IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXOSMITHKLINE BIOLOGICALS SA, and GLAXOSMITHKLINE LLC, Plaintiffs, v. MODERNA, INC., MODERNATX, INC., and MODERNA US, INC., Defendants.	C.A. Nos. 24-cv-1135 (GBW) 24-cv-1136 (GBW)[1] **PUBLIC VERSION**

MEMORANDUM OPINION AND ORDER

Pending before the Special Master is Plaintiffs GlaxoSmithKline Biologicals SA and GlaxoSmithKline LLC's (collectively, "Plaintiffs" or "GSK") motion to compel Defendants Moderna, Inc., ModernaTX, Inc., and Moderna US, Inc. (collectively, "Defendants" or "Moderna") to supplement their initial invalidity contentions to: (1) identify the specific combinations of references that Moderna contends render obvious each asserted claim; (2) limit the number of obviousness combinations to no more than 12 for each asserted claim; and (3) identify the specific claim limitations that Moderna contends are not enabled, along with the supporting arguments for those contentions (the "Motion").[2] D.I. 105 (1135 case); D.I. 103 (1136 case).

On October 10, 2025, GSK submitted its opening letter brief in support of the Motion

[1] C.A. No. 24-cv-1135 (GBW) is referred to as the "1135 case," and C.A. No. 24-cv-1136 (GBW) is referred to as the "1136 case."

[2] In accordance with Special Master Order #2, GSK submitted "a formal motion and proposed form of order setting forth the precise relief sought" via email to the Special Master and all counsel of record. D.I. 105 (1135 case); D.I. 103 (1136 case).

("Op. Br."). Moderna submitted its answering brief in opposition to the Motion ("Ans. Br.") on October 15, 2025. The Special Master held a hearing on the Motion via videoconference on October 16, 2025.[3]

Having considered the parties' letter briefing and arguments presented at the hearing, IT IS HEREBY ORDERED that the Motion (D.I. 105 (1135 case); D.I. 103 (1136 case)) is **DENIED IN PART** and **GRANTED IN PART** for the reasons set forth below.

I. BACKGROUND[4]

GSK asserts claims against Moderna for infringement of eleven patents. D.I. 1 (1135 case); D.I. 1 (1136 case). On August 25, 2025, Moderna served its initial invalidity contentions. D.I. 81 (1135 case); D.I. 84 (1136 case). On October 3, 2025, GSK narrowed the number of asserted claims from 311 to 90 in the 1135 case and from 175 to 71 in the 1136 case.[5] Fact discovery closes on July 29, 2026, and the claim construction hearing is scheduled for April 23, 2026. D.I. 35 (1135 case) at 2, 11; D.I. 38 (1136 case) at 2, 11. The deadline for Moderna to finally supplement the identification of all invalidity references and serve final invalidity contentions is set for 60 days after the Court issues a claim construction order. D.I. 35 (1135 case) at 12; D.I. 38 (1136 case) at 12. The deadline for the parties to meet and confer to narrow the asserted claims and invalidity

[3] A court reporter was present for the October 16, 2025 hearing and provided a copy of the hearing transcript ("Hrg. Tr.") to the Special Master on October 20, 2025.

[4] The background and procedural history of this consolidated action are previously set forth in the Special Master Memorandum Opinion and Order (Public Version) docketed at D.I. 107 (1135 case) and D.I. 105 (1136 case). Rather than restating the full background and procedural history, the Special Master includes only those portions most relevant to the discovery motion addressed in this Memorandum Opinion and Order.

[5] The parties disagree as to whether GSK narrowed to 161 or 183 asserted claims on October 3, 2025. *See, e.g.*, Op. Br. at 3 ("GSK voluntarily narrowed from 311 asserted claims to 90 in the 1135 case and from 175 asserted claims to 71 in the 1136 case."); Ans. Br. at 3 ("GSK claims to have reduced the number of claims being asserted to 183."). For consistency, the Special Master refers to 161 asserted claims in this Memorandum Opinion and Order.

theories prior to trial" is June 14, 2027. *Id.*

II. LEGAL STANDARD

The Delaware Default Standard for Discovery provides that defendant "shall produce to the plaintiff its initial invalidity contentions for each asserted claim, as well as the related invalidating references (e.g., publications, manuals and patents)." D. Del. Default Standard, ¶ 4(d). Contentions made under the Delaware Default Standard, which includes invalidity contentions, are considered "initial disclosures" under Rule 26(a). *First Quality Tissue, LLC v. Irving Consumer Prods. Ltd.*, No. 19-428-RGA, 2020 WL 6286862, at *2 (D. Del. Oct. 27, 2020) (citation omitted). Contentions are intended to give a party notice of the opposing party's theories early in the case, but they are not required to prove the case. *See Wi-LAN Inc. v. Vizio, Inc.*, No. 15-788-LPS, 2018 WL 669730, at *1 (D. Del. Jan. 26, 2018) (holding that contentions should provide notice of the proponent's theories and need not prove the case).

III. ANALYSIS

A. Whether Moderna Must Supplement Its Initial Invalidity Contentions.

GSK seeks to compel Moderna to supplement its initial invalidity contentions to identify the specific obviousness combinations on which it intends to rely for each asserted claim. Op. Br. at 1. GSK argues that Moderna has not provided notice of its obviousness contentions because Moderna has not identified a single concrete obviousness combination in any of its pleadings, obviousness appendices, or obviousness claim charts. *Id.* GSK argues that Moderna has asserted an essentially unlimited number of possible obviousness combinations while maintaining a right to rely on references not yet disclosed. *Id.* at 1–2 ("Defendants' cover pleadings assert the right to rely on more than ***one trillion*** different combinations for ***each*** claim in ***each*** asserted patent.") (emphases in original); *see also id.* at 2 ("Mathematically, Defendants' contentions preserve more

than one trillion (1,000,000,000,000) combinations for each claim."); *see also id.* at 2 ("Defendants maintain that the lists referenced in their obviousness appendices are 'exemplary' and 'not exhaustive.'"); Hrg. Tr. 9:12–14 ("[T]he obviousness combinations that Moderna has asserted are really unlimited in their contentions.").

GSK contends that it voluntarily narrowed the number of asserted claims from 311 to 90 in the 1135 case and from 175 to 71 in the 1136 case, but that Moderna has refused to narrow its invalidity contentions or commit to a reasonable number of specific obviousness combinations per asserted claim. Op. Br. at 3. GSK argues that because it has narrowed its case, Moderna should likewise be required to do the same. *Id.* at 3; *see also id.* ("Now that GSK has voluntarily narrowed to less than half of its originally asserted claims, Defendants should also narrow their invalidity contentions in a truly commensurate manner…."). GSK maintains that Moderna should be required to narrow its invalidity contentions to no more than 12 obviousness combinations per asserted claim because this is fair at this stage of the case and consistent with precedent in this District. *Id.* at 3–4; *see also* Hrg. Tr. 18:4–8 ("[W]e need to understand what we're dealing with in terms of obviousness so we can take fact or third-party discovery of the actual obviousness theories that Moderna is going to run.").

In response, Moderna argues that GSK's Motion should be denied because its initial contentions provide the requisite notice, comply with the timing requirements set forth in the Scheduling Order, and are commensurate in scope with GSK's large number of asserted claims. Ans. Br. at 1, 3; *see also id.* at 1 (arguing "Moderna provided *hundreds of pages of narrative explanation* and t*housands of pages of claim charts* identifying—in extensive detail—the prior art disclosures that render invalid the *over 500 patent claims that were being asserted*, all of which are broken down element-by-element") (emphases in original); *id.* ("Moderna's Initial Contentions

are commensurate in scope with GSK's asserted claims, and, in accordance with the Court's Scheduling Order"); *id.* ("GSK initially asserted *over 500 patent claims* and today still asserts 183 claims, covering over 50 claim elements.") (emphasis in original).

Moderna contends that GSK improperly seeks final contentions before they are required under the Scheduling Order and before the parties have conducted any meaningful discovery. *Id.* at 1 ("GSK's unreasonable demands come *before* GSK has produced all relevant documents and ESI; *before* a single deposition has been taken; . . . and well *before* the Court-ordered deadline for the parties' Final Contentions.") (emphases in original); *see also id.* at 4 (stating that "[t]here's a time and place for reducing invalidity defenses" and the "Court already ordered the parties to meet and confer to narrow claims and invalidity theories prior to trial"); Hrg. Tr. 39:20–40:1 ("The scheduling order also has a deadline for the parties to meet and confer to reduce claims and defenses prior to trial. This is in June of 2027, over a year and a half from now.").

Moderna argues that, consistent with this Court's precedent, its invalidity contentions identify four groups of prior art references—with sub-clusters of references within each group—that combine to render the asserted claims obvious. Ans. Br. at 2 ("[T]he Groups contain many common and overlapping disclosures, which together illustrate the ubiquity of the prior art embodiments and technologies while simultaneously setting forth an overarching theory of obviousness, perfectly in line with this Court's precedent.") (citing *RoboticVISIONTech, Inc. v. ABB Inc.*, No. 22-1257-GBW, 2024 WL 1990970, at *4 (D. Del. May 6, 2024).

GSK's motion to compel Moderna to supplement its initial invalidity contentions is **DENIED**. Moderna's initial invalidity contentions provide reasonable notice to GSK of its obviousness theories at this stage of the case, particularly given that GSK continues to assert a substantial number of claims across 11 patents.

Consistent with the Scheduling Order and the District of Delaware Default Standard, Moderna has provided initial invalidity contentions for each asserted claim and identified the known related invalidating references. The fact that Moderna's contentions result in a multitude of possible combinations does not, by itself, mean that they fail to provide sufficient notice, particularly at this relatively early stage of the case and given the large number of asserted claims. *See, e.g.*, *Multimedia Patent Tr. v. Apple Inc.*, No. 10-2618, 2012 WL 12868250, at *3 (S.D. Cal. Nov. 5, 2012) (stating "district courts have found similar disclosures sufficient even when the total number of possible obviousness combinations runs into the billions"). Rather, it reflects that at this stage a substantial amount of case narrowing remains to be done, which the Scheduling Order contemplates, and the Special Master expects that parties will undertake as the case progresses particularly through to final contentions. *See* D.I. 35 (1135 case) at 12 ("[N]o later than 60 days after the Court issues a claim construction order, Defendants must serve final invalidity contentions."); D.I. 38 (1136 case) at 12 (same).

The Special Master finds the Court's decision in *RoboticVISIONTech* instructive. *See* 2024 WL 1990970, at *2–3. In *RoboticVISIONTech*, the plaintiff moved to compel the defendant to supplement its initial invalidity contentions "to identify the prior-art references and combinations on which it intends to rely, and explain how those combinations satisfy the limitations of the asserted claims." *Id.* at *3. The plaintiff argued that the contentions were deficient because, among other reasons, they "list over a hundred alleged prior-art references that do not appear in the claim charts," state that "additional references could be substituted for the references detailed in the charts without explaining why those substitutions could be made," and "reserve [the defendant's] right to identify other invalidating combinations." *Id.* The defendant responded that its initial invalidity contentions were sufficient because they "organize its prior art references into groups

and articulate an overarching theory of obviousness that applies to each and every possible combination of prior art within those groups." *Id.*

The Court denied the plaintiff's motion to compel. *RoboticVISIONTech*, 2024 WL 1990970, at *3. The Court found that the motion was premature in view of the deadline for final contentions. *Id.* (explaining that "[i]f [the defendant] does not adequately chart its prior-art references—such that its initial invalidity contentions fail to put [the plaintiff] on notice of [the defendant's] invalidity positions—prior to the deadline for final invalidity contentions, then [the defendant] will be precluded from arguing that those prior-art references are invalidating"); *see also id.* ("[T]he Court is confident that [the plaintiff's] objection to [the defendant's] use of 'exemplary' or 'illustrative' claim charts will be resolved as the case is narrowed.").

Like the contentions in the *RoboticVISIONTech*, for each asserted patent, Moderna's contentions identify four groups of references that it contends render each asserted claim obvious based on one or more references from one group, in combination with one or more references from the other groups and the knowledge of a person of ordinary skill in the art. *See, e.g.*, Ans. Br. Ex. 2 at 24–27 (identifying four groups of prior art references and disclosing that the asserted claims would have been obvious to a person of ordinary skill of the art in view of one or more of the Group 1 references in combination with one or more of the references from the other groups and the knowledge of a person of ordinary skill in the art); *see also id.* at 27–31 (disclosing groups of references and explaining the motivation to combine them that would render claim 1 of the '770 Patent obvious to a person of ordinary skill); Hrg. Tr. 48:17–49:2 ("[T]here are four different groups of references that Moderna has identified, exemplary groups. . . . [A]nd each of these groups have a limited finite number of references identified within them and not only that but they have sub-clusters within those groups.").

Moderna's contentions provide detailed narratives explaining what the references in those groupings disclose, including citations to exemplary references and their relevant teachings of the claim limitations. *See, e.g.*, Ans. Br. Ex. 2 at 13–17 (providing narrative descriptions and citations to prior art references disclosing the use of lipid delivery systems employing cationic lipids for the in vivo delivery of nucleic acids); *see also* Hrg. Tr. 49:15–18 ("And beyond that, the contentions also then go on to provide a detailed narrative about those very same group references."). Moderna's contentions also provide disclosures regarding motivations to combine references, which similarly include citations to exemplary references and their relevant teachings. *See, e.g.*, Ans. Br. Ex. 2 at 19–24 (explaining why "[a] skilled person would have been motivated to combine the prior art teachings . . . and would have had a reasonable expectation of success"); *see also* Hrg. Tr. 50:11–17 ("The contentions go on . . . tying the whole theory together with an overarching theory of the motivation to combine these references, the reasonable expectation of success of achieving those combinations.").

Additionally, Moderna's contentions include claim charts that identify, on an element-by-element basis, how the prior art references in each group disclose every limitation of the asserted claims. *See, e.g.*, Op. Br. Ex. 4 (providing 390-page claim chart for asserted claims of the '770 Patent); *see also* Hrg. Tr. 50:1–10 ("These citations are also mirrored in the highly detailed claim charts that accompany that narrative explanation. One of those claim charts was provided by GSK. . . . And all this detail, that's just for group 2. Each of the other groups also has its own set of detailed narrative that accompanies it.").

Because Moderna's contentions identify groups of references similar to those in *RoboticVISIONTech*—including exemplary references and combinations that it contends teach the relevant claim limitations—together with claim charts and the additional disclosures noted above,

the Special Master is persuaded that these contentions provide GSK with adequate notice of Moderna's obviousness theories at this stage of the case, given the significant number of asserted claims. Moderna's contentions will be further developed and refined as the case proceeds through fact discovery, claim construction, GSK's further narrowing of the asserted claims, and final invalidity contentions. *See RoboticVISIONTech*, 2024 WL 1990970, at *3 (expressing confidence that objections to initial invalidity contentions "will be resolved as the case is narrowed"); *see also Cerebrum Sensor Techs., Inc. v. Revvo Techs., Inc.*, No. 24-245-JLH-SRF, D.I. 93 (D. Del. Feb. 5, 2025) ("Defendant's contentions will be further developed and refined as the case proceeds through discovery, claim construction, and expert reports.") (denying motion to compel supplementation); D.I. 35 (1135 case) at 12 (ordering that "no later than 60 days after the Court issues a claim construction order, Defendants must serve final invalidity contentions" and for the parties "to meet and confer to narrow the asserted claims and invalidity theories prior to the start of trial"); D.I. 38 (1136 case) at 12 (same).

Accordingly, GSK's motion to compel Moderna to supplement its initial invalidity contentions in this regard (D.I. 105 (1135 case); D.I. 103 (1136 case)) is **DENIED**.

B. Whether Moderna Must Supplement Its Initial Invalidity Contentions to Identify the Specific Claim Limitations Not Enabled.

GSK seeks to compel Moderna to supplement its initial invalidity contentions to specify which claim limitations Moderna contends are not enabled. Op. Br. at 4–5. GSK contends that Moderna's contentions are insufficient because they fail to identify which claim limitations are at issue for each claim or which arguments apply to each limitation. *Id.* (citing *Integra LifeSciences Corp. v. Hyperbranch Med. Tech., Inc.*, 223 F. Supp. 3d 202, 204 (D. Del. 2016)); *see also* Hrg. Tr. 29:21–30:5 ("[W]e don't have enablement contentions in hand from Moderna that provide contentions on a claim-by-claim or limitation-by-limitation basis. . . . Moderna set forth their

enablement contentions on a family-by-family basis."), 31:10–12 ("And we should understand what these true contentions are now so again we can take discovery on them.").

GSK further contends that Moderna's *Wands* factor analysis is deficient because it has not been tied to specific claim language in the asserted patents. Op. Br. at 5 (citing *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)); *see also* Hrg. Tr. 30:19–23 ("So this *Wands* discussion that they have set forth is particularly untethered to the limitations of the claims or even specific patents."), 71:11–18 ("The *Wands* factor analysis that was done by Moderna talked about various concepts. It doesn't necessarily talk about claim limitations. And this whole lipid delivery vehicle, that's not a limitation in any of the claims.").

In response, Moderna maintains that its enablement contentions are sufficient and comply with the Scheduling Order. Ans. Br. at 5 (arguing that the contentions "put GSK on notice" and "are fully compliant with the Scheduling Order"). Moderna contends that GSK is effectively seeking final contentions, whereas the Scheduling Order requires only initial contentions at this stage. *Id.* (citing D.I. 35 (1135 case) at 2, 17); *see also* Hrg. Tr. 58:21–59:2 ("And for this stage of the proceedings where we haven't even begun discovery, we're still in initial invalidity contentions land, we think it is more than sufficient to put GSK on notice."). Moderna also contends that GSK incorrectly relies on *Integra* to argue that initial invalidity contentions must include an element-by-element enablement analysis. Ans. Br. at 5 ("*Integra* has no analysis or discussion of enablement, and relevant authority does not support GSK's position."); *see also* Hrg. Tr. 60:18–23 ("[The court in *Integra*] was just telling the defendant you have to put them on notice of which portions of section 112 you're asserting for each of these claim elements that you have listed here.").

Moderna argues that, unlike the contentions at issue in *Integra*, its contentions identify both

the subject matter not enabled by the specification and the specific claim elements lacking enablement. *Id.* at 5 (citing Ans. Br. Ex. 4 at 36–39, 41–44); *see also* Hrg. Tr. 61:14–16 ("Those are all common features that you find across all of the asserted claims in those families."). Moderna maintains that its initial invalidity contentions provide sufficient notice to GSK because they explain why the specification does not enable the full scope of the invention. *Id.* at 5 (citing *Baxalta Inc. v. Genentech, Inc.*, 81 F.4th 1362, 1364 (Fed. Cir. 2023); *Amgen Inc. v. Sanofi*, 598 U.S. 594 (2023)).

GSK's motion to compel Moderna to supplement its initial invalidity contentions is **GRANTED IN PART** to the extent specified below. Subject to the caveat below, the Special Master finds that Moderna's initial invalidity contentions provide GSK with sufficient notice of its non-enablement contentions at this stage of the case. Although Moderna provides its contentions on a patent family-by-family basis, the Special Master finds that this analysis is sufficient to put GSK on notice of its lack-of-enablement theory for the asserted claims in each patent family, at least at this early stage. For example, the contentions identify exemplary claims for patents in each family and certain aspects allegedly missing from those claims that Moderna argues render them not enabled. *See, e.g.*, Ans. Br. Ex. 4 at 36–40 (discussing '770 Patent claim 1; '682 Patent claims 1, 17, 30, 31, 48, 70; '467 Patent claim 5), 51–53 (discussing '6534 Patent claims 1, 3, 24, 27, 28). The contentions also identify subject matter concerning alleged unpredictability in the prior art—specifically, the encapsulation rate within lipid delivery vehicles and the efficacy of RNA vaccines—which Moderna contends renders the asserted claims not enabled by the specification. *See e.g., id.* at 41–44 (discussing non-enablement relating to, e.g., "RNA," "Cationic Lipid," "PEG-Lipid," "Other Lipids," and "Molar Ratios"). These contentions will be further developed and refined as the case proceeds through fact discovery, claim

construction, GSK's further narrowing of the asserted claims, and final invalidity contentions.

The Special Master, however, finds some merit in GSK's argument that Moderna's *Wands* analysis does not explicitly tie certain concepts to specific claim language in the asserted patents. *See* Op. Br. at 5. Accordingly, to the extent Moderna contends that the subject matter "RNA," "Cationic Lipid," "PEG-Lipid," "Other Lipids," and "Molar Ratios" correspond, respectively, to specific elements of the asserted claims that lack enablement, Moderna is ordered to supplement its contentions to identify the specific elements it currently knows for at least two exemplary claims in each patent family referenced in its non-enablement contentions. It is reasonable at this stage of the case to require Moderna to supplement its contentions in this regard, given its representation that the contentions "[f]urther address specific claim elements lacking enablement." Ans. Br. at 5 (citing Ans. Br. Ex. 4 at 41–42 ("RNA" and "cationic lipid"), 43–44 ("PEG-lipid," "Other Lipids," and "Molar Ratios")). *See also* Hrg. Tr. 61:6–9 ("We have over 20 pages of *Wands* factor analysis identifying specific subject matter that's lacking enablement"), 61:14–16 ("Those are all common features that you find across all of the asserted claims in those families."); *see also Integra*, 223 F. Supp. 3d at 204 ("Plaintiffs are entitled to know, at minimum, the specific part of Section 112 that [defendant] contends is not met for the relevant limitations, based on information known to [defendant] at the current (pre-claim construction) phase of the case.").

Accordingly, GSK's motion to compel Moderna to supplement its initial invalidity contentions to identify the specific claim limitations that Moderna contends are not enabled (D.I. 105 (1135 case); D.I. 103 (1136 case)) is **GRANTED IN PART**.

IT IS HEREBY ORDERED that within fourteen (14) days of this Memorandum Opinion and Order, as outlined above, Moderna shall supplement its contentions to identify the specific elements it currently knows that correspond, respectively, to "RNA," "Cationic Lipid," "PEG-

Lipid," "Other Lipids," and "Molar Ratios" for at least two exemplary claims in each patent family cited in its non-enablement contentions.

IV. CONCLUSION

For the foregoing reasons, IT IS ORDERED that Plaintiffs' Motion (D.I. 105 (1135 case); D.I. 103 (1136 case)) is **DENIED IN PART** and **GRANTED IN PART**.

* * *

This Memorandum Opinion and Order is preliminarily submitted under seal as a precaution because the parties' briefing was filed under seal. Within three (3) business days of this Order, the parties shall jointly email the Special Master and advise of any proposed redactions.

IT IS SO ORDERED.

Dated: November 11, 2025

Monte T. Squire

Special Master Monté T. Squire