if trial precedes the Board's Final Written Decision and favors institution if the opposite is true") (internal quotation marks omitted); *Google LLC v. Parus Holdings, Inc.*, IPR2020-00846, Paper 9 at 21 (PTAB Oct. 21, 2020) ("Here, . . . Petitioner is the defendant in the parallel proceeding. This fact could weigh either in favor of, or against, exercising discretion to deny institution, depending on which tribunal was likely to address the challenged patent first."). As discussed *supra* § II.B.2, trial in the district court is likely to precede our final written decision. Accordingly, this factor weighs in favor of exercising our discretion to deny institution.

6. *Other Circumstances Including the Merits (Factor 6)*

We take "a holistic view of whether efficiency and integrity of the system are best served by denying or instituting review" when evaluating these factors. *Fintiv*, Paper 11 at 6. We have considered the circumstances and facts before us in view of *Fintiv* Factors 1–5. As discussed above, Factor 1 is neutral, Factors 2, 3, and 5 weigh in favor of discretionary denial of institution, and Factor 4 weighs marginally against discretionary denial. On balance, we conclude that the evidence of record on Factors 1–5 favors exercising our discretion to deny institution of an *inter partes* review.

Following *CommScope*, where, as here, our analysis of the first five *Fintiv* Factors favors denial of institution, we address the merits of the Petition to determine whether, on this preliminary record, the merits are compelling. *CommScope Technologies LLC v. Dali Wireless, Inc.*, IPR2022-01242, Paper 23 at 4–5; Guidance Memo 3–5.

III. COMPELLING MERITS ANALYSIS

A. Legal Principles

"In an [*inter partes* review], the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable." *Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016) (citing 35 U.S.C. § 312(a)(3).

A claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed invention and the prior art are such that the claimed invention would have been obvious at the time the invention was made to a person having ordinary skill in the relevant art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). The question of obviousness is resolved on the basis of underlying factual determinations including: (1) the scope and content of the prior art; (2) any differences between the claimed subject matter and the prior art; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness when presented. *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966). Moreover, "[a]n obviousness determination requires finding both that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable

expectation of success in doing so." *CRFD Rsch., Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (internal quotation marks and citation omitted).

B. Level of Ordinary Skill in the Art

Petitioner describes a person of ordinary skill in the art ("POSA" or "skilled artisan") as follows:

> [A] research team with (1) or more researchers with an advanced degree and experience in the fields of nucleic acids, including RNA-mediated mechanisms and/or nucleic acid therapeutics, gene therapy, and modified mRNA, working with (2) one or more individuals with an advanced degree and experience in drug delivery of nucleic acid drugs, including lipid-based drug delivery systems, and (3) one or more individuals with an advanced degree and experience in vaccines and/or virology, molecular medicine, and/or infectious diseases.

Pet. 15 (citing Ex. 1002 ¶ 11; Ex. 1004 ¶ 16).

Patent Owner contends that "a POSA would have had an M.D. and/or Ph.D in immunology, virology, biochemistry, chemistry, or a related discipline, and three or more years of work experience in such fields, and would have been part of a team including biochemists, chemists, drug delivery scientists, and/or clinicians." Prelim. Resp. 4.

The parties seem to be in agreement that the POSA would have included, or been part of, a research team. Pet. 15; Prelim. Resp. 4. The parties also propose that the POSA would have experience and expertise in similar subject matter. For example, Petitioner proposes that the POSA would have expertise in vaccines and/or virology while Patent Owner proposes that the POSA would have expertise in virology and been part of a team including clinicians. *Id.* Similarly, the parties agree that the POSA

would have expertise in drug delivery. The principal difference between the parties' definitions seems to be that Petitioner's definition is more specific than Patent Owner's definition. For example, Petitioner proposes expertise in the field of nucleic acids including nucleic acid therapeutics while Patent Owner proposes expertise in biochemistry.

For purposes of this Decision, we do not consider the differences between the parties' definitions to be material; we would reach the same result under either definition. To the extent the parties believe the differences between the two definitions of the POSA are material, we invite them to brief the issue at trial. In reaching this decision, we find the additional detail in Petitioner's definition to be helpful. As, Petitioner's description of a POSA appears consistent with the subject matter of the '600 patent and with the prior art of record, we apply it for purposes of this decision. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995); *In re Oelrich*, 579 F.2d 86, 91 (CCPA 1978). In applying Petitioner's definition of the POSA, we make one addition resulting from the fact that Petitioner's definition does not specify a duration of work experience. Where Petitioner's definition specifies work experience, we consider the duration of such experience to be three or more years (consistent with Patent Owner's suggested duration).

C. Claim Construction

We interpret a claim "using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b)." 37 C.F.R. § 42.100(b) (2020). Under this standard, we construe the claim "in accordance with the ordinary and customary meaning of such

claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent." *Id.*

Petitioner proposes that, for purposes of this proceeding, the claims should be given the claim construction advanced by Patent Owner and adopted by the district court in the Massachusetts Litigation. Pet. 21. Petitioner, thus, proposes that the claims be construed as follows:

- **betacoronavirus**: "an enveloped, positive-sense, single stranded RNA virus of zoonotic origin that belongs to one of the four lineages of the betacoronavirus genus of the subfamily Coronavirinae (e.g., OC43, HKU1, MERS-CoV, and SARS-CoV)."
- **S protein**: a "spike protein," which is "a structural protein forming a spike."
- **open reading frame**: "in a DNA, a continuous stretch of DNA beginning with a start codon, and ending with a stop codon and encodes a polypeptide, or, in an mRNA, a corresponding stretch of mRNA."
- **subject**: "a mammal."

Id.; *see also* Ex. 1035 (district court's order on claim construction). Patent Owner states that it "agrees the constructions adopted by the district court and referenced by the Petitioner should apply for this proceeding." Prelim. Resp. 4 (internal citation omitted).

Absent any apparent dispute between the parties as to how the claims should be construed, we do not find it necessary to construe the claims at this stage of the proceeding. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) ("[W]e need only construe terms 'that are in controversy, and only to the extent necessary to resolve the controversy'" (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng'g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *Wellman, Inc. v. Eastman Chem.*

Co., 642 F.3d 1355, 1361 (Fed. Cir. 2011) ("[C]laim terms need only be construed 'to the extent necessary to resolve the controversy'").

D. Overview of the Asserted Prior Art

Petitioner contends that each of the asserted references below is prior art. Pet. 16–20. Patent Owner does not contest the prior-art status of these references. Prelim. Resp. 10–13.

1. *Schrum (Ex. 1009)*

Schrum is a U.S. patent application that published October 10, 2013. Ex. 1009, code (43). Schrum relates generally to compositions "comprising modified nucleic acid molecules which may encode a protein" and, further, "nucleic acids useful for encoding polypeptides capable of modulating a cell's function and/or activity." Ex. 1009, Abstr.

In summarizing the invention, Schrum teaches that, "[i]n one aspect[,] a method of producing a polypeptide of interest in a mammalian cell or tissue is described." *Id.* ¶ 5. Further, Schrum discloses that "[t]he method comprises contacting the mammalian cell or tissue with a formulation comprising a modified mRNA encoding a polypeptide of interest," and that the "formulation may be, but is not limited to, nanoparticles." *Id.* Schrum discloses that the "formulations of modified mRNA may comprise a fusogenic lipid [(e.g., DSPC)], cholesterol and a PEG lipid." *Id.* ¶ 8 ("The formulation may have a molar ratio 50:10:38.5:1.5–3.0 (cationic lipid:

fusogenic lipid: cholesterol: PEG lipid)"); *see also id.* ¶¶ 35, 38 (describing lipid nanoparticle composition).

Schrum includes a section titled "Activation of the Immune Response: Vaccines." *Id.* ¶¶ 340–350. In that section, Schrum teaches, *inter alia*, that in embodiments, "mRNA molecules may be used to elicit or provoke an immune response in an organism," where the delivered mRNA "may encode an immunogenic peptide or polypeptide." *Id.* ¶ 340. Schrum discloses that the "modified nucleic acid molecules and/or mmRNA . . . may encode an immunogen" that "may activate the immune response." *Id.* ¶ 342.

Schrum further discloses that the mRNA "encoding an immunogen may be delivered to a vertebrate in a dose amount large enough to be immunogenic to the vertebrate." *Id.* In support, Schrum cites and "incorporate[s] by reference in [its] entirety" Geall (Ex. 1010, herein). *Id.* According to Schrum, "[t]he modified nucleic acid molecules or mmRNA of the invention may encode a polypeptide sequence for a vaccine." *Id.* ¶ 343. Schrum teaches that the mmRNA may, as a non-limiting example, "be self-replicating mRNA [and] may encode at least one antigen." *Id.* ¶¶ 344–345; *see also id.* ¶¶ 346 ("[T]he self-replicating modified nucleic acids or mmRNA of [the] invention may be formulated using methods described herein or known in the art."), 349 ("[T]he modified nucleic acid molecules and mmRNA may encode all or part of a positive-sense or a negative-sense stranded RNA virus genome[.]").

Schrum includes several working examples. In Example 16, for instance, Schrum describes *in vivo* studies wherein mRNA, "modified with 5-methylcytosine and pseudouridine," and encoding a protein, was "formulated as lipid nanoparticles [(LNPs)]." *Id.* ¶ 995. The LNP formulations were administered to mice intravenously in various doses and protein expression (for G-CSF and Factor IX) was confirmed. *Id.* ¶¶ 995–999.

2. *Geall (Ex. 1010)*

Geall is an international patent application that published January 12, 2012. Ex. 1010, code (43). Geall relates generally to "RNA encoding an immunogen" that is "delivered to a large mammal" to "elicit an immune response." *Id.* at Abstr.

Geall teaches that "[t]he RNA can be delivered as naked RNA" but, to enhance entry of the RNA into cells and subsequent cellular effects, "the RNA is preferably administered in combination with a delivery system." *Id.* at 3:25–31. According to Geall, "useful delivery systems of interest" include liposomes, polymer microparticles, and cationic oil-in-water emulsions. *Id.* (disclosing that liposome delivery is preferred).

Geall teaches that "[t]he invention involves *in vivo* delivery of RNA which encodes an immunogen." *Id.* at 12:1. "The RNA can trigger innate immunity pathways and is also translated, leading to expression of the immunogen." *Id.* at 12:1–2. According to Geall, "[t]he RNA is +-stranded, and so it can be translated without needing any intervening replication steps such as reverse transcription." *Id.* at 12:4–5. Further, Geall discloses, "[p]referred +-stranded RNAs are self-replicating." *Id.* at 12:6–17

(disclosing that, with a preferred self-replicating RNA molecule (or replicon), delivery of the molecule "lead[s] to the production of multiple daughter RNAs").

Geall teaches that RNA molecules used with the invention "encode a polypeptide immunogen." *Id.* at 15:33–34 (disclosing that, after delivery, translation of the RNA elicits an immune response in the recipient). According to Geall, "[t]he immunogen may elicit an immune response against a bacterium, a virus, a fungus or a parasite." *Id.* at 15:34–35. Further, Geall teaches, "[t]he immunogen will typically be a surface polypeptide" such as "a spike glycoprotein." *Id.* at 16:6–7. Geall teaches that, in embodiments, the immunogen elicits an immune response against one of several listed viruses. *Id.* at 18:12–20:23. Geall identifies "Coronavirus" among the listed viruses. *Id.* at 19:26–29. And, more specifically, Geall discloses that "[v]iral immunogens include, but are not limited to, those derived from a SARS coronavirus" where "[t]he coronavirus immunogen may be a spike polypeptide." *Id.*

3. *Yang (Ex. 1011)*

Yang is an article in Nature magazine, published in April 2004. Ex. 1011, 561. Yang reports on an animal-model study related to DNA vaccination against SARS-CoV. *See generally id.*

Yang notes prior SARS outbreaks arising from SARS-CoV and earlier public health measures to contain such outbreaks. *Id.* at 561. According to Yang, "concerns remain over the possibility of future recurrences" of SARS outbreaks and "[f]inding a vaccine for this virus therefore remains a high priority." *Id.*

Yang describes an animal (i.e., mouse) vaccination model that "examine[d] immune protection against [SARS-CoV] viral replication in the respiratory tract as a measure of vaccine efficacy." *Id.* at 562.

Yang teaches that "DNA encoding the spike (S) glycoprotein of the SARS-CoV induces T cell and neutralizing antibody responses, as well as protective immunity, in a mouse model." *Id.* at 561 ("Gene-based vaccination for the SARS-CoV elicits effective immune responses that generate protective immunity in an animal model."). Moreover, "[t]he humoral immune response includes the generation of neutralizing antibodies. This humoral immunity alone can inhibit pulmonary viral replication in a murine challenge model and suggests that DNA vaccination with the SARS-CoV S glycoprotein gene results in protective immunity." *Id.* at 563. Yang reports that "[v]iral replication was reduced by more than six orders of magnitude in the lungs of mice vaccinated with these S plasmid DNA expression vectors, and protection was mediated by a humoral but not a T-cell-dependent immune mechanism." *Id.* at 561; *see also id.* at 562 ("In this analysis, the most potent immunogen, SARS SΔCD, led to $>10^6$-fold reduction in viral load in the lungs compared with a control group injected with vector alone, in which mean viral titres of $>10^8$ were observed[.]"). According to Yang, these "results suggest that antibodies against SARS-CoV S glycoprotein protect against a SARS-CoV challenge and do not enhance infection in this animal model." *Id.* at 563 (discussing a need for future testing of SARS vaccine candidates for immunogenicity, safety, and efficacy in humans).

4. *Altmeyer (Ex. 1012)*

Altmeyer is an international patent application that published December 15, 2005. Ex. 1012, code (43). Altmeyer relates generally to "[n]ucleic acid molecules, polypeptides, immunogenic compositions, vaccines, and methods of making and using the nucleotides and encoded polypeptides associated with the Spike protein of SARS Corona Virus (SARS CoV)." *Id.* at Abstr.

Altmeyer discloses "DNA and RNA sequences" that "encode Spike polypeptides." *Id.* ¶ 60 (teaching that such sequences hybridize to SEQ ID NOS: 2, 3 & 6, as disclosed, under conditions of moderate or severe stringency). According to Altmeyer, "[t]he polypeptides encoded by these novel nucleic acids are referred to herein as 'Spike polypeptides' or 'Spike proteins.'" *Id.* ¶ 61 ("[T]hese terms refer to a genus of polypeptides that further encompasses proteins having the amino acid sequence of SEQ ID NO: 4 or SEQ ID NO: 7" as well as polypeptides with a "high degree of similarity (at least 90% homology) with such amino acid sequences" and polypeptides and proteins that "are immunoreactive."); *see also id.* ¶¶ 64–67 (describing Spike polypeptides and variants thereof, and their use to prepare antibodies that bind to the Spike polypeptides).

Altmeyer describes methods of RNA and/or DNA vaccination. *See, e.g.*, *id.* ¶¶ 97–98. According to Altmeyer, "[t]he method also includes administering any combination of nucleic acids encoding Spike polypeptides . . . with or without carrier molecules[] to an individual." *Id.* Altmeyer discloses that the individual is an animal and preferably a mammal, including, a human, mouse, rabbit, etc. *Id.* ("In an especially preferred

embodiment, the mammal is a human."). Altmeyer teaches that skilled artisans are cognizant of the concept, application, and effectiveness of "nucleic acid vaccine technology" and that this technology "allows the administration of nucleic acids encoding Spike polypeptides, naked or encapsulated, directly to tissues and cells without the need for production of encoded proteins prior to administration." *Id.* ("Such nucleic acid vaccine technology includes, but is not limited to, delivery of naked DNA and RNA and delivery of expression vectors encoding Spike polypeptides.").

Altmeyer discloses, in Example 5, an example of RNA vaccination of mice. *Id.* ¶¶ 114–116. In that example, Altmeyer teaches that "[m]ice were immunized intramuscularly with SFV[13] Spike RNA, followed by intraperitoneal (IP) injection of Spike protein at day 14 and at day 35." *Id.* Altmeyer discloses that serum samples from immunized mice "showed the presence of recombinant Spike-specific antibodies." *Id.* (citing Figs. 6–8). According to Altmeyer, "data indicate that the Spike protein expressed in the SFV vector could be successfully immunopurified in its native conformation, and that this purified protein induces high titer anti-SARS antibodies in mice." *Id.*

E. Ground 2: Obviousness over Schrum and Geall

In our compelling merits analysis, we focus on Petitioner's Ground 2 because, on the present record, we consider Ground 2 to present the

[13] Altmeyer discloses that "SFV" refers to the Semliki Forest Virus vector. *See, e.g.*, Ex. 1012 ¶ 41.

strongest case for unpatentability of one or more of the challenged claims at this time. We address the remaining grounds in Section § IV below.

Petitioner asserts that claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 are unpatentable as obvious over the combination of Schrum and Geall. Pet. 38–66.[14] We provided an overview of Schrum and Geall above. Below we provide our analysis of Petitioner's obviousness showing. We begin by summarizing Petitioner's Ground 2. We then consider Patent Owner's arguments that Petitioner failed to identify a teaching of the spike protein in the prior art, that Petitioner failed to establish a motivation to pursue an mRNA composition, that Petitioner failed to establish a reasonable expectation of success, and that objective indicia of non-obviousness demonstrate the non-obviousness of the claimed composition.

Finally, we consider whether the totality of the evidence rises to the level of compelling merits. For the reasons discussed below, we determine that Petitioner has established a reasonable likelihood of prevailing on its assertion that at least one of the challenged claims are unpatentable based on Ground 2 and that Petitioner's showing, in fact, rises to the level of "compelling merits" according to the Office's current guidance and Board precedents. *CommScope* at 3–4 (quoting Guidance Memo at 4 ("[W]hen determining whether there is a compelling unpatentability challenge, the

[14] Petitioner supports its challenge to claim 1 with testimony from Drs. Griffin and Moon. Ex. 1002 ¶¶ 67–81; Ex. 1004 ¶¶ 58–76. Dr. Moon's testimony focuses on the lipid nanoparticle elements of the claim and Dr. Griffin's testimony focuses primarily on the remainder of the claim limitations, with both declarants cross-referencing the testimony of the other, as applicable.

Board evaluates whether the Petition presents challenges 'in which the evidence, if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence.")); *OpenSky Indus., LLC v. VLSI Tech. LLC*, IPR2021-01064, Paper 102, 49–50 (PTAB Oct. 4, 2022) (precedential) ("*OpenSky*") (explaining that "[a] challenge can only 'plainly lead to a conclusion that one or more claims are unpatentable' . . . if it is highly likely that the petitioner would prevail with respect to at least one challenged claim").

1. *Summary of Petitioner's Ground 2 as Applied to Claim 1*

Petitioner contends that Schrum discloses mRNA vaccines that encode an immunogen and that have "identical mRNA and lipid nanoparticle components to that claimed in the '600 patent." Pet. 40. Petitioner asserts that Schrum discloses all of the limitations of claim 1 except that Petitioner relies upon Geall as suggesting a composition where Schrum's mRNA encodes "a betacoronavirus (BetaCoV) S protein or S protein subunit." *Id.* at 38–40.[15]

Petitioner contends that Geall discloses "immunogenic RNA vaccines encoding the S protein of SARS-CoV." *Id.* at 40. According to Petitioner, the S protein "was known to be the most promising antigen for development of a SARS-CoV vaccine." *Id.* With the support of Dr. Griffin, Petitioner asserts that the POSA would have reason to combine Geall and Schrum because Schrum "identifies and incorporates Geall" and because "the two

[15] In connection with Ground 1, Petitioner asserts that Schrum discloses this claim limitation and thus anticipates the challenged claims. We address Petitioner's anticipation arguments *infra* § IV.A.

references are in the same field of endeavor." *Id.* at 41 (citing Ex. 1002 ¶¶ 112–114 (testimony of Dr. Griffin to this effect). In addition, Petitioner asserts that the POSA would have good reason to "create an mRNA vaccine encoding the spike protein of SARS-CoV." *Id.* To support this proposition, Petitioner cites Yang's teaching that "a DNA vaccine encoding the spike (S) glycoprotein of the SARS-CoV induces T cell and neutralizing antibody responses, as well as protective immunity, in a mouse model." Ex. 1011, 561 (cited at Pet. 41). Petitioner also cites Du's[16] teaching that "[a]mong all structural proteins of SARS-CoV, S protein is the main antigenic component that is responsible for inducing host immune responses, neutralizing antibodies and/or protective immunity against virus infection" and that "S protein has therefore been selected as an important target for vaccine and antiviral development." Ex. 1031, 229 (cited at Pet. 41).

Petitioner contends that the POSA would reasonably have expected success in combining Schrum and Geall because Schrum teaches that methods of synthesizing mRNA were known in the art and provides examples where administration of protein-encoding mRNA formulated in lipid nanoparticles expressed the encoded protein. Pet. 41–42 (citing Ex. 1009 ¶¶ 291, 320, 942, 963, 995–999, 1000–1001; Ex. 1002 ¶ 115; Ex. 1004 ¶¶ 72, 81).

Petitioner's assertions above are backed by the cited prior art and by the testimony of its declarants, Drs. Griffin and Moon. On this preliminary

[16] Du et al., *The Spike Protein of SARS-CoV – A Target for Vaccine and Therapeutic Development,* 7 Nature Rev. Microbiology 226–236 (2009) ("Du").

record, we determine that Petitioner's arguments and evidence show a reasonable likelihood that Petitioner will prevail in its assertion that at least one of the challenged claims is unpatentable as obvious over the combination of Schrum and Geall. Indeed, as we discuss below, we find that Petitioner has made a compelling merits showing on the alleged obviousness of at least claim 1 over Schrum and Geall. We turn now to Patent Owner's arguments.

2. *Patent Owner's Arguments Regarding Identification of a Spike Protein*

Patent Owner argues that institution should be denied because Petitioner failed "to argue [that] Schrum or Geall teaches 'form[ing] a spike' under Petitioner's claim construction." Prelim. Resp. 46. We do not find this argument persuasive.

As discussed above, Geall discloses vaccines where RNA encoding an immunogen is administered to a large animal. Ex. 1010, 2:3–4. Among the immunogens Geall teaches may be encoded by its RNA vaccine are "those derived from a SARS coronavirus." *Id.* at 19:26–27. More specifically, Geall discloses that the "coronavirus immunogen may be a spike polypeptide." *Id.* at 19:29–30. Dr. Griffin testifies that the POSA "would have understood the disclosure of 'spike polypeptide' from a SARS coronavirus in Geall as referring to a structural protein forming a spike." Ex. 1002 ¶ 72 n. 118 (cited at Pet. 23, 38). On this preliminary record, Dr. Griffin's presently-unrebutted testimony corresponds to Petitioner's claim construction and sufficiently shows that the combination of Geall and

Schrum would be understood by the POSA as teaching an mRNA encoding a BetaCoV (e.g., SARS) protein forming a spike.

At least at this preliminary stage, we determine that Petitioner's showing that the cited art suggests an mRNA vaccine encoding BetaCoV S protein is compelling. Petitioner identifies where Geall discloses a BetaCoV S protein and provides expert testimony explaining how this disclosure corresponds to the language of the claim. On the present record, we do not agree with Patent Owner that this showing is deficient and Patent Owner does not direct us to persuasive evidence rebutting Petitioner's showing. Accordingly, the evidence of record plainly supports that Geall discloses an RNA vaccine encoding a structural protein that forms a spike.

3. *Patent Owner's Arguments Regarding Motivation to Pursue mRNA Vaccine Compositions*

Patent Owner argues that Petitioner has not established that the POSA would have been motivated to pursue mRNA vaccine compositions for four reasons: 1) Petitioner does not established that the POSA would have started with Schrum's disclosure of mRNA vaccines, 2) the prior art reflects that the POSA would have been skeptical of mRNA vaccines, 3) Petitioner does not account for the preference in the art for self-replicating RNA vaccines, and 4) Petitioner does not provide sufficient reason to pick betacoronavirus spike protein from Geall's list of immunogens. We address each of these arguments in turn.

a) Arguments Regarding the Sufficiency of Schrum's Disclosure of mRNA Vaccines

Patent Owner argues that the POSA would not have been motivated to "start from Schrum's passing reference to mRNA vaccines." Prelim. Resp. 47. According to Patent Owner, "Schrum dedicates over 185 pages to therapeutic use of mRNA, and its only working examples relate to therapeutic or standard research proteins." *Id.* This contrasts with Schrum's "Activation of Immune Response: Vaccines" subsection, which comprises only 10 paragraphs and lacks a working example. *Id.* Patent Owner asserts that "Petitioner identifies no reason a POSA would have started from this brief reference in Schrum." *Id.*

We do not agree because, where obviousness is concerned, Schrum must be considered for all that it teaches, not just what it allegedly focuses on or exemplifies. *In re Mouttet*, 686 F.3d 1322, 1331 (Fed. Cir. 2012) ("A reference may be read for all that it teaches, including uses beyond its primary purpose."); *In re Lamberti*, 545 F.2d 747, 750 (CCPA 1976) ("the fact that a specific symmetric dialkyl is taught to be preferred is not controlling, since all disclosures of the prior art, including unpreferred embodiments, must be considered"). As the Supreme Court has made clear, the obviousness inquiry is "*expansive* and *flexible*," not narrow or rigid. *KSR*, 550 U.S. at 415 (emphasis added). Here, Schrum teaches using mRNA molecules encoding an immunogenic peptide to provoke an immune response. *See e.g.,* Ex. 1009 ¶ 340. Schrum further teaches that the immune response may be "elicited by delivering a lipid nanoparticle" containing, for example, mRNA and "formulated for use in a vaccine such as, but not

limited to, against a pathogen." *Id.* ¶ 397. Accordingly, we are not persuaded by Patent Owner's argument that Schrum makes only passing reference to vaccines.

In addition, Schrum's disclosure of provoking an immune response by administering mRNA encoding an antigen (i.e., a vaccine) is consistent with and supported by its disclosure of administering mRNA encoding a therapeutic protein. *Id.* ¶¶ 950, 963, 995–999, 1000–1021. In both cases, administration of mRNA causes cells to produce a desired protein. *See* Ex. 1002 ¶ 114 (Dr. Griffin's presently unrebutted testimony that Schrum discloses a "successful method of delivery" for mRNA and "demonstrates that administration of protein-encoding mRNA formulated in lipid nanoparticles can express the encoded protein.").

Schrum's disclosure that its delivery method can be used for a vaccine is further compatible with its disclosure that its method reduces innate immune response, increasing the efficiency of protein production. *See e.g.,* Ex. 1009 ¶¶ 3 ("Thus, there is a need to develop formulation compositions comprising a delivery agent that can effectively facilitate the in vivo delivery of nucleic acids to targeted cells without generating an innate immune response."), 50 ("The modified nucleic acid molecules of the present disclosure are capable of reducing the innate immune activity of a population of cells into which they are introduced, thus increasing the efficiency of protein production in that cell population."), 98 ("As described herein, the modified nucleic acids and mmRNA of the invention do not substantially induce an innate immune response of a cell into which the mRNA is introduced."); Ex. 1002 ¶ 42 ("In order for mRNA vaccines to

work as planned, the exogenous mRNA has to successfully enter the patient's cells and remain present long enough to be translated into quantities of protein sufficient to trigger a response from the ***adaptive*** immune system. In this regard, scientists would want to avoid a response from the ***innate*** immune system to the mRNA therapeutic that could reduce protein production and cause cell death.") (footnote omitted).

Accordingly, we do not see any tension between Schrum's disclosure of therapeutic uses of its delivery method and the use of its method for vaccination. For this additional reason, we are not persuaded by Patent Owner's argument that Schrum focuses on therapeutic uses of mRNA or, even if that was Schrum's focus, that Schrum's disclosure undermines the reasons for using mRNA as part of a vaccine.

b) Arguments Regarding the Skepticism of mRNA Vaccines

Patent Owner argues that "in the early 2010s, the non-traditional vaccine field was nascent" and "[r]esearchers considered options other than mRNA because there was skepticism that mRNA vaccines would result in sufficient immunogen expression to stimulate the immune system and generate long-lasting immune response." Prelim. Resp. 48. As support, Patent Owner quotes Petsch[17] and Kallen.[18] We consider each of these references in turn.

[17] Petsch et al, *Protective Efficacy in in Vitro Synthesized, Specific mRNA Vaccines Against Influenza A Virus Infection,* 30 Nature Biotechnology No. 12, 1210–1216 (2012) (Ex. 2025, "Petsch").

[18] Kallen et al., *A Novel, Disruptive Vaccination Technology,* 9 (10) Human Vaccines & Immunotherapeutics 2263–2276 (2013) (Ex. 2024, "Kallen").

Patent Owner quotes the following statement from Petsch: "So far, ***successful mRNA immunization*** resulting in protection from infectious disease ***has never been reported***. … [W]hether mRNA vaccines induce protective antibody responses and are efficacious in infectious disease ***is not clear***." *Id.* (emphasis added by Patent Owner). While this statement is accurately quoted, on this preliminary record, we do not consider Petsch to support skepticism as to whether mRNA vaccines would work. To the contrary, Petsch appears to address the absence of clarity as to whether mRNA vaccines induce a protective antibody response by teaching that they do, in fact, generate such a response.

Immediately after indicating that it was "not clear" whether mRNA vaccines generate a protective response, Petsch reports: "[h]ere we validated the mRNA vaccine approach for a B cell-dependent mode of protection against an infectious disease, influenza." Ex. 2025, 1211. Indeed, Petsch is replete with teachings that mRNA vaccines provide protective antibody response. *See, e.g., id.* at Abstr. ("Here we show that mRNA vaccines induce balanced, long-lived and protective immunity to influenza A virus infection in even very young and very old mice."), 1212 ("[W]e conclude that the mRNA vaccine effectively induced long-lived (and even lifelong) protection in mice"), 1213 ("In summary, our findings suggest the feasibility of single-dose immunization against influenza with a multicomponent HA [hemagglutinin] and NA [neuraminidase] mRNA vaccine"), 1214–15 ("To investigate whether mRNA vaccination was immunogenic in large animals approaching average human body weight (60 kg), we immunized 3-month-old female domestic pigs. . . . [T]he mRNA vaccine was clearly

immunogenic in pigs."), 1215 ("[T]his experiment therefore established efficacy of mRNA vaccination in large animals."), 1216 ("In summary, we introduce an mRNA vaccine platform that combines the simplicity, safety and focused immune response of subunit vaccines with the immunogenicity of live viral vaccines. Our findings open attractive perspectives for immunization against a broad range of pathogens."). On this preliminary record and on balance, Petsch appears to support, not skepticism, but an expectation that mRNA vaccines can induce sufficient immunogen expression to stimulate the immune system and generate long-lasting immune response.

Although the current record lacks testimony explaining Petsch, Patent Owner's characterizations of Petsch in Investigator's Brochures further support that Petsch does not reflect skepticism. For example, in an Investigator's Brochure dated September, 2016, Patent Owner characterized Petsch as providing "[p]roof of concept for the use of an mRNA vaccine in prophylaxis against influenza A virus infection." Ex. 2050, 12 (2016 Investigator's Brochure); *see also* Ex. 2051, 198 (2017 Investigator's Brochure making same statement); Ex. 2052, 11 (2019 Investigator's Brochure making similar statement). We recognize that this representation may have occurred after the priority date for the '600 patent, but the study it holds out as providing "proof of concept" (Petsch) is dated December 2012, before any possible priority date to which the challenged claims may be entitled.[19] For this additional reason, we are not persuaded by Patent

[19] The Investigator Brochure in Exhibit 2050 is dated September 23, 2016, which predates the earliest of the '600 patent's non-provisional priority

Owner's argument that Petsch demonstrates that the POSA would have been skeptical of mRNA vaccines. *Cf. Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1364 (Fed. Cir. 2007) (holding that "the expectation of success need only be reasonable, not absolute").

On this preliminary record, Kallen similarly appears to detract from Patent Owner's position that the POSA would have been skeptical of mRNA vaccines. Patent Owner quotes Kallen's statement that "naked mRNA 'achieved high antigen expression but only weak immunostimulation'" (Prelim. Resp. 48), but Petitioner's proposed combination does not rely on "naked mRNA." Rather, Petitioner proposes that it would have been obvious to use modified mRNA formulated in lipid nanoparticles as suggested by at least Schrum. Pet. 38–42. Further, Kallen appears to distinguish between "naked mRNA" and mRNA delivered in protective lipids. Ex. 2024, 2263–2264 ("It was shown that subcutaneous injection of liposome-encapsulated mRNA, but not naked mRNA encoding the nucleoprotein (NP) of influenza virus elicited NP-specific cytotoxic T cells (CTLs))." The present record lacks evidence connecting "naked mRNA" to Petitioner's proposed combination. Absent such evidence, Patent Owner's Kallen-based skepticism argument is unavailing.

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applications. We do not find it necessary at this stage to determine here whether the '600 patent is entitled to the priority date of any of its provisional applications. This Investigator Brochure, along with certain other exhibits of record, was submitted as part of authorized pre-institution briefing concerning positions taken by Patent Owner in other writings, including submissions to the FDA, that Petitioner alleges are inconsistent with Patent Owner's arguments here. Papers 10 and 13.

c) Arguments Regarding an Alleged Preference in the Art for Self-replicating RNA Vaccines

Patent Owner cites Geall 2013,[20] as teaching that self-replicating RNA is "more efficient for gene expression *in situ*" and argues that Geall itself suggests that self-replicating RNA has advantages over mRNA. Prelim. Resp. 48. According to Patent Owner, "Petitioner's summary suggestion that a POSA would have been motivated to pursue mRNA vaccines does not account for this." *Id.* We do not find this argument persuasive.

Geall 2013 teaches that there are "two major forms of RNA vaccines: (1) conventional, non-amplifying mRNA molecules and (2) RNA replicons engineered from the genomes of positive-stranded RNA viruses." Ex. 1016, 153. According to Geall 2013, "[b]oth approaches have their distinct advantages and limitations" (*id.* at 153) and both are viable options (*id.* at 154 ("RNA vaccines (both mRNA and replicons) are effective at eliciting antigen-specific humoral and cellular immune responses in animal models of infectious and non-infectious diseases."). For both approaches, Geall 2013 cites clinical trials that support efficacy. *See e.g., id.* at 154 ("Messenger RNA vaccine candidates have been tested in human clinical trials targeting metastatic melanoma and renal cell carcinoma, and tumor antigen-specific antibody and T cell responses were seen. Unpublished results of trials targeting prostate and non-small cell lung cancer have also shown mRNA vaccines to be safe, well tolerated and immunogenic") (internal citations omitted). Geall 2013 then concludes that "[t]his growing body of preclinical

[20] Geall et al, *RNA: The New Revolution in Nucleic Acid Vaccines,* 25 Seminars in Immunology 152–159 (2013) (Ex. 1016, "Geall 2013").

and clinical evidence demonstrates proof of concept that vaccines based on RNA, whether ***conventional mRNA or self amplifying replicons, are effective*** at eliciting functional immunity and should be rigorously tested." *Id.* (emphasis added).

We acknowledge that Geall itself describes self-replicating RNA vaccines as preferred. Ex. 1010, 12:6 ("Preferred +-stranded RNAs are self-replicating"). But that does not necessarily render the use of mRNA nonobvious. *Medichem, S.A. v. Rolabo S.L.*, 437 F.3d 1157, 1165 (Fed. Cir. 2006) ("[A] given course of action often has simultaneous advantages and disadvantages, and this does not necessarily obviate motivation to combine."); *In re Susi*, 440 F.2d 442, 446 n.3 (CCPA 1971) (holding that disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or non-preferred embodiments.). That is particularly true where, as here, Petitioner relies on Geall principally for its identification of a target immunogen. The current record, which lacks testimony supporting Patent Owner's argument, suggests that the POSA would consider that an immunogen targeted by a self-replicating RNA vaccine could also be targeted by mRNA vaccine. Ex. 1016, 154 ("vaccines based on RNA, whether conventional mRNA or self-amplifying replicons, are effective at eliciting functional immunity").

d) Arguments Regarding the Selection of Betacoronavirus Spike Protein as an Immunogen

Patent Owner argues that "Geall has no single disclosure of an 'RNA vaccine encoding SARS-CoV spike protein'; it, at most, lists ***over 500*** potential target immunogens, without singling out betacoronavirus." Prelim.

Resp. 49. According to Patent Owner, this is fatal to Petitioner's challenge because "Petitioner articulates no reason a POSA would have pursued a betacoronavirus antigen, let alone a betacoronavirus spike protein, from among Geall's over 500 immunogens." *Id*. at 49. We disagree.

Petitioner explains that the POSA would have "good reason to combine Schrum's disclosure of an mRNA vaccine encoding an 'immunogenic peptide or polypeptide'—*i.e.*, 'mmRNA encoding an immunogen'—with Geall's disclosure of an RNA vaccine encoding the SARS-CoV spike protein" because Schrum incorporates Geall by reference and because both references are directed to the same field of endeavor. Pet. 41 (citing Ex. 1009 ¶¶ 340, 342; Ex. 1002 ¶¶ 112–114). In addition, Petitioner relies upon the knowledge in the art—as reflected in Yang and Du—as providing "good reason to create an mRNA vaccine encoding the spike protein of SARS-CoV." *Id.* (citing Ex. 1011 (Yang) and Ex. 1031 (Du)). On this preliminary record, we agree that Petitioner has established that the POSA would have been motivated to use SARS-CoV S protein as an immunogen in Schrum's mRNA vaccines.

We begin our analysis of Patent Owner's arguments by considering Patent Owner's assertion that the POSA would have lacked motivation to pursue a vaccine against SARS-CoV. We then consider whether the POSA would have been motivated to specifically target the S protein of SARS-CoV.

Schrum discloses that the mRNA in its vaccine may encode an RNA virus immunogen. Ex. 1009 ¶ 349. We recognize that the list of viral immunogens in Geall is long (Ex. 1010, 18:11–20:23), but that does, by

itself, render the selection of an immunogen from that list nonobvious. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 335 (1945) ("Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle."); *see also Merck & Co. v. Biocraft Laboratories, Inc.*, 874 F.2d 804, 807 (Fed. Cir. 1989) ("That the [prior art reference] discloses a multitude of effective combinations does not render any particular formulation less obvious."). For this reason alone, we are not persuaded by Patent Owner's argument that the POSA lacked reasons to pursue a vaccine against SARS-CoV.

In addition, the prior art—as reflected in, for example, Yang and Du—provides good reason to select SARS-CoV from Geall's list of viral immunogens. Ex. 1011, 561 ("Public health measures have successfully identified and contained outbreaks of the severe acute respiratory syndrome (SARS) coronavirus (SARS-CoV)1–5, but concerns remain over the possibility of future recurrences. Finding a vaccine for this virus therefore remains a high priority."); Ex. 1031, 226 ("Although the outbreaks of SARS seem to be over, SARS is still a safety concern because of the possible reintroduction of a [SARS like]-CoV into humans and the risk of an escape of SARS-CoV from laboratories."); *see also,* Ex. 2030 (explaining that "the precursor of the SARS-CoV remains in its natural bat reservoir, and reemergence of a human-adapted SARS-like coronavirus remains a plausible public health concern"). Even the '600 patent recognizes, as background, that SARS outbreaks remained a concern. Ex. 1001, 3:4–9 ("Because of a

concern for reemergence or a deliberate release of the SARS coronavirus, vaccine development was initiated.").

As to the selection of a specific coronavirus protein, the spike protein is the only coronavirus protein specifically named in Geall. Ex. 1010, 19:23–24. In addition, the prior art—as reflected in, for example, Yang and Du—provides good reason for the POSA to have targeted the spike protein. Yang discloses that "a DNA vaccine encoding the spike (S) glycoprotein of the SARS-CoV induces T cell and neutralizing antibody responses, as well as protective immunity, in a mouse model." Ex. 1011, 561. More specifically, Yang teaches that mice "immunized with . . . plasmid DNAs encoding S protein and challenged 30 days after the final boost . . . with 10^4 $TCID_{50}$ units of SARS-CoV" show a "> 10^6–fold reduction in viral load in the lungs compared with a control group" and "[a] 60- to 300-fold reduction of virus titre in the nasal turbinates." *Id.* at 562. Yang also suggests that the viral genes it identifies may be useful in other delivery systems. *Id.* at 563 ("The definition of effective viral genes reported here can guide the choice of inserts for such gene-based vaccination approaches. For example, the SDCD mutant can be expressed in other vector delivery systems for analysis, alone or in various combinations."). On this preliminary record, which lacks testimonial evidence from Patent Owner, we agree that Yang helps to support a motivation to use the SARS-CoV spike protein, as taught in Geall, as an immunogen in Schrum's mRNA vaccines.

Du discloses that SARS-CoV is an "enveloped, single, and positive-stranded RNA virus" whose genome encodes a "non-structural replicase polyprotein" and four structural proteins, including "spike (S), envelope (E),

membrane (M), and nucleocapsid (N) proteins." Ex. 1031, 226. According to Du, "[t]he S protein plays key parts in the induction of neutralizing-antibody and T-cell responses, as well as protective immunity, during infection with SARS-CoV." *Id.* at Abstr. Du explains that the S protein has been identified as a target for vaccine development:

> Among all structural proteins of SARS-CoV, S protein is the main antigenic component that is responsible for inducing host immune responses, neutralizing antibodies and/or protective immunity against virus infection. ***S protein has therefore been selected as an important target*** for vaccine and anti-viral development.

Id. at 229 (emphasis added). Du also discusses testing vaccines based on the full length of the S protein and concludes that such testing "suggest[s] that the full-length S protein is highly immunogenic and induces protection against SARS-CoV challenge and that neutralizing antibodies alone may be able to suppress virus proliferation, further justifying the rationale that vaccines can be developed based on the S protein." *Id.* at 229. Finally, Du discloses: "It is likely . . . that S protein-based vaccines will bear fruit in the near future, as they have been proven to induce long-term and potent neutralizing antibodies and/or protective immunity against SARS-CoV." *Id.* at 234. On this preliminary record, we agree that Du helps to support a motivation to use the SARS-CoV spike protein, as taught in Geall, as an immunogen in Schrum's mRNA vaccines.

The balance of the evidence at this stage supports that the POSA would have had good reason to select SARS-CoV S protein as an immunogenic target for use in Schrum's mRNA vaccines.

e) Conclusion Regarding Motivation to Combine

Based on the preliminary record, we determine that Petitioner has provided a compelling, evidence-based rationale for combining the relevant teachings of Schrum and Geall. As discussed above, Schrum identifies and incorporates Geall by reference and relates to the same field of endeavor. Patent Owner does not currently dispute this. In addition, the knowledge in the art—as reflected in at least Yang and Du—provided good reasons to create an mRNA vaccine encoding the spike protein of SARS-CoV. Patent Owner's arguments regarding skepticism of mRNA vaccines appear to be, on the present record, undermined by the very art Patent Owner cites as well as by its own statements to the FDA. Finally, Patent Owner's arguments that Schrum's disclosure of mRNA vaccines is insufficient and that the art demonstrated a preference for saRNA vaccines are not supported by the current record and do not otherwise undermine Petitioner's showing based on controlling precedents. Accordingly, the current record plainly supports that the POSA would have been motivated to combine Schrum and Geall in the manner set forth in the Petition.

4. *Patent Owner's Arguments Regarding Expectation of Success*

Patent Owner argues that Petitioner has not established that the POSA would have reasonably have expected success for five reasons: 1) Petitioner has not established an expectation that the composition of Schrum and Geall would work, 2) Petitioner fails to account for the differences between Geall's saRNA (self-amplifying RNA) and the claimed mRNA, 3) the field was skeptical of mRNA vaccines, 4) the POSA would not extend the

teachings of Yang and Du to mRNA, and 5) the POSA would have been skeptical of the coronavirus spike protein as a vaccine antigen. We address each of these arguments in turn.

a) Arguments that the Composition of Schrum and Geall Would Not Work

Patent Owner argues that the cited art does not include any working examples and that in the absence of working examples, Petitioner "does not explain why a POSA would have expected an unmade, untested mRNA-LNP [lipid nanoparticle] to encode a betacoronavirus structural protein 'forming a spike.'" Prelim. Resp. 50–51. Patent Owner then asserts that "Petitioner cites no prior art teaching that such a composition would produce a protein that folds to 'form[] a spike.'" *Id.* at 51. Patent Owner concludes, "[w]ithout evidence of how the proposed mRNA-LNP-betacoronavirus antigen combination would be expected to work, Petitioner fails to provide a sufficient rational underpinning supporting a reasonable likelihood of reasonable expectation of success." *Id.*

We do not find this argument persuasive at least because we do not understand the claims to require the protein encoded by the mRNA to actually form a spike. The challenged claims speak only to the composition of the mRNA, not to the characteristics of the protein the mRNA may ultimately express. Put another way the claims do not require that the protein the recited composition causes to be expressed have any particular properties, much less that it fold to form a spike.[21]

[21] To the extent either party disagrees with this reading of the challenged claims, they are invited to brief the issue during trial.

Moreover, as we discuss in greater detail elsewhere herein, other evidence of record, including evidence submitted by Patent Owner, further supports a finding that mRNA vaccines were known to be effective. *See, e.g.*, Ex. 1016, 154 (both mRNA and replicon vaccines "effective" at eliciting humoral response); Ex. 2025, 1212–1213 ("the mRNA vaccine effectively induced long-lived" protection). At least Yang supports an expectation of success related to the immunogenicity of an expressed BetaCoV spike protein in animal models. *See* § III.D.3. And Patent Owner's own representations, including to the FDA, suggest that prior studies with DNA and saRNA delivery systems are informative—supporting a "proof of concept" with mRNA vaccines encoding a spike protein. *See* §§ III.E.3.b., III.E.4.b., and III.E.4.e (citing, for example, Exs. 2050 and 2054).

b) Arguments that Petitioner Failed to Account for Differences Between Geall's saRNA and the Claimed mRNA

Patent Owner argues that "Geall is limited to ***sa***RNA, or self-replicating RNA, ***not*** mRNA." Prelim. Resp. 51–52.[22] Patent Owner then asserts that saRNA and mRNA are "materially different" and that the claims

[22] Schrum suggests that self-replicating RNA is a species of mRNA. Ex. 1009 ¶ 345 ("mmRNA may be self-replicating mRNA"); *see also,* Ex. 2028, 194 (discussing "[c]ytoplasmic delivery of a self-amplifying mRNA"); Ex. 2005, 2118 (discussing delivery of "self-amplifying mRNA"); *but see* Ex. 2027, 262 ("Two major types of RNA are currently studied as vaccines: non-replicating mRNA and virally derived, self-amplifying RNA").

of the '600 patent do not encompass saRNA.[23] *Id.* at 52. As support, Patent Owner cites the declaration of Dr. Geall (the sole inventor of Geall (Ex. 1010)) submitted during prosecution of U.S. Patent Application No. 13/808,153, teaching that saRNA elicited RSV F IgGs in mice but mRNA at the same dose did not. *Id.* (citing Ex. 2026, 406–407). Patent Owner argues that Petitioner fails to account for the differences between mRNA and saRNA and provides "no basis to conclude [that] a POSA would reasonably expect success with an ***mRNA-LNP*** composition encoding betacoronavirus spike protein 'forming a spike.'" *Id.* at 53.

We do not find this persuasive for several reasons. First, we do not read Geall as limited to saRNA. For example, Geall broadly discloses that "[t]he invention involves *in vivo* delivery of RNA which encodes an immunogen." Ex. 1010, 12:2. And Geall expressly describes self-amplifying RNA only as "preferred," implying that Geall also encompasses RNA that is not self-replicating. *Id.* at 12:6 ("Preferred +-stranded RNAs are self-replicating"); *In re Susi*, 440 F.2d at 446 n.3. Indeed, as noted by Dr. Griffin, Geall teaches that the RNA "can be translated without needing any intervening replication steps," which suggests that RNA amplification or replication is not strictly necessary for translation of the desired immunogen. Ex. 1010, 12:4–5; Ex. 1002 ¶ 72 n.115.

[23] For purposes of this decision, we do not find it necessary to construe the claims to determine whether they exclude saRNA. Rather, we accept Patent Owner's premise that saRNA is excluded. To the extent either party contends that construction of "mRNA" is warranted, they are invited to brief the issue.

Second, Petitioner relies on Geall principally for its identification of a target immunogen. The current record, which lacks testimonial support from Patent Owner, tends to support that the POSA would consider that an immunogen targeted by a self-replicating RNA vaccine could also be targeted by mRNA vaccine. *See, e.g.*, Ex. 1016, 154 ("vaccines based on RNA, whether conventional mRNA or self-amplifying replicons, are effective at eliciting functional immunity"); *see also,* Ex. 1011, 563 (discussing results of DNA vaccine explaining that "[t]he definition of effective viral genes reported here can guide the choice of inserts" for "other vector delivery systems").

Third, as Petitioner points out (Paper 13, 3), Patent Owner cited Geall in a section of its Investigator's Brochures titled "Proof-of-Concept With mRNA-Based Vaccines." Ex. 2050, 12 (2016 Investigator's Brochure); *see also* Ex. 2051, 198 (2017 Investigator's Brochure); Ex. 2052, 11 (2019 Investigator's Brochure). On the current record, this undermines Patent Owner's suggestion that Geall's teachings are somehow inapplicable to mRNA vaccines. Patent Owner argues that the Investigator's Brochures post-date the priority date for the '600 patent (Paper 10, 2), but Patent Owner does not currently contest that the study it cites as supporting "proof of concept" (Geall) is prior art. Further, the current record, which does not include testimonial evidence from Patent Owner, does not support that the POSA would have viewed Geall differently at the time of the Investigator's Brochures than at the asserted priority date for the '600 patent.[24]

[24] As previously noted, the Investigator Brochure in Exhibit 2050 is dated September 23, 2016.

Fourth, Dr. Geall's prosecution declaration does not persuade us that the POSA would have understood teachings related to saRNA immunogens to be inapplicable to mRNA immunogens. Dr. Geall's declaration appears to be directed primarily to dosing. Ex. 2026, 406 ("Prior to this invention, there was little guidance in the art with respect to proper dosage for RNA vaccines for large mammals."). Although it supports that saRNA can be used at much lower doses than mRNA, on the present record, we do not understand it to teach that immunogens targeted by saRNA are inapplicable to mRNA or that the POSA would have reasonably expected mRNA vaccines to be ineffective (particularly when considered with the balance of other evidence presently of record, as discussed above). *See id.* at 407–408 ("When self-replicating RNA (SAM) was combined with a delivery system (CNE) [cationic oil-in-water emulsions] comparable levels of F-specific IgGs were produced at an RNA dose that is ***1000 fold*** lower (at 0.015 μg). Such dramatic reduction of dosage was not observed with conventional mRNA or DNA vaccines . . . , even when the mRNA or DNA was formulated with CNE.").

c) Arguments Regarding Skepticism in the Field of mRNA Vaccines

Patent Owner argues that "[a]s of the patent, the field was skeptical of mRNA vaccines." Prelim. Resp. 53. As support, Patent Owner cites the same teachings from Kallen and Petsch discussed *supra* § III.E.3.b. On the current record, these arguments are not persuasive for the reasons discussed

above. Patent Owner also cites Pardi,[25] DeFrancesco,[26] and Geall 2013 as support. We discuss each of these references in turn.

Patent Owner relies on Pardi as supporting skepticism, quoting a passage in which scientists noted "concerns associated with mRNA instability, high innate immunogenicity and inefficient *in vivo* delivery." Ex. 2027, 261 (quoted at Prelim. Resp. 53). In this passage, Pardi explains why "early promising results" with mRNA "did not lead to substantial investment in developing mRNA therapeutics." *Id.* We are not persuaded that this is demonstrative of skepticism regarding mRNA vaccines because Pardi goes on to teach that "[o]ver the past decade, major technological innovation and research investment have enabled mRNA to become a promising therapeutic tool in the fields of vaccine development and protein replacement therapy." *Id.* More specifically, Pardi discloses that "[v]arious mRNA vaccine platforms have been developed in recent years and validated in studies of immunogenicity and efficacy." *Id.* at 262. One of the articles Pardi cites to support this statement is Petsch, which is dated 2012. *Id.* at 262, 276 (describing Petsch as "demonstrat[ing] that directly injected, non-replicating mRNA can induce protective immune responses against an infectious pathogen"). Accordingly, on the current record, we are not persuaded that Pardi evidences skepticism of mRNA vaccines that undermines the POSA's reasonable expectation of success.

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[25] Pardi et al., *mRNA Vaccine – A New Era in Vaccinology*, 17 Nature Reviews 261–279 (2018) (Ex. 2027, "Pardi").
[26] DeFrancesco, *The 'Anti-hype' Vaccine*, 35 Nature Biotechnology 193–197 (2017) (Ex. 2028, "DeFrancesco").

Patent Owner quotes DeFrancesco's statement that "few in the research community considered RNA a good starting point" to support its argument that the field was skeptical of mRNA vaccines. Prelim. Resp. 53–54 (quoting Ex. 2028, 193). DeFrancesco makes this statement in the context of explaining the history of why RNA vaccine development "languished" behind DNA vaccine development. Ex. 2028, 193. This statement is not persuasive of skepticism because, on the current record, we are unable to link the time when "few . . . considered RNA a good starting point" to the critical date for the challenged claims. Further, DeFrancesco's teaching that support from the US Defense Department's Defense Advanced Research Projects Agency ("DARPA") spurred "advances in RNA vaccine technology" suggests that perceptions of whether RNA was "a good starting point" may have changed by such critical date. Indeed, DeFrancesco teaches that "[i]n recent years, . . . ways of making, delivering and expressing mRNA have improved and flagship companies such as CurVac and Moderna have sprung up, attracting both researchers and investors." *Id.* at 194; *see also generally, id.* at 193–197. Absent further explanation, DeFrancesco's teaching that "few . . . considered RNA a good starting point" is not persuasive of skepticism of mRNA vaccines that undermines the POSA's reasonable expectation of success.

Patent Owner relies on Geall 2013 as supporting that "the field focused on ***other*** vaccine types – *e.g.*, saRNA (like Geall) – not mRNA." Prelim. Resp. 54 (citing Ex. 1016, 154). We do not find this persuasive because, as discussed *supra* § III.E.3.c, Geall 2013 teaches that mRNA and self-replicating RNA each have advantages and disadvantages with both

showing efficacy at eliciting antigen-specific humoral and cellular immune responses. Ex. 1016, 153 (discussing "conventional, non-amplifying mRNA" and "RNA replicons," and teaching that "[b]oth approaches have their distinct advantages and limitations"), 154 (teaching that "RNA vaccines (both mRNA and replicons) are effective at eliciting antigen-specific humoral and cellular immune responses in animal models of infectious and non-infectious diseases"). That a POSA may have weighed the advantages and disadvantages and chosen saRNA over mRNA does not support that the POSA would not have *reasonably* expected success using mRNA, particularly where the current record tends to support that mRNA, like saRNA, was known to be effective in eliciting an immune response.

d) Arguments Regarding Extending the Teachings of Yang and Du to mRNA Vaccines

Patent Owner argues that Yang does not support an expectation of success because Yang "reported results with a truncated S protein," which Patent Owner asserts is different from the claimed "S protein or S protein subunit." Prelim. Resp. 54. This argument is not persuasive because, on the present record, we fail to discern a difference between a "S protein subunit" and a "truncated S protein."[27]

Patent Owner argues that "Yang only studied ***DNA*** vaccines, ***not*** mRNA" and that "DNA and mRNA are materially different in ways that affect their use for vaccines." Prelim. Resp. 54. More specifically, Patent

[27] To the extent either party contends that the term "subunit" requires construction to aid us in determining the relevance of Yang's alleged truncated protein, they are invited to brief the issue during trial.

Owner contends that "mRNA was known to be more unstable and prone to degradation than DNA" and that "data comparing DNA and mRNA vaccines suggested vaccine types were ***not*** interchangeable." *Id.* at 54–55. As support, Patent Owner cites Brito[28] as teaching that "major differences" were observed when comparing saRNA, mRNA, and DNA vaccines for RSV and that, at the same dose where saRNA induced an immunogenic response, "***mRNA was unable to induce responses***." Prelim. Res. 55 (citing Ex. 2005, 2119, 2124, Fig. 2).

We recognize the evidence that there are differences between DNA, mRNA, and saRNA vaccines, even where those vaccines encode the same immunogen. But, on the current record, we are not persuaded that these would detract from the POSA's reasonable expectation of success in using Schrum's lipid nanoparticles to deliver mRNA encoding an immunogen. Indeed, Brito teaches that "[r]ecently, mRNA has emerged as an alternative to pDNA [plasmid DNA] with a number of high profile reports using mRNA for vaccine and gene therapy applications" and that "[a]s a vaccine, mRNA has some clear advantages over pDNA." Ex. 2005, 2118. Although Brito does report an experiment where "mRNA was unable to induce response[]" it explains that this non-response was "perhaps due to the low dose being tested here." *Id.* at 2124. While using mRNA rather than DNA or saRNA may require a dose adjustment, on the current record, Brito does not support that the POSA would lack a reasonable expectation that Geall's (or Yang's)

[28] Brito et al., *A Cationic Nanoemulsion for the Delivery of Next-generation RNA Vaccines*, 22 Molecular Therapy 2118–2129 (2014) (Ex. 2005, "Brito").

immunogen would work in Schrum's mRNA lipid nanoparticles. Indeed, Yang expressly contemplates that its immunogen "can be expressed in other vector delivery systems for analysis." Ex. 1011, 563.

Patent Owner argues that Petitioner's reliance on Du is "misplaced" because Du does not discuss mRNA and is directed only to "attenuated virus, DNA, viral vector, and protein vaccines." Prelim. Resp. 55. For the reasons already discussed, we are not persuaded that differences between delivery mechanisms would diminish the POSA's expectation of success in using Geall's immunogen in Schrum's mRNA lipid nanoparticles.

e) Arguments that the POSA would have been Skeptical of Targeting Coronavirus Spike Proteins as a Vaccine Antigen.

Patent Owner also argues that there was "widespread skepticism regarding pursuit of a coronavirus spike protein as a vaccine antigen." Prelim. Resp. 55–56. More specifically, Patent Owner asserts that there was concern that targeting coronavirus spike proteins could "undesirably lead to ***enhancement of disease.***" *Id.* According to Patent Owner, "Du ***itself*** identifies '***concerns about the safety and ultimate protective efficacy of vaccines that contain the full-length SARS-CoV S protein***'—despite inducing some neutralizing antibody response—because such vaccines may induce 'harmful immune responses' causing liver damage or enhanced infections." *Id.* at 56 (citing Ex. 1031, 229–230). Patent Owner also cites Vennema[29] as teaching that "kittens immunized with a viral vector encoding

[29] Vennema et al., *Early Death After Feline Infectious Peritonitis Virus Challenge due to Recombinant Vaccinia Virus Immunization*, 64 Journal of Virology 1407–1409 (1990) (Ex. 2029, "Vennema").

the coronavirus S protein died following exposure to a coronavirus" and that the vaccine "worsened disease." *Id.* (citing Ex. 2029, 1409). Thus, Patent Owner contends, Vennema "suggested structural proteins ***other than*** S protein were better vaccine candidates." *Id.* Finally, Patent Owner cites Jaume[30] as teaching that "some vaccines targeting spike protein caused antibody-dependent enhancement of infection, whereas others did not." *Id.* (citing Ex. 2030, 10590). These arguments are, at present, unavailing.

The record does include some evidence that a vaccine based on a SARS CoV S protein may have posed safety concerns. Patent Owner is correct, for example, that Du teaches that full-length S protein-based SARS vaccines may induce liver damage or enhanced infection. Ex. 1031, 229–230. But this teaching is counterbalanced by Du's teaching that the S protein is the "main antigenic component that is responsible for inducing host immune responses" and therefore "an important target for vaccine and anti-viral development" (*id.* at 229) as well as by its conclusion that "***it is likely . . . that S protein-based vaccines will bear fruit in the near future***, as they have been proven to induce long-term and potent neutralizing antibodies and/or protective immunity against SARS-CoV" (*id.* at 234 (emphasis added)).

Somewhat more concerning, in terms of the expectation that a vaccine with an S protein could be used without creating unacceptable risks, are the

[30] Jaume et al., *Anti-Severe Acute Respiratory Syndrome Coronavirus Spike Antibodies Trigger Infection of Human Immune Cells via a pH- and Cysteine Protease-Independent FcyR Pathway*, 85 Journal of Virology 10582–10597 (2011) (Ex. 2030, "Jaume")

teachings of Vennema and Jaume. Vennema teaches that kittens immunized with feline infectious peritonitis virus ("FIPV") S protein experienced early death "thought to be caused by antibody-dependent enhancement (ADE) of infection" when challenged with FIPV. Ex. 2029, 1407. Jaume further investigates ADE, noting that it is potentially an issue for vaccines using SARS-CoV S protein. Ex. 2030, Abstr.

These disclosures are, however, balanced by other teachings that S protein-based vaccines may not trigger ADE. For example, Yang discusses that development of a vaccine for FIPV "has been complicated by possible immune potentiation of the disease," which we understand to reference ADE. Ex. 1011, 563. Yang then teaches, however, that a DNA vaccine encoding SARS-CoV S glycoprotein "generat[ed] neutralizing antibodies" and these "antibodies against SARS-CoV S glycoprotein protect against SARS-CoV challenge and ***do not enhance infection*** in [Yang's] animal model." *Id.* at 563 (emphasis added). Even Jaume found that two of five S protein SARS-CoV vaccines provided protective immunity without triggering ADE. Ex. 2030, 10595 ("Our results show that ADE was dependent on the immunization strategy with two of five candidate vaccines displaying obvious neutralizing capabilities without triggering SARS CoVpp."). Although Vennema and Jaume support some degree of uncertainty about the risks with S-protein based vaccines, on the present record, we are not persuaded that would negate a POSA's reasonable expectation of success. *Pfizer,* 480 F.3d at 1364 (holding that "the expectation of success need only be reasonable, not absolute").

In addition, as Petitioner explains (Paper 13, 5), Patent Owner's arguments that the POSA would not have expected a vaccine encoding SARS-CoV S protein to be safe are somewhat at odds with statements of Patent Owner made or submitted to the FDA.[31] For example, a Division of Microbiology and Infectious Disease ("DMID") Protocol 20-0003, dated February 14, 2020, states:

> Prior preclinical studies have demonstrated that coronavirus spike (S) proteins are immunogenic and S protein-based vaccines, including deoxyribonucleic acid (DNA) and mRNA delivery platforms, are protective in animals. Prior clinical trials of vaccines targeting related coronaviruses and other viruses have demonstrated that DNA and mRNA-based vaccines are safe and immunogenic. It is therefore anticipated that mRNA-1273 will generate robust immune responses to the 2019-nCoV S protein.

Ex. 2054, MOD_000477497. We recognize that this statement was made after the filing date of earlier, related applications to which the '600 patent claims priority. However, to the extent the prior preclinical studies and clinical trials it references constitute prior art to the '600 patent, the statement appears contrary to Patent Owner's argument in this case. We further recognize that, as Patent Owner explains, this statement "do[es] not concern disease enhancement." Paper 10, 4. But unless the evidence reflects developments assuaging concerns about ADE, and those developments arose only after the critical date for the challenged claims, it

[31] *See* 87 Fed. Reg. 45764–67 (July 29, 2022) (addressing parties' duty to disclose to the Patent Office (and the Board in trial proceedings) information material to the patentability of challenged claims, including conflicting or inconsistent statements submitted to other agencies, such as the FDA).

would seem disingenuous for Patent Owner to make the above representation to the FDA without mentioning ADE given the concerns Patent Owner now contends would have counseled against the use of S-protein based SARS vaccines.

Patent Owner's other statements describing the art also appear to provide: 1) additional examples where SARS-CoV S protein vaccination was found not to be associated with ADE (Ex. 2057, 2 (describing 2004 and 2007 prior art references as showing that S protein-based vaccines were not associated with disease enhancement, but also describing a 2005 study as reporting that vaccination with S protein resulted in enhanced liver pathology)), 2) additional evidence that a vaccine targeting the S protein would be safe (Ex. 2055, MOD_000471992 (describing a 2008 prior art reference as disclosing that a DNA vaccine expressing SARS S protein was "safe and well tolerated" as well as "immunogenic")), and 3) additional evidence supporting that the S protein was a "primary target" (Ex. 2054, MOD_000477505 (citing nine references dated from 2015–2019[32] as supporting that "[t]he coronavirus spike (S) protein mediates attachment and entry of the virus into host cells, making it a primary target for neutralizing antibodies that prevent infection")).

As is often the case, a given course of action comes with potential advantages and disadvantages. Where obviousness is concerned, a key is the balancing of the respective advantages and disadvantages. *See Medichem*, 437 F.3d at 1165; *Winner Int'l Royalty Corp. v. Wang*, 202 F.3d 1340, 1349

[32] On the present record, it is not clear how many, if any, of these references are prior art or otherwise evidence the state of the art at the relevant time.

n.8 (Fed. Cir. 2000) (explaining that benefits, both lost and gained, should be weighed against one another). Like the motivation issue, whether the POSA would have reasonably expected success is highly fact-intensive inquiry.[33] And, those issues will be best decided on a fully-developed record that includes trial-tested expert testimony from *both* parties further addressing, for example, the references cited by Patent Owner above, the alleged inconsistent statements Patent Owner made to the FDA, and the expected benefits of targeting a SARS-CoV S protein through an mRNA-based vaccine versus alleged safety concerns with S-protein based vaccines. At this stage, we are not persuaded that Patent Owner's argument on safety and efficacy undermines the POSA's reasonable expectation of success for the reasons discussed above.[34]

f) Conclusion Regarding Expectation of Success

At least at this preliminary stage of the proceeding, we determine that Petitioner has provided compelling, evidence-based reasoning why the POSA would have reasonably expected success in combining the teachings

[33] *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006) ("The presence or absence of a motivation to combine references in an obviousness determination is a pure question of fact"); *Par Pharm., Inc. v. TWi Pharma., Inc.*, 773 F.3d 1186, 1196 (Fed. Cir. 2014) ("The presence or absence of a reasonable expectation of success is also a question of fact.").

[34] To the extent Patent Owner maintains the position that concerns regarding safety and efficacy negate an expectation of success, Patent Owner should address the extent to which expectation of success in this case requires an expectation of safety and efficacy given that the challenged claims are directed to compositions and do not require that the claimed composition have any particular level of efficacy or safety.

of Schrum and Geall to arrive at the claimed subject matter. Petitioner points out, and Patent Owner does not dispute, that methods of synthesizing mRNA were known in the art and that Schrum provides examples where administration of protein-encoding mRNA formulated in lipid nanoparticles expressed the encoded protein. On the current record, we are not persuaded by Patent Owner's argument that the POSA would have considered teachings regarding the utility of spike protein as an immunogen irrelevant on the basis that the spike protein was administered using a different delivery vehicle—e.g., saRNA or DNA rather than the claimed mRNA. And, on the present record, we are not persuaded that Patent Owner's evidence that spike protein-based vaccines may trigger AED is sufficient to negate a reasonable expectation of success. Accordingly, the current record plainly supports that the POSA would have a reasonable expectation of success in combining Schrum and Geall as set forth in the Petition.

5. *Objective Indicia of Nonobviousness*

Patent Owner argues that objective indicia of obviousness confirm the nonobviousness of the challenged claims. Prelim. Resp. 66–70. Patent Owner contends that a nexus between its alleged objective indicia (industry praise, failure of others, and skepticism) and the challenged claims is "presumed" because Patent Owner's "COVID-19 vaccine, Spikevax® embodies and is coextensive with the claims." *Id.* at 65–68 (arguing that the claimed subject matter encompasses Spikevax). Patent Owner argues that Spikevax was "praised as saving lives and the global economy." *Id.* at 67–68 (citing publications in, for example, the New York Times (Ex. 2037), and awards received by Patent Owner for its work on Spikevax (Exs. 2040–

2042)). Patent Owner contends that others had tried, but failed, to develop mRNA medicines. *Id.* at 69 (arguing that "Spikevax® and Petitioner's Comirnaty®" were the "first commercial mRNA products (vaccine or therapeutic)" and citing other, allegedly unsuccessful, clinical trials related to mRNA HIV-1 and mRNA rabies vaccines (Exs. 2043–2046)). And, Patent Owner argues, there was "significant industry skepticism around mRNA medicines" before Spikevax. *Id.* at 68–69 (citing, e.g., Pardi (Ex. 2027) about an alleged lack of early, significant investment in mRNA therapeutics because of perceived issues with mRNA stability and delivery; citing, e.g., Yang (Ex. 1011, 563) and Vennema (Ex. 2029, 1409) about possible disease enhancing activity with vaccines using a spike protein).

Patent Owner's argument and evidence about alleged objective indicia of nonobviousness does not weigh in favor of denying Petitioner's challenge at this stage. We discuss below.

As an initial matter, there is no indication on this record that Petitioner was aware of Patent Owner's specific arguments on the alleged objective indicia such that Petitioner should have preemptively addressed it in the Petition. Under such circumstances, and considering the fact-intensive nature of objective indicia, we determine that Petitioner should be given an opportunity to develop and present rebuttal argument and evidence on such indicia at trial in this proceeding. *See, e.g.*, *Invata, LLC v. Opex Corp.*, IPR2022-01604, Paper 8 at 10 (PTAB Mar. 17, 2023) (declining to give weight to objective indicia at the institution stage, and allowing Petitioner an opportunity to test Patent Owner's evidence through discovery and trial); *MOM Enterprises, LLC v. Elaine and Reinhold W. Vieth*, IPR2023-00726,

Paper 10 at 44–45 (PTAB Sept. 15, 2023) (same); *Amneal Pharms., LLC v. Supernus Pharms., Inc.*, IPR2013-00368, Paper 8 at 12–13 (PTAB Dec. 17, 2013) (same)). We will reevaluate argument about objective indicia of nonobviousness as appropriate on a fully-developed record.

Moreover, we are not persuaded on the present record that Patent Owner has established a sufficient nexus between the claims and the asserted objective indicia of nonobviousness. Prelim. Resp. 65–69. Such indicia are "only relevant to the obviousness inquiry 'if there is a nexus between the claimed invention and the [objective indicia].'" *In re Affinity Labs of Tex., LLC*, 856 F.3d 883, 901 (Fed. Cir. 2017) (quoting *Ormco Corp. v. Align Tech., Inc.*, 463 F.3d 1299, 1312 (Fed. Cir. 2006)). "The patentee bears the burden of showing that a nexus exists." *WMS Gaming Inc. v. Int'l Game Tech.*, 184 F.3d 1339, 1359 (Fed. Cir. 1999); *Fox Factory, Inc. v. SRAM, LLC*, 944 F.3d 1366, 1373 (Fed. Cir. 2019) (explaining that nexus may be presumed "when the patentee shows that the asserted objective evidence is tied to a specific product and that product embodies the claimed features, and is coextensive with them") (internal quotations marks and citation omitted).

Patent Owner argues that a nexus should be "presumed" because the challenged claims are "coextensive" with Spikevax. Prelim. Resp. 65–69. Petitioner's evidence falls short of making that showing. First, Patent Owner provides no declarant testimony that compares the claims with the features of Spikevax, much less any testimony that establishes Patent Owner's vaccine is "coextensive" with the claims. *Volvo Penta of the Americas, LLC, v. Brunswick Corp.*, 81 F.4th 1202, 1211 (Fed. Cir. 2023)

(holding conclusory assertions and limited expert testimony that only confirms a patentee's products embody the claims "is insufficient to show a presumption of nexus"). Second, even assuming Spikevax is within the scope of the claims as Patent Owner argues, that alone does not establish coextensiveness. *See id.*; *see also Fox Factory*, 944 F.3d at 1377 (holding a nexus is not established simply by showing that "the patent claims broadly cover the product that is the subject of the evidence of secondary considerations"); *Application of Tiffin*, 448 F.2d 791, 791–792 (CCPA 1971) (finding that "appellants' evidence of commercial success and the satisfaction of a long-felt need, both the success and the need being with respect to 'cups' used in vending machines, was sufficient to overcome the Patent Office's case of prima facie obviousness" for claims reciting "cups" but not for claims "reciting 'containers' generally"); *see also In re Ikeda Food Research Co., Ltd.* 758 Fed. Appx. 952, 959–960 (Fed. Cir 2019) (affirming Board's determination of obviousness where asserted objective indicia was not commensurate in scope with claims); *In re Greenfield*, 571 F.2d 1185, 1189 (CCPA 1978) (same).

The claims purport to encompass immunogenic vaccines encoding a spike protein (or subunit) for any betacoronavirus. *See supra* § I(D). Yet betacoronavirus is a genus of viruses and is broader than the specific SARS-CoV-2 virus (and its variants) for which Patent Owner submits alleged objective indicia. *Compare, e.g.,* Ex. 2010, 28 (prescribing information cited by Patent Owner on Spikevax for SARS-CoV-2 Omicron variant lineage XBB.1.5), *with* Ex. 1029, 810 (taxonomic tree for the sub-family *Coronavirinae*, listing betacoronavirus as one of several genera, itself

including four separate lineages, such as SARS-related coronavirus under lineage B, and murine coronavirus and Betacoronavirus 1 under lineage A). Patent Owner does not, on this preliminary record, address the breadth of the claims against the comparative narrowness of its evidence.

We recognize Patent Owner's contentions about alleged industry praise, failure of others, and industry skepticism related to mRNA therapeutics. However, without a sufficient nexus showing, and with no evidence that Petitioner was aware of Patent Owner's assertions, we give that argument and evidence no weight at this stage.[35]

6. *Claims 2, 4–6, 8–12, 16, 17, 20, 21, and 26*

Petitioner contends that claims 2, 4–6, 8–12, 16, 17, 20, 21, and 26 are taught or suggested in the prior art, and that the skilled artisan would have predictably modified the prior art to the extent needed to arrive at the claimed subject matter with a reasonable expectation of success. Pet. 42–48. Petitioner's contentions are supported by citation to the prior art and expert testimony. *Id.* Patent Owner does not differentiate its arguments by claim, relying on the same arguments for all of the claims. On this preliminary record, and for the reasons discussed above, we do not find Patent Owner's rebuttal arguments persuasive.

7. *Conclusion Regarding Compelling Merits*

For the reasons set forth above, we determine that Ground 2 of the Petition presents a compelling meritorious challenge. That is, "the evidence,

[35] Patent Owner's arguments here on skepticism also materially overlap with argument that we addressed above. *See* Section §§ III.E.3.b and IIII.E.4.c.

if unrebutted in trial, would plainly lead to a conclusion that one or more claims are unpatentable by a preponderance of the evidence." Guidance Memo 4. As the Director explains in *OpenSky,* however, this finding "should not be taken as a signal to the ultimate conclusion after trial" because "all relevant evidence likely will not have been adduced at the point of institution [and] trial should produce additional evidence that may support a determination in the Final Written Decision that unpatentability has not been adequately proven." *OpenSky*, IPR2021-01064, Paper 102 at 49– 50. Here, we note that the current record does not include evidence tying Spikevax to the challenged claims and thus we accorded no weight to Patent Owner's evidence of objective indicia and that Patent Owner has not supported its contentions with citation to expert testimony.

Because we find that Ground 2 of the Petition presents a compelling meritorious challenge to at least claim 1 of the '600 patent, we decline to exercise discretion to deny institution under § 314(a). Guidance Memo 5 ("[T]he PTAB will not deny institution based on Fintiv if there is compelling evidence of unpatentability."); *CommScope*, Paper 23 at 4 (same).

IV. ANALYSIS OF GROUNDS 1, 3, AND 4

A. Ground 1: Anticipation by Schrum

To show anticipation under 35 U.S.C. § 102, each and every claim element, arranged as in the claim, must be found in a single piece of prior art. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359 (Fed. Cir. 2008).

Petitioner argues that claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 are anticipated by Schrum. Pet. 22–38. Patent Owner opposes this argument.

Prelim. Resp. 36–46. The parties' arguments on claim 1 are illustrative and summarized below, followed by our discussion. According to Petitioner, Schrum "disclose[s] the same standard mRNA and lipid nanoparticle components" claimed in the '600 patent and further discloses, through Schrum's incorporation-by-reference of Geall, "encoding the spike (S) protein of a betacoronavirus, SARS-CoV, in an mRNA composition" as claimed. Pet. 22.

More specifically, Petitioner argues that Schrum discloses administering an mRNA vaccine to elicit an immune response in a mammal. Pet. 22–23 (citing, e.g., Ex. 1009 ¶¶ 3–5, 340, 342). According to Petitioner, this disclosure meets claim 1's preamble (if it is limiting). *Id.* For claim 1's recitation that the mRNA encodes a BetaCoV S protein or S protein subunit, Petitioner argues this limitation is met through Schrum's incorporation of Geall's disclosure, including Geall's teaching that "the immunogen elicits an immune response" against "viruses" including "SARS coronavirus" and that "[t]he coronavirus immunogen may be a spike polypeptide." Ex. 1010, 18:11, 19:26–29; Pet. 24–25. Petitioner acknowledges that Geall lists SARS-CoV spike protein among several other potential immunogens, but argues that Schrum and Geall together are nonetheless anticipatory. Pet. 25–26 (citing, e.g., *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1376 (Fed. Cir. 2005)).

Altogether, Petitioner argues that "Schrum discloses combining the components of claim 1, as arranged in the claim" in a manner "more than sufficient to be anticipatory." Pet. 27. Moreover, Petitioner contends, a "POSA would readily envisage creating the modified mRNA compositions

(*i.e.*, vaccines) described in Schrum—including those encoding the betacoronavirus S protein—using the disclosed lipid nanoparticles." *Id.* (citing Ex. 1009 ¶¶ 342, 378, 397).

Patent Owner raises four counterarguments. Prelim. Resp. 36 (summarizing arguments). ***First***, Patent Owner contends, Petitioner has not shown that Schrum/Geall discloses an S protein as claimed. *Id.* at 44–45. ***Seccond,*** Patent Owner argues that Petitioner has not shown Schrum and Geall, even assuming Geall is incorporated in its entirety into Schrum,[36] arrange the elements in the same way recited in claim 1. *Id.* at 37–41 (citing, e.g., *In re Arkley*, 455 F.2d 586, 587 (CCPA 1972)). ***Third***, Patent Owner argues that Petitioner has not shown that a POSA would "at once envisage" claim 1's method from the disclosure of Schrum/Geall. *Id.* at 41–43 (citing, e.g., *Kennametal, Inc. v. Ingersoll Cutting Tool Co.*, 780 F.3d 1376, 1381 (Fed. Cir. 2015)). And ***fourth***, according to Patent Owner, Petitioner has not established that a POSA would be led to a "small recognizable class with common properties," which class includes the claimed subject matter, from among, at best, an alleged genus of mRNA compositions and immunogens described in Schrum/Geall. *Id.* at 43–44 (citing, e.g., *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1084 (Fed. Cir. 2008)).

[36] Patent Owner assumes for purposes of its preliminary response that Geall's disclosure is incorporated-by-reference into Schrum. Prelim. Resp. 36 n.4. For purposes of this decision, we also consider Geall's teachings to be fully incorporated into Schrum. We may, thus, refer to this collective disclosure as Schrum/Geall in addressing the anticipation arguments herein.

Patent Owner's first argument—i.e., that Schrum/Geall does not disclose an S protein as claimed—is unavailing on this preliminary record for the reasons discussed above. *See supra* §III.E.3.a.

Patent Owner's remaining arguments may have some merit and Patent Owner may prevail on such arguments at trial (assuming the argument is preserved in the Patent Owner Response). We determine, however, that Petitioner's anticipation challenge and any counterargument from Patent Owner should be considered and resolved on a fully-developed evidentiary record,[37] especially because we have decided that at least Ground 2 meets the standard for institution and all grounds must, therefore, be included in trial. *See SAS*, 138 S. Ct. at 1355. We provide the discussion below based on the preliminary record to give guidance to the parties.

Patent Owner's second argument is that Petitioner's anticipation challenge should fail because Schrum/Geall does not combine or arrange those elements exactly as set forth in claim 1. Prelim. Resp. 37–41. More specifically, Patent Owner contends, Petitioner must pick and choose from unrelated disclosures and long lists in Schrum/Geall to arrive at claim 1's subject matter. *Id.* (arguing such picking and choosing cannot show anticipation). According to Patent Owner, Petitioner cites from one "generic" section of Schrum about mRNA vaccines, yet, in that section, Schrum describes at least "***two*** payload options"—mRNA and saRNA. *Id.*

[37] *Mylan Pharm., Inc. v. Merck Sharp & Dohme Corp.*, 50 F.4th 147, 152–154 (Fed. Cir. 2022) (explaining that "[a]nticipation is a question of fact" and affirming the Board's finding that the asserted art did not anticipate the claimed salt).

at 38 (citing Ex. 1009 ¶¶ 340–350). Because that section does not disclose claim 1's recitations about the lipid nanoparticle formulation, Patent Owner contends Petitioner points to "a ***separate*** section of Schrum" to suggest that Schrum's mRNA molecules may be encapsulated in lipid nanoparticles. *Id.* at 40 (citing Ex. 1009 ¶ 409). And, to find the BetaCoV spike (S) protein, Patent Owner contends that Petitioner relies on Geall's listing of immunogens "spanning ***seven pages*** and over ***500*** different immunogen options." *Id.* at 38 (citing Ex. 1010, 15:32–22:35). Patent Owner contends that Petitioner is, therefore, picking the claimed combination of mRNA vaccine, encapsulated in a lipid nanoparticle, and encoding a BetaCoV spike protein from "at least ***one thousand***" possible combinations (i.e., two payload options (x) five hundred immunogens) disclosed in Schrum/Geall. *Id.* at 39.

Whether a POSA would need to engage in forbidden picking and choosing to anticipate claim 1's subject matter is best resolved on a fully-developed record. Answering this question will likely turn on the breadth of the Schrum/Geall disclosure and the extent to which there is a sufficiently close connection between the relevant teachings. *Arkley*, 455 F.2d at 587 (holding that an anticipating reference "must clearly and unequivocally disclose the claimed compound or direct those skilled in the art to the compound without *any* need for picking, choosing, and combining various disclosures *not directly related to each other by the teachings of the cited reference*") (emphasis added).

Based on the preliminary record, we are somewhat skeptical that a POSA reading Schrum/Geall would consider the teachings about mRNA

vaccines and encapsulation of such vaccines in lipid nanoparticles to be unrelated. Schrum discloses generally that the modified mRNA of the invention can be formulated into lipid nanoparticles and, in embodiments, that "the lipid nanoparticle may be formulated for use in a vaccine such as, but not limited to, against a pathogen." *See, e.g.*, Ex. 1009 ¶¶ 378, 397;[38] *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001) (explaining that anticipation does not require actual performance of what a reference describes).

We see some merit in Patent Owner's contention that Schrum's paragraph citing Geall does not *specifically direct* the POSA to Geall's listed immunogens or the claimed BetaCoV spike (S) protein in particular. Prelim. Resp. 40–41. The paragraph is somewhat "generic" and, in context, appears to refer to Geall for immunogenic "dose amounts." *Id.* (arguing that the paragraph, quoted in full, cites Geall for a discussion of dose amounts and "***not*** any particular immunogen"); Ex. 1009 ¶ 342. Petitioner's suggestion that Schrum incorporates Geall "for [its] teaching of disclosed immunogens" may, thus, be overstated. Pet. 23–24.

Notwithstanding the above, this same paragraph states that Geall (and one other reference) is "incorporated by reference in [its] entirety." Ex. 1009 ¶ 342. If *all* of Geall's teachings are added, Schrum/Geall's

[38] *See also* Ex. 1009 ¶ 346 (teaching that the "mmRNA of the invention may be formulated using methods described herein or known in the art" and identifying, as a "non-limiting example," the methods in Geall 2012 (Ex. 2021), which describes formulating self-amplifying RNA vaccines in lipid nanoparticles). Schrum states that Geall 2012 is "incorporated by reference in its entirety." Ex. 1009 ¶ 346.

comprehensive disclosure would then include a list of immunogens—including a listing of a BetaCoV spike protein. Ex. 1010, 19:26–29 (disclosing that the immunogen may be derived from a "SARS coronavirus" and "may be a spike polypeptide"). Schrum without Geall does not appear to identify any specific immunogen. But, with Geall's incorporated disclosure, it seems reasonable and logical that a POSA reading Schrum's teachings about using mRNA vaccines to encode immunogenic proteins would look to the only listing of immunogens available in the now-expanded reference. *See* Ex. 1009 ¶¶ 340–350. In that sense, a POSA may well understand the listing of immunogens—even if lengthy—as being related to Schrum/Geall's more general disclosures about mRNA vaccines that encode immunogens.[39]

To summarize, we see Patent Owner's second argument as raising the question whether Schrum/Geall discloses mRNA lipid nanoparticle vaccines with sufficient clarity that the POSA would not need to pick and choose to

[39] *Sinclair,* 325 U.S. at 333 (reversing determination that patent was not anticipated by prior art explaining, "[r]eading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put into the last opening in a jig-saw puzzle"); *Eli Lilly and Co. v. Los Angeles Biomedical Res. Inst. at Harbor-UCLA Med. Ctr.*, 849 F.3d 1073, 1074–75 (Fed. Cir. 2017) (noting that anticipatory prior art may be such that a POSA would reasonably understand or infer that the claimed subject matter is disclosed, while art that merely "suggests" the claimed subject matter is not sufficient under § 102); *In re Gleave*, 560 F.3d 1331, 1334–38 (Fed. Cir. 2009) (explaining that, "[f]or the purposes of whether they are anticipatory, lists and genera are often treated differently," and affirming anticipation of claims to "antisense" sequences by art "expressly list[ing] every possible fifteen-base-long [sense] oligodeoxynucleotide sequence in IGFBP-2," in a list with "more than 1400 sequences").

identify them as a delivery vehicle such that all that remains to anticipate the claims is to select BetaCoV spike (S) protein as the immunogen to be encoded by the mRNA vaccine. We find that this question is best resolved on a more complete record at trial.

In its third argument against anticipation, Patent Owner contends that Petitioner's assertion that a POSA would "envisage" the claimed subject matter is insufficient. Prelim. Resp. 41–43. According to Patent Owner, Petitioner does not support its contention that a POSA would "readily envisage" the method of claim 1 from Shrum/Geall—noting that the Petition "includes [only] two conclusory sentences" on this question. *Id.* at 42 (citing Pet. 27). Further, Patent Owner argues, Petitioner provides "no reason a POSA would at once envisage the claimed combination from among a thousand options." *Id.* at 43.

Insofar as Petitioner is invoking a theory based on a POSA "envisaging" claim 1's subject matter, Petitioner provides little explanation. Petitioner includes one sentence, and no declarant testimony, that directly addresses this issue. Pet. 27. Based on the Federal Circuit's guidance, whether a POSA would "at once envisage" the claimed subject matter from a single reference depends on multiple factual considerations—including, *inter alia*, the number and diversity of possible options/combinations in the reference. *See, e.g.*, *Mylan*, 50 F.4th at 153–154 (declining to impose a bright-line number of options that may be envisaged in a "limited class," explaining it "depends on the 'class'" and reinforcing that "[t]he key term

here is 'limited'")[40]; *Blue Calypso, LLC v. Groupon, Inc.*, 815 F.3d 1331, 1343–44 (Fed. Cir. 2016) (affirming finding of anticipation by reference that "disclose[d] a limited number of [advertising] tools" and disclosed combining tool functionalities); *In re Ruschig*, 343 F.2d 965, 973–74 (CCPA 1965) (reversing anticipation rejection by art disclosing 130 and 156 possible compounds; distinguishing from the 20 compounds in *Petering* derived by substituting "closely related units" such as "H and CH(3)" at certain molecular positions, unlike the "widely differing" and "diverse" chemical substituent combinations of the art in the rejection at issue).[41]

Patent Owner's criticism of Petitioner's "envisaging" theory is not without basis. As already noted, the Petition includes little analysis supporting it. Moreover, as asserted by Patent Owner, the disclosure of immunogens in Schrum/Geall is broad and encompasses many hundreds of options. Ex. 1010, 15:32–22:35. Indeed, Schrum/Geall discloses that such immunogens may be derived from, and elicit immune responses to, not only

[40] In *Mylan*, the court held that "the Board did not err in finding that a class of 957 predicted salts" that may (or may not) form if combining disclosed acids and compounds "is insufficient to meet the 'at once envisage' standard set forth in *Petering*." *Mylan* 50 F.4th at 154 (finding 957 possible salts "is a far cry from the 20 compounds 'envisaged' by the narrow genus in *Petering*"); *In re Petering*, 301 F.2d 676, 681 (CCPA 1962).

[41] As the court in *Ruschig* further explained, *Petering* was distinguished because that case involved "some 20 compounds in a limited class, the members of which were very similar to one another in structure and all of which possessed the same properties." *In re Ruschig*, 343 F.2d at 973–74 (holding that, even by dissecting the art's example compounds and "recombin[ing] them into different compounds than those named, we do not get a small recognizable class with common properties").

viruses and viral proteins, but bacteria, fungi, and parasites. Ex. 1010, 15:32–21:19; *see also id.* at 15:34–16:7, 21:20–22:35 (also listing several "allergens" and "tumor antigens" among the immunogens). Petitioner leaves essentially unexplained at this stage how and why the "at once envisage" precedents apply under these circumstances. We will revisit as appropriate on a fully-developed record.

In its fourth argument against anticipation, Patent Owner asserts that, for a disclosed genus to anticipate a claimed species, the anticipatory reference must "lead a [POSA] to a small recognizable class with common properties." Prelim. Resp. 43 (citing *Sanofi-Synthelabo*, 550 F.3d at 1084). According to Patent Owner, although "Schrum and Geall disclose, at most, a broad genus of at least a thousand options, Petitioner does not mention or apply this standard." *Id.*; *see also id.* at 44 (arguing "Petitioner makes no showing that Geall's listed immunogens would have common properties").

Patent Owner's argument is subsumed into our discussion above about the sufficiency of Petitioner's showing on an "envisaging" theory. Despite Patent Owner's suggestion to the contrary, the language about a "small recognizable class with common properties" taken from *Sanofi-Synthelabo* did not announce a new or different anticipation "standard." To the contrary, the quoted language comes originally from *Ruschig* and concerned whether a POSA would at once "envisage" a claimed species based on the "mechanistic dissection and recombination" of parts of chemical compounds exemplified in the prior art. *In re Ruschig*, 343 F.2d at 974–75. And, the court held that such an approach was not permissible because, unlike the situation in *Petering* where the court determined that a

POSA would "at once envisage" the claimed species from a broader genus disclosed in the art, the resulting class of possible combinations in *Ruschig* was neither "small" nor representative of compounds with "common properties." *Id.* (citing and distinguishing *Petering*); *Sanofi-Synthelabo*, 550 F.3d at 1084 (citing *Ruschig* for genus/species anticipation and explaining that, in *Ruschig*, "the court declined to find the disclosed genus anticipatory of everything within its scope").[42] Thus, the "small recognizable class with common properties" language is simply another articulation of considerations relevant to whether a POSA would at once envisage the claimed species within a genus disclosed in the art. This is a question we will decide, if necessary, based on a complete trial record.

B. Ground 3 (Obviousness over Schrum and Yang) and Ground 4 (Obviousness over Schrum and Altmeyer)

Petitioner additionally argues that claims 1, 2, 4–6, 8–12, 16, 17, 20, 21, and 26 would have been obvious over Schrum in combination with Yang (Ground 3), or Schrum in combination with Altmeyer (Ground 4). Pet. 48–57 (Ground 3), 57–69 (Ground 4).

Taking claim 1 as illustrative, Petitioner's arguments for Grounds 3 and 4 largely mirror those under Ground 2, except that, in Grounds 3 and 4, Petitioner additionally relies on Yang and Altmeyer, respectively, for disclosure of an immunogen that is a SARS-CoV spike (S) protein. *See,*

[42] Further, in *Sanofi-Synthelabo*, the Federal Circuit affirmed the district court's determination that a reference's generic statement about compounds existing in enantiomers was not a sufficient, anticipatory disclosure of a separated dextrorotatory enantiomer of PCR 4099, as claimed. *Sanofi-Synthelabo*, 550 F.3d at 1084.

e.g., Pet. 48–49 (citing Ex. 1011, 561–562), 58–59 (citing Ex. 1012, Abstr., ¶¶ 60, 98). Petitioner also cites results disclosed in Yang and Altmeyer as suggesting to the POSA that nucleic-acid vaccines targeting the S-protein of SARS-CoV would be immunogenic and successful, and supporting the POSA's motivation to use mRNA vaccines as disclosed in Schrum to encode and express that protein. *Id.* at 50–52 (citing Ex. 1011, 561–562; Ex. 1020, 10 (describing advantages of mRNA vaccines over DNA vaccines), 59–61 (citing Ex. 1012 ¶ 116, Figs. 7–8).

Petitioner supports its contentions on Grounds 3 and 4 with testimony from Drs. Griffin and Moon. Ex. 1002 ¶¶ 141–150 (testifying, *inter alia*, that "mRNA vaccines were known to have significant advantages over DNA vaccines" including "better protein production" and avoidance of "integrat[ion] into the host cell" genome), 174–184 (testifying, *inter alia*, that Altmeyer "reports on data demonstrating that mRNA administered in an effective amount induces an immune response to the BetaCoV S protein or S protein subunit.")" (citing Ex. 1012 ¶ 116). Patent Owner provides no rebuttal testimony from a qualified declarant of its own at this stage.

Patent Owner's counterarguments for Grounds 3 and 4 are also similar to those addressed above under Ground 2. We discuss briefly below.

Patent Owner contends that Petitioner fails to identify a "Spike" protein in the proposed combination of Schrum with Yang or Altmeyer. Prelim. Resp. 58, 62. This argument is unpersuasive on this preliminary record as already explained. At least Schrum, through its incorporation-by-reference of Geall, appears to teach or suggest a betacoronavirus spike protein as construed. *See supra* § III.E.2.

Patent Owner contends that a POSA would not have been motivated to pursue mRNA vaccines over the exemplified DNA vaccines (of Yang) or viral vector vaccines (of Altmeyer). *Id.* at 57–58 (arguing the field had concerns with mRNA, including its stability, and had focused instead on DNA vaccines), 60–62 (arguing mRNA was considered relatively unstable and vector vaccines were generally regarded as the most efficient means of nucleic acid delivery). These arguments are unavailing. As discussed above, the art suggested that mRNA vaccines were active and had advantages over, for example, DNA vaccines. *See, e.g.*, Ex. 1020, 10–11 (noting "reports on nucleotide-based vaccines showed that vaccines produced on DNA or mRNA basis had similar activity" and early focus on DNA vaccines was "erroneous" relative to the lower costs, faster production, and flexibility of mRNA vaccines, especially "for pandemic scenarios," along with the fact that "mRNA carries no risk of genomic integration," giving mRNA "an inherent safety advantage over DNA-based therapeutics").[43] Moreover, even if the art perceived that DNA or viral-vector vaccines were better in some respects, that would not necessarily

[43] To the extent Patent Owner maintains the position that concerns about mRNA stability or innate immunogenicity would have discouraged its use, Patent Owner should address whether POSAs would have expected known LNP formulation techniques and nucleotide base modifications (e.g., pseudouridine for uridine) to mitigate those concerns. *See, e.g.*, Exs. 1021, 165 (disclosing that "nucleoside modifications suppress the potential of RNA to activate DCs [(dendritic cells)]"); Ex. 1032, 231 (describing development of lipid delivery systems to protect mRNA from *in vivo* degradation); Ex. 1062, 1:8–9 (describing "[l]ipid nanoparticles (LNP) are the most clinically advanced drug delivery systems").

support a conclusion of nonobviousness. *In re Fulton*, 391 F.3d 1195, 1200 (Fed. Cir. 2004) ("[O]ur case law does not require that a particular combination must be the preferred, or the most desirable, combination described in the prior art in order to provide motivation for the current invention."); *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 800 (Fed. Cir. 2021) ("[It is] not necessary to show that a combination is the *best* option, only that it be a *suitable* option.") (internal quotation marks omitted).

Patent Owner also argues that a POSA would not have reasonably expected success in combining Schrum with Yang or Altmeyer to reach the claimed subject matter. Prelim. Resp. 58–60, 62–65 (cross-referencing counterargument for Ground 2). Patent Owner contends that Petitioner's reliance on different vaccine types (e.g., DNA, viral vector) is insufficient to provide a reasonable expectation as to mRNA vaccines. *Id.* We do not, on this record, agree. That neither Yang nor Altmeyer expressly disclose mRNA vaccines is not decisive because that disclosure is supplied by Schrum, which also suggests that such vaccines can be made and would induce an immune response in the recipient. *See, e.g.*, Ex. 1009 ¶¶ 340–350. We addressed above Patent Owner's arguments about alleged skepticism and potential disease enhancement with mRNA vaccines. *See* §§ III.E.3.b, III.E.4.c, and III.E.4.e. Whether Dr. Griffin is misreading Altmeyer's results (as argued by Patent Owner (Prelim. Resp. 63–64)) or whether other characteristics of DNA or viral vector vaccines would mean a POSA would conclude that any results with such vaccines are inapposite to mRNA vaccines are questions we will revisit, as necessary, on a fully-developed record.

V. CONCLUSION

We determine that there is a reasonable likelihood that Petitioner would prevail with respect to at least one of the claims challenged in the Petition. We further decline to deny the Petition on a discretionary basis. We, therefore, institute *inter partes* review.

Any argument not raised in a Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. In addition, nothing in this Decision authorizes Petitioner to supplement information advanced in the Petition in a manner not permitted by the Board's Rules.

VI. MOTIONS TO SEAL

Patent Owner and Petitioner have each filed motions to seal. Paper 11 (Patent Owner Motion to Seal ("PO Mot.")); Paper 12 (Petitioner's Motion to Seal ("Pet. Mot.")).

Patent Owner moves to seal Exhibits 2050–2052, 2056, 2057, and portions of Exhibit 2060. PO Mot. 1–4. Patent Owner also moves for entry of a protective order. Ex. 2059 ("Modified Protective Order"); Ex. 2058 (redline showing differences between "Modified Protective Order" and the Board's Default Protective Order). Petitioner moves to seal portions of Petitioner's Preliminary Statement Regarding Patent Owner's Inconsistent Statements (Paper 13 ("Pet. Prelim. Stmt.")). Pet. Mot. 1; *see also* Paper 15 (public/redacted version of Pet. Prelim. Stmt.). Neither motion is opposed.

The Board recognizes "a strong public policy for making all information filed in a quasi-judicial administrative proceeding open to the public, especially in an inter partes review which determines the

patentability of claims in an issued patent and therefore affects the rights of the public." *Garmin Int'l v. Cuozzo Speed Techs., LLC*, IPR2012-00001, Paper 34 (PTAB Mar. 14, 2013), 1–2. Except as otherwise ordered by the Board, the record of an *inter partes* review shall be made available to the public. 35 U.S.C. § 316(a)(1); 37 C.F.R. § 42.14.

The moving party bears the burden of showing that the relief requested should be granted. 37 C.F.R. § 42.20(c). The standard for granting a motion to seal is "for good cause." 37 C.F.R. § 42.54(a).

Patent Owner contends that good cause exists to seal the exhibits that are the subject of its motion. PO Mot. 2–4. More specifically, Patent Owner contends that the exhibits comprise confidential investigator brochures about Patent Owner's vaccine candidates (Exs. 2050–2052), confidential pre-investigational new drug application meeting materials (Ex. 2056), an unpublished technical vaccine paper from one of Patent Owner's scientists (Ex. 2057), and a chart (Ex. 2060) that contains confidential excerpts from the foregoing exhibits. *Id.* Patent Owner also contends that Exhibits 2050–2052, 2056, and 2057 have been designated as confidential (or highly confidential) and subject to a protective order in the related litigation. *Id.*

Having considered the exhibits and Patent Owner's unopposed argument, we determine that Patent Owner has shown good cause to seal the exhibits in question. The exhibits appear to include Patent Owner's confidential technical information related to its vaccine products in which Patent Owner has an interest in keeping private; and such interest, at this

stage, outweighs the public's need for access to that information.[44] Exhibits 2050–2052, 2056, and 2057 are, thus, sealed subject to further order from the Board. For the same reasons, Exhibit 2060 is sealed, and we note Patent Owner's submission of Exhibit 2061, which is a partially-redacted, public-version of Exhibit 2060.

We have also considered Patent Owner's unopposed motion for a protective order, which motion is granted. As shown in Exhibit 2058, the proposed changes to the Board's Default Protective Order are minimal, removing access to certain party representatives including employees. Ex. 2058, 1–2. Those changes appear to be justified under the circumstances to prevent, for example, the parties' employees from inadvertently accessing the opposing party's confidential technical information. PO Mot. 4–5. The Modified Protective Order (Exhibit 2059) is, therefore, entered and will control access to confidential materials in this proceeding absent a further order from the Board modifying such access.

Petitioner's motion to seal is also granted. Petitioner establishes good cause to seal portions of Paper 13 (for which a public/redacted version is also provided in the record as Paper 15) for the same reasons explained above on Patent Owner's motion. Petitioner's Paper 13 includes information taken from the same exhibits that are the subject of Patent Owner's motion and which Patent Owner has designated as confidential, protective order material. Pet. Mot. 1.

[44] This balancing of interests may change at later stages of this proceeding and depending, for example, on the extent to which the Board may rely on the allegedly confidential materials in any Final Written Decision.

VII. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that, pursuant to 35 U.S.C. § 314(a), *inter partes* review of all challenged claims of the '600 patent is instituted on all grounds of unpatentability set forth in the Petition.

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(a) and 37 C.F.R. § 42.4, notice is given of institution of trial commencing on the entry date of this Decision.

FURTHER ORDERED that Patent Owner's Motion to Seal (Paper 11) is *granted*, and Exhibits 2050–2052, 2056, 2057, and 2060 are sealed;

FURTHER ORDERED that Petitioner's Motion to Seal (Paper 13) is *granted*, and Paper 14 is sealed;

FURTHER ORDERED that the Modified Protective Order (Ex. 2059) is entered; and

FURTHER ORDERED that, within ten (10) days of this Decision, the parties will meet and confer and submit an agreed-to, public-version of the Decision with redactions as appropriate.

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