EXHIBIT 48

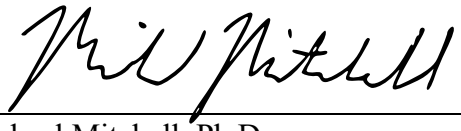
HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Plaintiffs*, v. MODERNA, INC. and MODERNATX, INC., *Defendants*.	C.A. No. 22-252-MSG
MODERNA, INC. and MODERNATX, INC., *Counterclaim-Plaintiffs*, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GMBH *Counterclaim-Defendants.*	**JURY TRIAL DEMANDED** **CONTAINS INFORMATION MODERNA, ALNYLAM, AND PLAINTIFFS DESIGNATED HIGHLY CONFIDENTIAL – OUTSIDE COUNSEL'S EYES ONLY**

OPENING EXPERT REPORT OF DR. MICHAEL MITCHELL

Dated: November 25, 2024



Michael Mitchell, Ph.D.

(Moderna Executive Committee Update, May 15, 2012). As I will discuss throughout the rest of this section, despite substantial effort to use technology other than LNPs to deliver mRNA, Moderna proceeded with LNPs (in particular, LNPs of Plaintiffs' invention) as its delivery platform for clinical programs.

238. From 2013 onwards, Moderna continued to use the 50:38.5:10:1.5 target ratio extensively, including for its early clinical work, and acknowledged repeatedly the extent to which its composition was rooted in prior siRNA-lipid particle work, including work done by Tekmira. For example, in a February 6, 2014 PowerPoint presented by Örn Almarsson, then head of delivery sciences at Moderna, there is a slide entitled "LNPs of mRNA" and it says "[a]dapted from the siRNA field." MRNA-GEN-01044245 at -267. On the next slide entitled "LNP Formulation," one of the graphics shown is an illustration of a nucleic acid-lipid particle presented by Ian MacLachlan on behalf of Plaintiffs' predecessor Tekmira at the 2013 International mRNA Health Conference. MRNA-GEN-01044245 at -268. Dr. Stephen Hoge, Moderna's President, noted that he attended this conference and has stated his belief that he saw Ian MacLachlan's presentation there. Hoge 5/22/2024 Tr. 63:3-18. When Nobel Laureate Katalin Karikó presented her Keynote Lecture at the 2023 International mRNA Health Conference, she noted that Ian MacLachlan's lecture provided the "first time I heard somebody publicly talk about lipid nanoparticle formulated mRNA; prior to that only siRNA . . . . [Ian] presented here [at] this meeting 10 years ago that it was in vivo studies, LNP mRNA and we heard about cancer as well as infectious disease vaccines." *See* GENV-00246910 (Katalin Karikó, Keynote Lecture, International mRNA Health Conference October 31, 2023) at 5:15-5:50. Moderna's February 2014 PowerPoint presentation further includes Tekmira's mRNA-LNP protein expression data. MRNA-GEN-01044245 at -270.

[redacted]

MRA-GEN-00741030 at -039. [redacted] MRNA-GEN-00741030 at -043. As discussed previously, T-junction mixing is a formulation process that was described in Jeffs 2005 and the '651 Patent, *see supra* Sections VI.B, VIII.A, and Moderna itself has cited Plaintiffs on numerous occasions when describing the T-junction process, *see e.g.*, MRNA-GEN-01056385 at -393; MRNA-GEN-00741101 at -109; MRNA-GEN-01746082 at -085; MRNA-GEN-00960795. In the summer of 2014, Moderna's goal for mRNA was "[i]intracellular delivery for transient gene expression" and its approaching for doing so included "[a]pplying technology from siRNA: 'LNPs,'" including technology developed by Plaintiffs. MRNA-GEN-00741101 at -107.

243. In the same month, September 2014, in a PowerPoint presentation to its Board, [redacted] MRNA-GEN-00792008 at -014; *see also* Hoge 5/22/2024 Tr.

45:9-47:1. "MC3" refers to the cationic lipid Moderna was using, which it associated with Tekmira. *See, e.g.*, MRNA-GEN-01067716 at -752 (Chemistry Update PowerPoint presentation, Jul. 17, 2015) (displaying MC3 on a slide entitled "Tekmira compounds"); MRNA-GEN-01290882 at -887 (Moderna PowerPoint presentation, June 26, 2014); MRNA-GEN-01061710 at -714-717 (handwritten notes from Dr. Benenato noting "Tekmira" next to contributions on 2014 publication entitled "Enhancing siRNA delivery by employing lipid nanoparticles"). In addition, "MC3-LNP" refers to an LNP with a lipid molar ratio of 50:38.5:10:1.5 (MC3:Cholesterol:DSPC:PEG-DMG-2K), Hoge 5/22/2024 Tr. 32:9-33:8, a composition which Moderna described as being "the same lipid composition used in the Alnylam Phase 3 TTR IV product" in a PowerPoint presentation from that same time period, MRNA-GEN-00741030 at -034-44. Furthermore, [redacted], in light of the slide discussed in ¶¶ 240-242. Putting all of this together, the available evidence indicates that by 2014, the LNP composition and formulation process taught by Plaintiffs "already enable[d] [Moderna's] development candidates," including a flu vaccine ultimately taken into a phase 1 clinical trial that yielded positive results. MRNA-GEN-00792008 at -014; *see infra* ¶ 248. Moderna further acknowledged the success of the 50:38.5:10:1.5 MC3 composition it was using, referring to it as the "gold standard." MRNA-GEN-01044890 at -930; Benenato 5/17/2024 Tr. 163:10-16 ("Q. And, in particular, these siRNA-optimized formulations were able to successfully deliver mRNA?" "Lipid nanoparticles that were used with siRNA could encapsulate mRNA and deliver mRNA."). The phrase "gold standard" indicates that the formulation—including and especially the target lipid molar ratios—was desirable and favorable for the mRNA delivery Moderna was pursuing, not inferior and unsuitable for that purpose.

261. It is my understanding that Moderna conducted clinical tests across five programs using the MC3-LNP, i.e., an LNP with lipid composition 50:10:38.5:1.5 (MC3:DSPC:cholesterol:PEG lipid): (1) influenza H7N9 (mRNA-1851), (2) influenza H10N8 (mRNA-1440), (3) Zika (mRNA-1325), (4) Chikungunya (mRNA-1388), and (5) RSV (mRNA MRK-1777). MRNA-GEN-02406026 at -029. As discussed in the above paragraphs, Moderna reported that the vaccines were well tolerated for each of the five programs. *Supra* ¶¶ 246-260; *see also* ALNY-01797729 at -744 (37th Annual J.P. Morgan Healthcare Conference Presentation). Moreover, as discussed above, other than issues related to the mRNA sequence of the mRNA-1325 Zika vaccine, Moderna also reported positive immunogenicity readouts for each of the programs' Phase 1 studies. *See also* ALNY-01797729 at -744 (37th Annual J.P. Morgan Healthcare Conference Presentation); MRNA-GEN-02406026 at -029; MRNA-GEN-02616812 at -839 (Moderna Inc., Form 10-K for the fiscal year ended December 31, 2018) ("[O]ur programs, based on the data observed, have demonstrated desired pharmacology, in the form of immunogenicity, in their Phase 1 clinical trials: H10N8 vaccine (mRNA-1440), H7N9 vaccine (mRNA-1851), RSV vaccine (mRNA-1777), [and] Chikungunya vaccine (mRNA-1388)[.]"). Moderna "opportunistically repurpose[d]" the LNP composition of the Alnylam/Tekmira collaboration TTR products and repeatedly achieved successful phase 1 readouts. *Supra* ¶ 245.

262. Moderna began transitioning to use the ionizable lipid SM-102 rather than MC3 in roughly the end of 2017 through 2019, but the company still used the lipid molar ratio of 50:10:38.5:1.5 (ionizable lipid:DSPC:cholesterol:PEG lipid) when making this transition. MRNA-GEN-00949251 at -253; MRNA-GEN-00601067. As I will describe below, similar to its early clinical studies using MC3, Moderna achieved positive readouts for early clinical studies leveraging this SM-102 LNP composition as well. *See, e.g.*, MRNA-GEN-01517834 at -834

102:DSPC:cholesterol:PEG). *See* MRNA-GEN-00601067 at -070. Similar to how Moderna has historically described its use of the target 50:10:38.5:1.5 formulation, Moderna's documents discussing the use of this ratio for CMV's clinical trials allude to this formulation being taken from Plaintiffs' work and performing successfully for Moderna. *See, e.g.*, MRNA-GEN-00539393 at -400 ("In some instances, the lipid composition of LNPs has been based on the historical ratios of 50 mol% ionizable lipid, 38.5 mol% cholesterol, 10 mol% DSPC, and 1.5 mol% PEG-DMG that was initially developed for hepatic delivery of siRNA and has translated well for delivery of multiple modalities to multiple target areas."). Moderna also described the Phase 1 results from its CMV clinical study as positive. *See, e.g.*, MRNA-GEN-01156478 at -500 (Moderna Inc., Form 10-K for the fiscal year ended December 31, 2019) ("In 2019, we believe that positive Phase 1 data from our infectious disease vaccine portfolio, including our CMV vaccine, and chikungunya antibody program reduced the risk of our prophylactic vaccines and systemic secreted and cell surface therapeutics modalities, which we have now designated core modalities.").

265. To my knowledge, Moderna has publicly represented that it obtained positive results with various of its Phase 1 clinical trials that used LNPs with a 50:10:38.5:1.5 SM-102 target composition, including CMV (mRNA-1647) (discussed above), Zika (mRNA-1893), HMPV-PIV3 (mRNA-1653), Personalized Cancer Vaccine (PCV) (mRNA-4157), and COVID-19 (mRNA-1273). *See, e.g.*, MRNA-GEN-00601067 at -070, -075, -084 (PowerPoint presentation by Jack Kramarczyk displaying use of the 50:10:38.5:1.5 target molar ratio in Phase 1 of mRNA-1647, mRNA-1893, and mRNA 1653); Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 101 (describing Moderna's use of the 50:10:38.5:1.5 target molar ratio in

Phase 1 and 2 of mRNA-1273); MRNA-GEN-00545575 at -581 (describing Moderna's use of the 50:10:38.5:1.5 target molar ratio for mRNA-4157); *infra* Section X.D.1; MRNA-GEN-01156478 at -504 (Moderna Inc., Form 10-K for the fiscal year ended December 31, 2019) ("Interim Phase 1 data for our hMPV/PIV3 vaccine (mRNA-1653) showed boosted serum neutralization titers against hMPV and PIV3 at all dose levels tested."), -506 ("There have been no dose-limiting toxicities or significant related toxicities observed in these patients to date. . . . As of June 2019, we have detected antigen specific T cell responses in both the monotherapy arm and in combination with pembrolizumab in the Phase 1 trial for mRNA-4157 [PCV]. We have also observed potential clinical activity in some patients receiving mRNA-4157 in combination with pembrolizumab in the Phase 1 trial."), -519 ("We believe that the positive safety and immunogenicity data obtained from six separate Phase 1 clinical trials with our prophylactic vaccines, including the most recent results with our CMV vaccine candidate (mRNA-1647), have provided support for a reduced risk profile with respect to key aspects of our approach and technology in infectious disease vaccines. We believe the clinical data demonstrate that our proprietary vaccine technology is generally well-tolerated and can elicit durable immune responses to viral antigens."), -527 ("We have demonstrated safety and tolerability and generated immunogenicity data in our Phase 1 trial; based on the interim Phase 1 data, we have initiated a Phase 2 trial with mRNA-1647."), -531 ("[T]he interim data showed that hMPV and PIV3 serum neutralizing antibody titers remained above baseline through seven months. mRNA-1653 was found to be generally well tolerated. No SAEs, adverse events of special interest, or adverse events leading to withdrawal were reported."); MRNA-GEN-01353539 at -565 (Moderna Inc., Form 10-K for the fiscal year ended December 31, 2020) ("mRNA-1273 was generally well-tolerated, with no serious adverse events reported through

Day 57. . . . [P]articipants in the Phase 1 study of mRNA-1273 retained high levels of neutralizing antibodies through 119 days following first vaccination . . . ."), -579 ("mRNA-1893 was well tolerated at all dose levels . . . . All dose levels of mRNA-1893 induced a strong neutralizing ZIKV-specific antibody response in baseline flavivirus seronegative participants."). In fact, Moderna has discussed how its successful Phase 1 trials—which leveraged LNPs with a 50:10:38.5:1.5 target composition—contributed to the Company's development of its vaccine programs including COVID-19:

> In 2019, we believe that positive Phase 1 data from our infectious disease vaccine portfolio, including our CMV vaccine, and chikungunya antibody program reduced the risk of our prophylactic vaccines and systemic secreted and cell surface therapeutics modalities, which we have now designated core modalities. In these core modalities, our strategy is to invest in additional development candidates using our accumulated innovations in technology, our process insights and our preclinical and clinical experience. As such, we have brought five new development candidates forward in early 2020: interleukin-2 ("IL-2"), programmed death-ligand 1 ("PD-L1"), a pediatric Respiratory Syncytial Virus ("RSV") vaccine, an Epstein-Barr Virus ("EBV") vaccine and a SARS-CoV-2 vaccine.

MRNA-GEN-01156478 at -500 (Moderna Inc., Form 10-K for the fiscal year ended December 31, 2019). It is my understanding that Moderna did not have a marketed product prior to the COVID-19 vaccine for various reasons, including due to Moderna's initial pursuit of vaccines it did not categorize as "commercial," *supra* ¶ 259, and the duration of time it takes to go through clinical trials and obtain product approval, MRNA-GEN-01075778 at -782; however, I have not seen evidence that any failures pertaining to the composition or formulation of its LNPs served as a contributing factor to a lack of commercial product.

266. I understand that, to support its present position in this case that the 50:10:38.5:1.5 ratio is unsuitable, Moderna has pointed to an instance in August 2018 where its initial CMV clinical product (with an internal code of mRNA-1443) failed an internal

demonstrate, any *in vitro* potency improvements with such a composition do not necessarily translate to the more relevant and important *in vivo* environment.

MRNA-GEN-00533651 at -662.

312. Moderna was not the only company searching for alternatives to Plaintiffs' benchmark LNP formulation. In a 2015 PowerPoint presented to Moderna by its collaborator, AstraZeneca, it states "80-90 nm DLinMC3-DMA/Chol/DSPC/PEG-lipid (50:38.5:10:1.5) LNPs are very difficult to beat – so far we have not succeeded!" MRNA-GEN-00741123 at -164. This statement appears at the end of the presentation, which details a year of extensive LNP work at AstraZeneca. MRNA-GEN-00741123.

313. To summarize, Moderna conducted substantial experimentation across a wide range of compositions with different lipid molar ratios, with a particular focus on compositions [redacted] Ultimately, however, Moderna found such formulations to be unsuitable and opted to use a composition with amounts of SM-102 that were very close to the 50% (*i.e.*, 48.5% and 48%), because such formulations were found to yield

equivalent immunogenicity. Consistent with these data, Moderna's own conclusions at the time, and my conclusions, Moderna never pursued, to my knowledge, an mRNA-LNP vaccine [redacted] *See, e.g.*, Hoge 5/22/2024 Tr. 304:14-311:14 [redacted]; Smith 5/14/2024 Tr. 342:10-17 [redacted]; MRNA-GEN-00587058 at -068-069 [redacted]; *see also* Kramarczyk 4/30/2024 Tr. 60:4-8 [redacted]

D. Moderna's Manufacturing Process Development

314. I understand that Moderna contends that one aspect of its LNP research involved "improving LNP manufacturing processes." Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 153. [redacted]

2. mRNA-1273 LNP

377. [redacted]

[redacted]

[redacted]

[redacted]

manufactured using the platform approach detailed below are identical, unless specifically noted." MRNA-GEN-02663285 at -286. In addition to the BLA, Moderna's manufacturing process for the Accused Product is further described and summarized in a June 26, 2020 PowerPoint presentation labeled RNA-1273 Briefing Book. MRNA-GEN-01118107.

D. Lipid Composition Targets

392. As discussed above, based on Moderna's discovery responses in this case and its regulatory submissions, it is my understanding that Moderna initially manufactured its COVID-19 vaccine for Phase 1 and Phase 2 clinical trials as well as certain lots used in the Phase 3 clinical trial using a target lipid molar ratio of 50:38.5:10:1.5 (SM-102:cholesterol:phospholipid:PEG2000-DMG) (the "**PVU Formulation**"), then Moderna subsequently modified the target lipid molar ratio to 48.5:38.9:11.1:1.5 when manufacturing the remainder of its Phase 3 clinical trials and lots for commercial sale (the "**v1 Formulation**"), and finally, in early 2022, Moderna modified the target lipid molar ratio of its COVID-19 vaccine again to 48.0:38.5:11.0:2.5 (the "**v2 Formulation**"). *See supra* Section X.A.

393. Moderna's use of these target lipid molar ratios is described in the pharmaceutical development section of its BLA as follows. *See* MRNA-GEN-02635779 at -784.

> The mRNA-1273 LNPs comprises four lipids: SM-102, DSPC, cholesterol, and PEG-lipid. The molar lipid ratio of 50:38.5:10:1.5 (ionizable lipid: cholesterol: DSPC: PEG-lipid) has been used in the literature for systemic delivery of LNPs. Further verification of the lipid composition was conducted using one of Moderna's vaccines. It was observed that slight variations in the percentage of SM-102, DSPC, or PEG-lipid can be made without a detectable difference in immunogenicity. Minor adjustments were made to the literature composition to harmonize with the platform composition, which resulted in a molar lipid ratio of 48.5:38.9:11.1:1.5 (ionizable lipid: cholesterol: DSPC: PEG-lipid). A further refinement in the lipid ratio was made to optimize colloidal stability by slightly increasing the PEG-lipid content to a new molar ratio (48.0:38.5:11.0:2.5) for ionizable lipid: cholesterol: DSPC: PEG-lipid).

potential regulatory implications, to delay the addition of introduction of 2.5 percent PEG until a future date[].”); Benenato 5/17/2024 Tr. 69:2-9 (“When COVID hit, at the time there was zero option for Moderna. SM-102 platform to be able to respond to the pandemic in speed that it did”), 70:1-4 (Q. “And so did having that clinically validated safe platform allow Moderna to more quickly deploy its COVID vaccine?” A. “I would say yes.”); MRNA-GEN-00823502 (Parsons Exhibit 11); MRNA-GEN-02635779 at -782-784 (BLA LNP Composition Justification, noting the literature use of the molar ratio 50:38.5:10:1.5 and how Moderna leveraged “historical knowledge” for the composition of the COVID-19 drug product).

399. As stated above, in addition to helping push Moderna's COVID vaccine into the clinic sooner, the use of this same 50:38.5:10:1.5 ratio had also helped Moderna move its prior clinical programs into clinical testing faster. *Supra* Section IX.A; *see, e.g.*, Kramarczyk 4/30/2024 Tr. 62:1-18 (“A central tenet to all of our product and process changes was to remain in alignment with our clinical development plan to not have an impact on our clinical development and timing of the product, acceleration or product progress towards licensure. A key element always of making product and process changes is to not disrupt the historic clinical data that was in place, in this case from Phase 1.”); Almarsson 5/31/2024 Tr. 88:8-16 (“Q . . . But why did Moderna use the same lipid composition as the Alnylam Phase 3 TTR product after having already looked at different formulations as you stated?” “A. There would be many reasons to select formulation [sic], including precedence in clinical trials.”), 238:18-20 (“[C]linical precedent is important in selecting formulations for human use.”).

2. The v1 Formulation

400. As previously noted, when it began manufacturing for Phase 3 clinical trials and commercial sale, Moderna modified the target lipid molar ratio of the mRNA-LNPs in its vaccine to 48.5:38.9:11.1:1.5 (the “**v1 Formulation**”). To my knowledge, Moderna formulated

its Phase 1 and Phase 2 lots, and the earliest of its Phase 3 drug product lots (7006320001, 7006320002, 7006320003, 7006320010) through early June using the PVU Formulation, and then subsequently switched to formulating its drug product lots using the v1 Formulation. *See, e.g.*, MRNA-GEN-00141068 at -089-090 (explaining that the lipid molar ratios were revised beginning with [redacted] PN50069), -074 (identifying DP lot number 6007520004 as the first PN50069 lot), -122 (indicating DP lot 6007520004 was manufactured on June 25, 2020); MRNA-GEN-00604539 at -549; Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 101; July 2020 NIH News Release.[99] As will be discussed below, it is my understanding that Moderna has repeatedly represented that the switch from the PVU to the v1 formulation was a minor change that had an insubstantial and minimal impact on the Accused Product.

401. Moderna describes its shift from the PVU Formulation to the v1 Formulation in its report PD-REP-0102, entitled "Change to [redacted] Molar Targets" approved on June 4, 2020. MRNA-GEN-00547580. As Moderna describes, this report was written for the purpose of "detail[ing] changes to lipid target concentration values for the [redacted]" of the Accused Product from PVU to v1. MRNA-GEN-00547580 at -580-582. In the report, Moderna notes that the switch to the target v1 Formulation involved a [redacted] (ultimately arriving at the target v1 Formulation). As depicted below, the [redacted] target molar ratio switched from [redacted] (PVU [redacted]) to [redacted] (v1/v2 [redacted])

[99] *Phase 3 Clinical Trial of Investigational Vaccine for COVID-19 Begins*, NIH News Releases, July 27, 2020 ("July 2020 NIH News Release"), available at https://www.nih.gov/news-events/news-releases/phase-3-clinical-trial-investigational-vaccine-covid-19-begins.

433. [redacted]

434. [redacted]

435. In light of all of the above statements made by Moderna and its employees regarding its change from the PVU formulation to the v1 formulation, I believe that Moderna selected the v1 formulation for IP purposes and to avoid delays that may have arisen with a more substantial change. I have not seen any data to suggest that the change in formulation (from PVU to v1) had any impact on the features, quality, or function of the Accused Product, including an impact on safety, efficacy, or stability, and Moderna's statements to FDA and internal documents confirm this conclusion.

3. The v2 Formulation

436. As noted above, in late 2021/early 2022, Moderna modified the target lipid molar ratio of its COVID-19 vaccine again to 48.0:38.5:11.0:2.5, which I understand Moderna refers to as the "**v2 Formulation**." *See, e.g.*, Moderna's Corrected Sixteenth Supplemental Objections

and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 101; MRNA-GEN-00088602; MRNA-GEN-02635779 at -784 (BLA Section 3.2.P.2.2 Drug Product). Unlike the switch from the PVU to the v1 Formulation, I understand that Moderna [redacted] when switching from the v1 to the v2 Formulation. *See* MRNA-GEN-00089246 (Scientific Advice Briefing Document) at -253 [redacted]), -254 [redacted] MRNA-GEN-01424228 (showing certain [redacted] part numbers, such as PN 40079, being used to formulate v1 and v2 Formulation drug product lots).

437. I understand that Moderna has represented in its BLA documents that the v2 Formulation was implemented "to optimize colloidal stability." MRNA-GEN-02635779 at -784. Nevertheless, that section of the BLA does not contain any data related to this purported change in "colloidal stability," and as I describe below, there is little data suggesting that this change makes any difference in Moderna's Accused Product. Dr. Parsons, Moderna's corporate designee on the technical reasons for Moderna's switch to the v1 and v2 Formulations and who was personally involved in the drafting of documents submitted to the FDA, was asked whether he "remember[ed] any time when you were involved in a communication with the FDA where you told them that this change would improve -- or where you showed them data that it would improve particle size stability?" and in response he testified "I don't remember a specific time." Parsons 6/7/2024 Tr. 240:18-241:6. When Moderna has made specific representations to the

[redacted]

E. Lipid Composition Testing

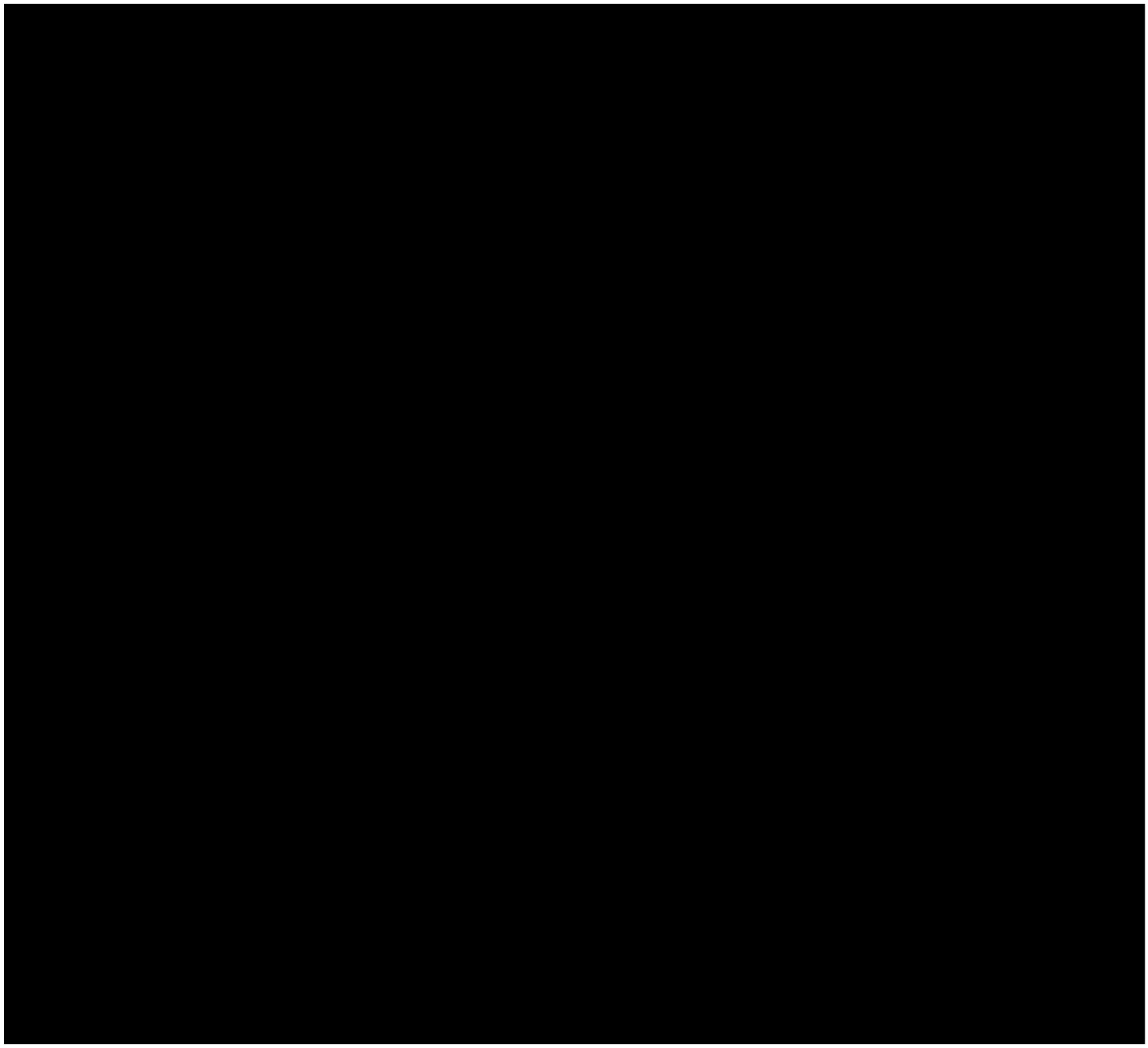
1. Certificates of Analysis

453. The results of Moderna's release testing in accordance with its product specifications for SM-102 LNP, mRNA-1273 LNP, and drug product are recorded in certificates of analysis ("COAs") that correspond to each released lot. *See, e.g.*, Li 6/11/2024 Tr. 70:20-22 ("[E]very batch is tested against its predefined specifications in order to release the product."), 44:20-22 ("[A]ll [of] our released product to be used in clinical studies or [for] human use needs to meet [a] predefined specification."), 56:20-21 ("[C]ertificate of analysis represent our release testing."); *see also* Boyer 5/20/2024 Tr. 92:1-10 ("Q. And what does that mean when the lot is released?" "It means that the quality organization has completed their release process so that the lot can be forward processed or distributed without restriction"). Moderna is required to provide COAs of the Accused Product to the FDA. MRNA-GEN-01415822 (Correspondence from Dr. Marks, Acting Director of the Office of Vaccines Research and Review at the FDA, Oct. 4, 2022) at -822 ("Please be reminded that, pursuant to Condition J of the LOA [Letter of Authorization], authorization of the vaccines (Moderna COVID-19 Vaccine and Moderna COVID-19 Vaccine, Bivalent) is conditioned on Moderna submitting the COA for each drug product lot to the EUA [Emergency Use Authorization] file at least 48 hours prior to vaccine

distribution. To meet this condition, the COA must include the established specifications and specific results for each quality control test performed on the final drug product lot. Furthermore, please be advised that Condition J applies to the exportation from the United States of authorized vaccines under the EUA. *See* Condition AA of the LOA."). These test results include lipid content testing performed by Moderna or its contract manufacturers, pursuant to validated methods described in standard operating procedures, as well as the results of Moderna's release testing for the percentage of RNA encapsulation. *See, e.g.*, Li 6/11/2024 Tr. 109:4-22, 263:7-264:5.

454. As discussed previously, Moderna's lipid content specifications—and accordingly the test results reported on its COAs—are not stated in terms of molar ratios, but in terms of concentrations (mg/mL). However, as with its specifications, the molar ratios can be calculated using the molecular weights of the lipid components. *Supra* Section X.A; *see also, e.g.*, Hoge 5/22/2024 Tr. 197:8-13; Ryan Declaration ¶ 5; Parsons 6/7/2024 Tr. 133:12-134:3 ("[W]e, of course, have certificates of analysis of all of those batches . . . . [T]hat would be my source of information to gather that data."). I further understand that Moderna has represented to the Court that its "certificates of analysis . . . and underlying data for every accused batch" contain "all information necessary" for "Plaintiffs . . . to assess infringement." *See* D.I. 183 (Letter to the Honorable Mitchell S. Goldberg in Opposition to Plaintiffs' Motion to Compel Samples) at 1.

455. Illustratively, the certificate of analysis for lot 8520100103, a drug product lot using the PVU Formulation and that Moderna used in its Phase 2 clinical trials, *see* MRNA-GEN-00988292 at -314, reports the following "Lipid Content" results:



MRNA-GEN-01374118 at -119.[101]

[101] Moderna changed its lipid content assay from SOP-0502 to SOP-1001, which has an effective date of October 2020, for lots made after its clinical trials. I understand that Moderna characterized these changes as having "[m]inimal impact [on the] assay." MRNA-GEN-01855277 at -330 ("Previous methods combined to contain sample preparations for [redacted] and mRNA-1273 DP. [redacted]

456. The mg/mL concentrations for SM-102, cholesterol, DSPC, and PEG2000-DMG (5.8 mg/mL, 2.4 mg/mL, 1.3 mg/mL, and 0.6 mg/mL) reported in the COA for lot 8520100103 can be converted to mol % values using the formulae previously described, *supra* Section X.A, as shown below. For these calculations I have displayed four significant figures for intermediate calculation steps and reported two decimal places in the resulting mol % values.

$$N_{\text{SM-102}} = \rho_{\text{SM-102}}/MW_{\text{SM-102}} = \frac{5.8\ \text{mg/mL}}{710.18\ \text{mg/mmol}} = 0.008167\ldots\ \text{mmol/mL}$$

$$N_{\text{Cholesterol}} = \rho_{\text{Cholesterol}}/MW_{\text{Cholesterol}} = \frac{2.4\ \text{mg/mL}}{386.65\ \text{mg/mmol}} = 0.006207\ldots\ \text{mmol/mL}$$

$$N_{\text{DSPC}} = \rho_{\text{DSPC}}/MW_{\text{DSPC}} = \frac{1.3\ \text{mg/mL}}{790.15\ \text{mg/mmol}} = 0.001645\ldots\ \text{mmol/mL}$$

$$N_{\text{PEG2000-DMG}} = \rho_{\text{PEG2000-DMG}}/MW_{\text{PEG2000-DMG}} = \frac{0.6\ \text{mg/mL}}{2440\ \text{mg/mmol}} = 0.0002459\ldots\ \text{mmol/mL}$$

$$X_{\text{SM-102}} = \frac{N_{\text{SM-102}}}{N_{\text{SM-102}}+N_{\text{Cholesterol}}+N_{\text{DSPC}}+N_{\text{PEG2000-DMG}}} = 50.21\%$$

$$X_{\text{Cholesterol}} = \frac{N_{\text{Cholesterol}}}{N_{\text{SM-102}}+N_{\text{Cholesterol}}+N_{\text{DSPC}}+N_{\text{PEG2000-DMG}}} = 38.16\%$$

$$X_{\text{DSPC}} = \frac{N_{\text{DSPC}}}{N_{\text{SM-102}}+N_{\text{Cholesterol}}+N_{\text{DSPC}}+N_{\text{PEG2000-DMG}}} = 10.12\%$$

$$X_{\text{PEG2000-DMG}} = \frac{N_{\text{PEG2000-DMG}}}{N_{\text{SM-102}}+N_{\text{Cholesterol}}+N_{\text{DSPC}}+N_{\text{PEG2000-DMG}}} = 1.51\%$$

[redacted] I further understand Moderna made additional edits to SOP-1001 in later versions over the course of its manufacturing, but that these edits were for "adding clarity to the methodology" and that the "fundamental principles and procedures [have] not changed." Li 6/11/2024 Tr. 78:8-79:15.

457. Cholesterol and DSPC are each non-cationic lipids; the total mol % of non-cationic lipid can be determined by adding together the mol % of the cholesterol and DSPC. In the case of lot 8520100103, the mol % non-cationic lipid is 48.28%.

458. The same calculations can be performed for lot 5005919001, which is the SM-102 LNP lot that was used to manufacture the PVU Formulation drug product lots used in Moderna's Phase 1 and Phase 2 clinical trials. *See* MRNA-GEN-00988292 at -314. The certificate of analysis for lot 5009119001 reports concentrations for SM-102, cholesterol, DSPC, and PEG2000-DMG of [redacted], *see* MRNA-GEN-00823114 at -114, corresponding to a lipid molar ratio of [redacted]. The mol % non-cationic from adding together the mol % values for cholesterol and DSPC is [redacted]

459. The tables in **Appendices 1 and 2** of my report summarize the same calculations based on Moderna's COAs for lots of [redacted] manufactured in the United States, or used in lots of drug product either manufactured in the United States, or manufactured using mRNA, [redacted] manufactured in the United States, identified from Moderna's genealogy spreadsheets, along with other spreadsheets listing the lots of drug product made or distributed in the United States. *See, e.g.*, MRNA-GEN-00939821; MRNA-GEN-01424227; MRNA-GEN-01424228; MRNA-GEN-01711164; MRNA-GEN-02645036; MRNA-GEN-02615390; MRNA-GEN-01382331; *see also, e.g.*, Moderna's Third Supplemental Objections and Responses to Plaintiffs' Second Set of Interrogatories (No. 11) (Apr. 29, 2024) at 7; Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 96-99. These tables also summarize the % RNA encapsulation reported in Moderna's COAs for drug product lots.

460. I note that the mg/mL concentration values for SM-102, cholesterol, DSPC, and PEG2000-DMG reported in Moderna's COAs (and accordingly reflected in the summary tables in the appendices to my report) include only one significant digit after the decimal point. I understand that this is a consequence of the fact that Moderna's specification limits for lipid content only include one decimal place, and its validated SOP for determining lipid content directs users to "[r]efer to the product specification for the appropriate significant figures to report." MRNA-GEN-00105506 at -529; *see also* MRNA-GEN-00021192 at -210 ("Report [lipid content] mg/mL results to one decimal place . . . ."); MRNA-GEN-00110477 at -494 (same). Moderna's justification of its lipid content specifications—which employ only one decimal point—further repeatedly affirm that the "acceptance criteria," *i.e.*, the specification limits, "have been defined based on the ability of the method to accurately quantify each lipid independently." MRNA-GEN-00038383 at -390; MRNA-GEN-01802742 at -749; MRNA-GEN-00304139 at -146; MRNA-GEN-00304213 at -222-223; MRNA-GEN-00453491 at -500; MRNA-GEN-00988801 at -810; MRNA-GEN-01032707 at -716; MRNA-GEN-02635314 at -326; MRNA-GEN-00039942 at -949; MRNA-GEN-00119403 at -410; MRNA-GEN-00115135 at -142; MRNA-GEN-00097825 at -834-835; MRNA-GEN-00191190 at -199-200; MRNA-GEN-00998152 at -161-162; MRNA-GEN-01032486 at -495-496; MRNA-GEN-02634802 at -815; MRNA-GEN-00101384 at -392; MRNA-GEN-00843735 at -739. I further understand that Dr. Huijuan Li, Moderna's designated corporate witness on its certificates of analysis, repeatedly deferred to Moderna's "predefined specification" when asked about the accuracy and precision of the Moderna's lipid content assay, the results of which as reported in Moderna's COAs are provided to the FDA. *See, e.g.*, Li 6/11/2024 Tr. 70:5-8 ("We provide batch analysis to FDA, and, yes, FDA would review those C of As."), 70:9-72:20 ("We are reporting per predefined

decimal places which is approved by the [FDA], and that's the foundation of reporting"). And when asked where he would look to confirm "whether a target ratio of 48.5 percent would yield batches with greater than 50 percent cationic lipid," Dr. Parsons confirmed that "certificates of analysis . . . would be my source of information to gather that data." Parsons 6/7/2024 Tr. 133:12-134:3; *see also* Kramarcyzk 4/30/2024 Tr. 73:3-9 ("We don't measure the mole percent directly of any batches. We measure the mass of the four lipids and then calculate the mole percent."). Moderna considered the rounding to one significant figure after the decimal point appropriate and sufficiently accurate for its official COAs on which it relied for releasing the product to the public and calculating the lipid molar ratios of the batches of its product.[102] I agree with Moderna's witnesses that it is appropriate to use Moderna's COAs to determine lipid molar ratios, as I have done in the calculation above and in **Appendices 1 and 2.**

2. Fractionation Testing

461. [redacted]

[102] As discussed above, I have reviewed Dr. Thompson's claim construction declaration, including his discussion of the standard rules of rounding. Following those rules, which I understand Moderna has not disputed, if the digit to the immediate right of the last digit in the to-be-rounded value is smaller than 5, it is eliminated and the last digit in the rounded value is unchanged. If the digit to the immediate right of that last digit is greater than or equal to 5, it is eliminated and the last digit in the rounded value is increased by one. *See, e.g.*, *United States Pharmacopeia, Twenty-Third Revision* ("USP 23") at 3-4. I understand that Moderna rounding in accordance with its SOP-0022, which follows the same standard procedure. *See* Li 6/11/2024 Tr. 121:21-122:9, 125:22-127:14; MRNA-GEN-02613934 at -955.

[redacted]

462. On October 2, 2020, Mr. Schariter—who was involved in some of the compositional heterogeneity testing described above—emailed his supervisor, Dr. Don Parsons, among others, with a request to run a "comprehensive study on the compositional heterogeneity of several mRNA-1273 batches," *i.e.*, batches of Moderna's COVID-19 product. MRNA-GEN-01274243 at -243; Schariter 5/8/2024 Tr. 116:2-117:6. Mr. Schariter proposed to fractionate the samples via three different methods—semi-preparative size exclusion chromatography; semi-preparative hydrophobic interaction chromatography; and density gradient ultracentrifugation—and to subsequently analyze those fractions in a number of ways, including via lipid content compositional heterogeneity. MRNA-GEN-01274243 at -243-244. [redacted]

463. In response to Mr. Schariter's email, Dr. Parsons responded that, while he "appreciate[d] the scientific motivation for the study," he wanted to "think through the potential outcomes and implications for what we hope will soon be a commercial product," as what they might learn could "pose uncomfortable questions." MRNA-GEN-01274243 at -243. Dr. Parsons asked to discuss Mr. Schariter's proposed testing in their one-on-one meeting. MRNA-GEN-01274243 at -243; Schariter 5/8/2024 Tr. 118:4-8. Mr. Schariter and Dr. Parsons both testified that they did not have any recollection of what was discussed at that one-on-one meeting. Schariter 5/8/2024 Tr. 119:17-120:2; Parsons 6/7/2024 Tr. 261:3-17, 265:7-16.

However, Mr. Schariter testified that he did not believe that he ultimately ran the proposed study. Schariter 5/8/2024 Tr. 120:3-5. Despite recognizing the scientific motivation and value of the study, [redacted] Moderna affirmatively chose not to obtain those data for its COVID-19 vaccine, which it could have done by conducting a "comprehensive study on the compositional heterogeneity of several mRNA-1273 batches" as one of Moderna's own scientists proposed and sought to conduct. MRNA-GEN-01274243 at -243. I am not aware of any scientific rationale that would justify Moderna's decision not to perform such studies; the decision to avoid such studies instead appears to have been motivated by Moderna's concern that the results of an investigation into the compositional heterogeneity of it COVID-19 vaccine would "pose uncomfortable questions." I understand from Moderna's witnesses that data from such a study do not exist (apart from the results described in the following paragraphs). *See, e.g.*, Schariter 5/8/2024 Tr. 146:9-148:15; Parsons 6/7/2024 Tr. 267:3-12.

464. Notwithstanding Dr. Parsons' apparent reluctance to study the compositional heterogeneity of Moderna's COVID-19 vaccine, [redacted]

[redacted]

465. [redacted]

[redacted]

466. [redacted]

[redacted]

[redacted]

467. [redacted]

468. [redacted]

[redacted]

469. [redacted]

470. [redacted]

471. [redacted]

[redacted]

472. [redacted] Indeed, Mr. Schariter himself had previously suggested running a similar set of analyses on Moderna's COVID-19 product. MRNA-GEN-01274243. At that time, Dr. Parsons "underst[ood] and appreciate[d] the scientific motivation for this study." MRNA-GEN-01274243 at -243. [redacted]

473. I understand that Plaintiffs requested various documents related to the above [redacted]

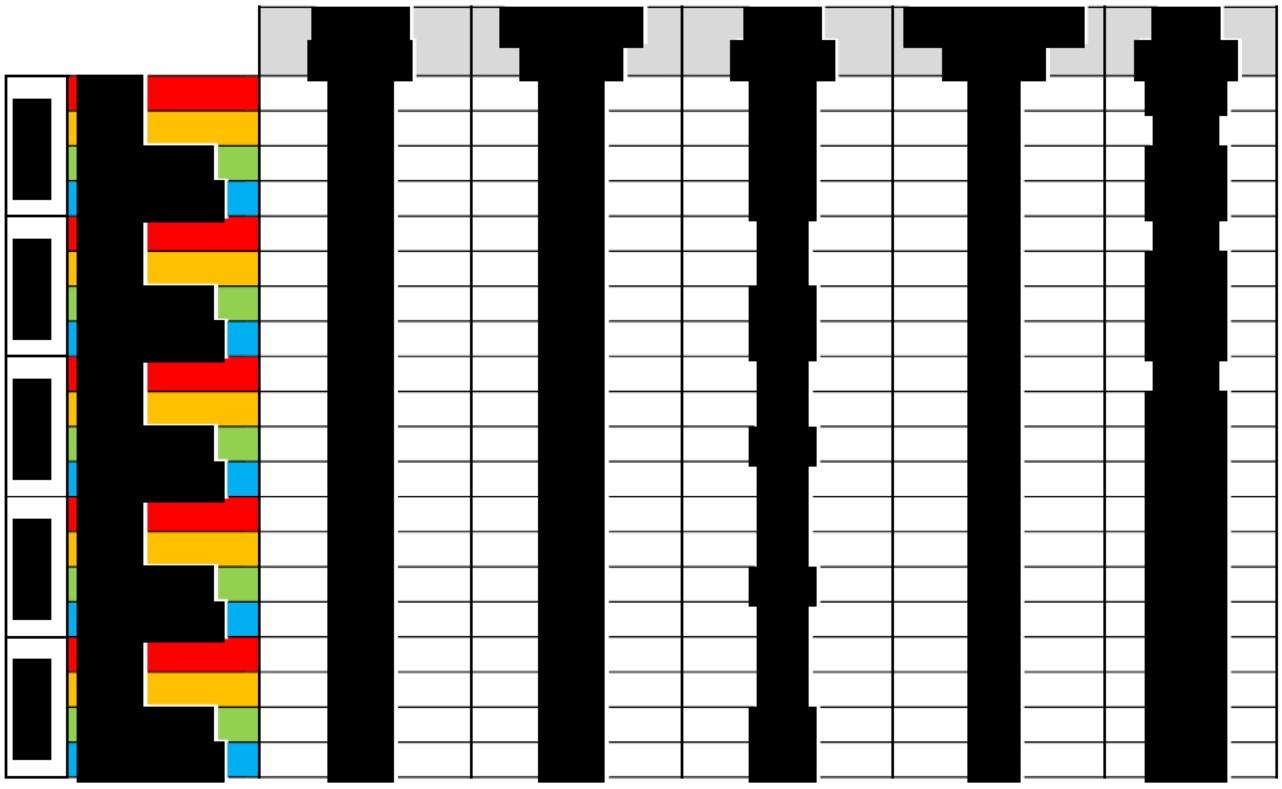
[redacted] I have therefore estimated the values using digital software to measure the distance between the data points and the set gridline values.

474. [redacted]

[redacted]

475. Software-reported lengths (for instance, in pixels, using Microsoft Paint or Adobe Photoshop) can be used to measure the length of the two purple lines. Here, using a zoomed-in view of the image above, the software-reported length for the left purple line is 622 pixels, while the right purple line is 380 pixels. [redacted]

476. The following table provides the results of applying the foregoing analysis to all of the datapoints shown on MRNA-GEN-01276328 at -351. The values shown below are for estimation purposes, and I have not adjusted the mol % values to account for the fact that the percentage values should sum to 100%.



XI. FRACTIONATION TESTING OF MODERNA'S COVID-19 VACCINE

497. I understand that in or around March 2021, nearly a year prior to filing this patent-infringement litigation, and in response to Moderna's contention that its COVID-19 vaccine did not infringe the Patents-in-Suit, Plaintiffs asked Moderna to provide "any mRNA-1273 samples that cannot be used in humans" to assess Moderna's claim. GENV-00247327 at -329. Moderna did not agree to provide samples at that time. GENV-00247327 at -328; *see also* D.I. 1 (Plaintiffs' Original Complaint for Patent Infringement) ¶ 61. After Plaintiffs filed their complaint for patent infringement in February 2022, I understand that Moderna moved to dismiss Plaintiffs' infringement claims on the basis of the "government contractor defense" under 35 U.S.C. § 1498. I understand Moderna did not produce samples, despite Plaintiffs' request, while that motion was pending. The Court denied Moderna's motion, after which, in December 2022, discovery in this litigation opened, and Plaintiffs re-raised their request to Moderna in this litigation for samples of the Accused Product. With the exception of three vials from LDP Lot No. 7009623001, *see* Letter from A. Afinogenova (Apr. 23, 2023), and a set of samples from lots being transferred to a third-party, *see* Email from A. Sheh to M. McLennan & A. Afinogenova (Nov. 20, 2023, 6:06 p.m.), Moderna declined to produce further samples until March 2024, months after Plaintiffs had filed a motion seeking to compel sample production, *see* D.I. 161 (Letter to the Honorable Mitchell S. Goldberg).

498. Following a hearing before the Court regarding that motion to compel, the parties entered into a stipulation regarding the production of samples. *See* D.I. 228 (Stipulation and Order Regarding Sample Production & Testing and Discovery Disputes), Exhibit A ("Sample Stipulation"). Pursuant to the Sample Stipulation, I understand that the parties agreed to select six drug product lots from each "unique mRNA-LNP part number," with three lots selected by Plaintiffs and three lots selected by Moderna. Sample Stipulation ¶ 1(a). As discussed above, I

understand each drug product lot to correspond to an mRNA-1273 LNP part number (or a combination of mRNA-1273 LNP part numbers) based on the mRNA-1273 LNP lot(s) used to manufacture the drug product lot. *See supra* Section X.B. The table below summarizes the lots selected by Plaintiffs or Moderna (or both) by mRNA-1273 LNP part number.

v1 / v2	mRNA-1237 LNP PN	Plaintiffs' Selected LDP	Moderna's Selected LDP
v1	50068[105]	N/A	7006520001
			7006520002
			7006520004
	50073[106]	7006520005	7006520006
		7006520008	7006520007
		7006520009	
	50075[107]	7006822286	7007621002
		7006822285	7007521033
		7006822277	7007621110
		7007621149	
		7006520026	
		7007522019	
	50089[108]	7006821495	7006821486
		7007521015	
		7007521017	
	50099	7006822281	7006822102
		7006822236	7006822119
		7006822139	7006822145
v2	50092	7009623002	7009422031
		7009623003	7009622014

[105] I understand that Plaintiffs initially selected lots 7006320005, 7006320008, and 7006720001 from part number 50068, but Moderna stated that no samples from these lots were available to be produced in this litigation. Email from A. Afinogenova to A. Sheh (Apr. 24, 2024).

[106] I understand that both parties selected lot 7006520009, because there are only five drug product lots associated with mRNA-1273 LNP part number 50073.

[107] I understand that Plaintiffs selected LDP lots 7007621149, 7006520026, and 7007522019 (v1/PN 50075) as replacement lots for the three lots from PN 50068 that Plaintiffs selected but could not be produced, per the Stipulation. *See* Email from F. Elenberg to A. Afinogenova et al. (May 9, 2024, 6:38 p.m.). However, I also understand that Moderna disputes inclusion of these lots within the Stipulation. Email from A. Afinogenova to F. Elenberg et al. (May 15, 2024, 10:00 p.m.).

[108] I understand that both parties selected lots 7007521015 and 7007521017, because there are only four drug product lots associated with mRNA-1273 LNP part number 50089.

v1 / v2	mRNA-1237 LNP PN	Plaintiffs' Selected LDP	Moderna's Selected LDP
		7009622018	7009422053
	50186[109]	7058823034	7036623005
		7029123015	7036623013
		7029123011	7036623016
	50211	7036623029	7036623028
		7036623030	7036623031
		7036623033	7036623035
	50092 / 50111	7010722054	7010722056
		7010722044	7010722059
		7010722046	7010722069
	50092 / 50141[110]	7015323058	7015222058
		7015323057	7015222071
		7016222004	7015322082
	50108 / 50115[111]	7013822019	7010722092

[109] I understand that Plaintiffs did not test lot 7058823034 from PN 50186 because Dr. Schuster possessed an insufficient amount of sample to test. For all samples tested, I understand that Dr. Schuster would use two vials of a given sample with standard fill volume of 0.50 mL per vial; however, the produced samples of 7058823034 had a fill volume of only 0.25 mL per vial. *See* Schuster Report Section VI.B. (n. 20). Therefore, the two vials of 7058823034 did not constitute a sufficient quantity to supply Dr. Schuster's analytical methods with the volumes that were required by the methodologies as described in his report. *Id.* It is my opinion that the mol % distribution within lot 7058823034 is substantially the same as the other lots in PN 50186 based on Moderna's repeated representations regarding the equivalency of lots within a part number as well as my own observations regarding the consistency of data within part numbers and within version types. *See supra* ¶¶ 354-358; *see infra* ¶ 655.

[110] I understand that the produced vials of 7016222004 from PN 50092 / 50141 comprise a unit formula 0.05 mg/mL (rather than the standard 0.10 mg/mL), and therefore these samples are roughly half as concentrated with respect to mRNA and lipid concentration as the rest of the v2 samples. *See* MRNA-GEN-01000299 at -303-304. It is my understanding that this sample was not tested because the sample testing methodology and qualification used by Dr. Schuster and his team (discussed below) were optimized for suitability to the standard 0.10 mg/mL and 0.20 mg/mL unit formulas, not to the 0.05 mg/mL formula that corresponds to the 6 months to 5 years pediatric booster vaccine. MRNA-GEN-00301861 at -871. It is my opinion that the mol % distribution within lot 7016222004 is substantially the same as the other lots in PN 50186 based on Moderna's repeated representations regarding the equivalency of lots within a part number as well as my own observations regarding the consistency of data within part numbers and within version types. *See supra* ¶¶ 354-358; *see infra* ¶ 655.

[111] It is my understanding that Plaintiffs originally requested lot 7010722015 from PN 50108 / 50115 and lot 7015923019 from PN 50108 / 50140, however, Moderna represented to Plaintiffs that it did not possess any samples for those lots, so Plaintiffs selected lot 7010722177 from PN 50108 / 50115 and lot 7015922012 for PN 50108/50140. Email from A. Afinogenova to A. Sheh (Jul. 3, 2024); Email from F. Elenberg to A. Afinogenova (Jul. 15, 2024). It is further my understanding that Moderna had not produced various COAs at the time of sample selection,

v1 / v2	mRNA-1237 LNP PN	Plaintiffs' Selected LDP	Moderna's Selected LDP
		7010722191	7010722104
		7010722177	7010722121
	50108 / 50140	7015922012	7015322024
		7015923016	7015322057
		7015322077	7015322058

See Letter from A. Afinogenova (Mar. 13, 2024); Letter from A. Sheh (Apr. 10, 2024); Letter from A. Afinogenova (May 2, 2024).

499. As before, I have identified how the lot numbers and the part numbers above correspond to the Moderna's v1 or v2 Formulation targets based on the "LNP-B" designation in the PVMP and other documents. *See, e.g.*, *supra* Section X.B; MRNA-GEN-02615390 at -402-07. Based on my review of the corresponding COAs, the parties' selected lots span a representative range of manufacturing and expiration dates and reported lipid concentrations by Moderna.[112]

including COAs for PNs 50108 / 50115 and PN 50108/50140, and refused to allow Plaintiffs to substitute in lots for which Moderna had provided COAs prior to shipment. Email from A. Sheh to A. Afinogenova (Jul. 11, 2024); Email from A. Afinogenova to A. Sheh (Jul. 12, 2024); Email from F. Elenberg to A. Afinogenova (Jul. 15, 2024).

[112] *See, e.g.*, MRNA-GEN-01373863; MRNA-GEN-01373833; MRNA-GEN-00021633; MRNA-GEN-00021637; MRNA-GEN-00021641; MRNA-GEN-00465661; MRNA-GEN-00180186; MRNA-GEN-00181745; MRNA-GEN-00116219; MRNA-GEN-00182709; MRNA-GEN-00185608; MRNA-GEN-00194711; MRNA-GEN-00466253; MRNA-GEN-00466082; MRNA-GEN-00465708; MRNA-GEN-00465698; MRNA-GEN-00466441; MRNA-GEN-00466401; MRNA-GEN-00466304; MRNA-GEN-00466284; MRNA-GEN-00094173; MRNA-GEN-00094189; MRNA-GEN-00467460; MRNA-GEN-00040969; MRNA-GEN-00078949; MRNA-GEN-00466943; MRNA-GEN-01372080; MRNA-GEN-01424385; MRNA-GEN-01551946; MRNA-GEN-01551934; MRNA-GEN-01551940; MRNA-GEN-01551978; MRNA-GEN-02613606; MRNA-GEN-02613483; MRNA-GEN-01551972; MRNA-GEN-02613527; MRNA-GEN-01551966; MRNA-GEN-00467335; MRNA-GEN-00467331; MRNA-GEN-00169071; MRNA-GEN-01551952; MRNA-GEN-00042183; MRNA-GEN-00168903; MRNA-GEN-00199319; MRNA-GEN-00466898; MRNA-GEN-00466893.

500. I understand that Dr. Schuster and his team at Coriolis Pharma performed ultracentrifugation fractionation studies on samples produced by Moderna. Dr. Schuster subsequently measured the lipid content of both the fractions and unfractionated samples produced by Moderna using LC-CAD to determine their lipid molar ratios.[113] I further understand that researchers at Coriolis under Dr. Schuster's direction performed other orthogonal characterization including DLS, as well as UV nanodrop and NTA to confirm the presence of mRNA-LNPs in each of the fractions. I have reviewed Dr. Schuster's report and data, which I understand are concurrently being submitted on behalf of Plaintiffs alongside this report.

501. For convenience, I have excerpted the data tables for selected lots from Section VII.B. of Dr. Schuster's report, which I discuss in further detail in below, *infra* Section XIII.F.1. Separate from the system suitability testing ("SST") criteria, which had to be satisfied in order for the data produced from a given LC-CAD run to be considered, Coriolis also established sample acceptance testing ("SAT") criteria to determine if each sample (native sample and fractionated samples) measurement met stringent standards of accuracy and precision. I understand from Dr. Schuster's report that "< QL" connotes samples whose values fell below Coriolis's established limit of quantification for a given assay, and I further understand that "SAT failed" connotes a fraction that has not passed the sample acceptance testing criteria of all lipids having RSD ≤ 5%. Schuster Infringement Report at Section VII.B; *infra* Section XIII.F.1. I understand that there were a few instances in which a separate SAT was not passed (e.g., empty check standard injection). Schuster Infringement Report at Section VII.B. All reported numerical values are above LOQ and have passed sample acceptance criteria.

[113] Dr. Schuster's molar ratio calculations follow the methodology I describe above, and similarly apply a molecular weight of 2,440 g/mol from PEG2000-DMG. *Supra* Section X.A.

502. The results for samples with Coriolis sample testing numbers A-1, A-2, A-3, A-4, B-7, and B-8 are unexpired.

A. Sample No. A-1 (PN 50211 / Moderna Lot No. 7036623028 / Sample Lot No. 023J23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "023J23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.278	38.818	11.735	2.169	0.442	0.389	0.097	0.028	0.935	1.001	0.829	1.294
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 5	52.022	35.705	10.270	2.004	0.334	0.349	0.066	0.015	0.641	0.977	0.641	0.762
Fraction 6	50.546	36.473	10.735	2.246	0.211	0.236	0.207	0.013	0.418	0.647	1.931	0.581
Fraction 7	49.020	37.378	11.163	2.439	0.370	0.322	0.051	0.044	0.754	0.861	0.460	1.814
Fraction 8	45.428	39.708	12.334	2.530	0.338	0.387	0.160	0.036	0.744	0.974	1.296	1.437
Fraction 9	42.629	41.533	13.344	2.493	0.198	0.259	0.083	0.021	0.463	0.624	0.625	0.859
Fraction 10	42.449	41.980	13.400	2.171	0.460	0.335	0.130	0.028	1.084	0.797	0.970	1.307

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "023J23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.11	3.50	0.22	0.08	2.037	0.043	6.75E+11
Fraction 1	181.19	5.85	0.23	0.05	< QL	< QL	4.60E+10
Fraction 2	170.40	5.20	0.24	0.06	< QL	< QL	2.67E+10
Fraction 3	148.10	3.90	0.24	0.09	< QL	< QL	3.06E+10
Fraction 4	125.59	3.70	0.22	0.07	< QL	< QL	3.47E+10
Fraction 5	107.41	3.03	0.17	0.04	0.142	0.023	4.62E+10
Fraction 6	101.69	1.99	0.17	0.07	0.248	0.040	9.28E+10
Fraction 7	106.86	1.87	0.21	0.06	0.571	0.037	1.74E+11
Fraction 8	125.85	3.55	0.18	0.06	1.018	0.053	2.57E+11
Fraction 9	161.23	3.05	0.19	0.07	0.784	0.039	2.08E+11

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 10	200.97	6.88	0.16	0.07	0.394	0.014	8.49E+10

B. Sample No. A-2 (PN 50211 / Moderna Lot No. 7036623029 / Sample Lot No. 025J23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "025J23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.836	39.292	11.638	2.235	0.094	0.100	0.035	0.019	0.201	0.256	0.302	0.869
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 5	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 6	50.983	36.254	10.458	2.305	0.319	0.356	0.085	0.027	0.626	0.982	0.814	1.193
Fraction 7	48.574	37.600	11.287	2.539	0.392	0.486	0.099	0.009	0.808	1.291	0.878	0.336
Fraction 8	45.064	39.964	12.385	2.587	0.461	0.329	0.175	0.052	1.023	0.824	1.412	1.999
Fraction 9	42.591	41.508	13.324	2.576	0.145	0.203	0.069	0.022	0.339	0.488	0.521	0.843
Fraction 10	42.795	41.512	13.496	2.197	0.278	0.325	0.076	0.007	0.648	0.784	0.565	0.313

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "025J23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	131.02	3.98	0.23	0.09	2.018	0.032	8.96E+11
Fraction 1	180.98	4.13	0.18	0.07	< QL	< QL	4.89E+10
Fraction 2	159.05	4.12	0.20	0.04	< QL	< QL	3.17E+10
Fraction 3	152.29	4.37	0.25	0.07	< QL	< QL	2.89E+10
Fraction 4	121.10	2.92	0.21	0.05	< QL	< QL	2.74E+10
Fraction 5	105.36	2.74	0.19	0.07	< QL	< QL	4.84E+10
Fraction 6	100.35	2.08	0.18	0.08	0.178	0.043	9.34E+10
Fraction 7	105.76	2.53	0.18	0.04	0.564	0.029	2.22E+11

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 8	122.64	2.09	0.18	0.06	1.011	0.023	3.29E+11
Fraction 9	160.86	4.54	0.16	0.07	0.742	0.010	2.18E+11
Fraction 10	201.36	4.12	0.15	0.06	0.457	0.063	1.13E+11

C. Sample No. A-3 (PN 50211 / Moderna Lot No. 7036623031 / Sample Lot No. 027J23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "027J23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.886	38.993	11.815	2.306	0.064	0.059	0.020	0.010	0.137	0.153	0.166	0.449
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.786	35.980	10.382	1.852	0.131	0.142	0.064	0.010	0.254	0.394	0.617	0.547
Fraction 5	51.990	35.381	10.527	2.102	0.085	0.127	0.049	0.009	0.163	0.360	0.469	0.420
Fraction 6	51.242	35.752	10.662	2.345	0.151	0.177	0.044	0.010	0.295	0.494	0.409	0.423
Fraction 7	49.160	36.955	11.318	2.567	0.102	0.100	0.035	0.007	0.207	0.272	0.313	0.279
Fraction 8	45.085	39.607	12.657	2.651	0.083	0.098	0.072	0.008	0.183	0.247	0.568	0.296
Fraction 9	42.755	40.928	13.712	2.605	0.060	0.076	0.100	0.012	0.140	0.187	0.732	0.463
Fraction 10	41.986	41.959	13.808	2.247	0.129	0.108	0.035	0.010	0.307	0.258	0.252	0.456

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "027J23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	131.47	3.26	0.22	0.06	1.930	0.029	8.28E+11
Fraction 1	181.77	8.20	0.14	0.11	< QL	< QL	3.68E+10
Fraction 2	165.12	2.61	0.19	0.08	< QL	< QL	2.89E+10
Fraction 3	135.13	4.16	0.21	0.07	< QL	< QL	3.31E+10
Fraction 4	118.95	3.05	0.16	0.05	< QL	< QL	3.80E+10
Fraction 5	106.74	1.99	0.12	0.06	0.164	0.029	5.49E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 6	102.99	2.68	0.15	0.06	0.330	0.011	1.12E+11
Fraction 7	109.85	1.61	0.18	0.07	0.569	0.029	1.59E+11
Fraction 8	126.56	2.29	0.22	0.05	1.123	0.005	3.16E+11
Fraction 9	159.60	4.29	0.19	0.05	0.686	0.042	1.71E+11
Fraction 10	204.19	5.87	0.27	0.11	0.421	0.028	9.88E+10

D. Sample No. A-4 (PN 50211 / Moderna Lot No. 7036623030 / Sample Lot No. 026J23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "026J23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.066	38.804	11.755	2.375	0.441	0.485	0.054	0.018	0.937	1.249	0.462	0.772
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 5	51.751	35.473	10.595	2.181	0.126	0.037	0.100	0.028	0.243	0.105	0.942	1.290
Fraction 6	50.803	35.977	10.848	2.371	0.304	0.249	0.063	0.020	0.598	0.691	0.577	0.851
Fraction 7	48.900	37.172	11.281	2.648	0.211	0.173	0.072	0.026	0.432	0.464	0.637	0.964
Fraction 8	45.015	39.778	12.406	2.800	0.389	0.395	0.028	0.027	0.865	0.994	0.227	0.957
Fraction 9	43.042	40.693	13.466	2.800	0.133	0.168	0.128	0.013	0.309	0.413	0.953	0.465
Fraction 10	40.056	42.743	14.656	2.545	0.295	0.401	0.118	0.015	0.735	0.939	0.805	0.599

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "026J23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	128.36	3.88	0.19	0.05	2.132	0.035	8.22E+11
Fraction 1	175.31	3.16	0.20	0.07	< QL	< QL	3.20E+10
Fraction 2	157.21	7.12	0.22	0.08	< QL	< QL	2.58E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 3	140.85	2.18	0.18	0.12	< QL	< QL	3.89E+10
Fraction 4	130.59	3.37	0.19	0.05	0.103	0.002	5.25E+10
Fraction 5	116.74	3.09	0.16	0.06	0.183	0.007	9.72E+10
Fraction 6	113.77	2.64	0.14	0.08	0.361	0.017	1.89E+11
Fraction 7	115.09	2.92	0.17	0.06	0.803	0.022	2.80E+11
Fraction 8	126.27	1.85	0.11	0.07	1.257	0.030	3.68E+11
Fraction 9	143.36	3.87	0.20	0.06	0.731	0.012	1.84E+11
Fraction 10	189.00	3.91	0.19	0.07	0.326	0.008	8.72E+10

E. Sample No. A-5 (PN 50186 / Moderna Lot No. 7036623016 / Sample Lot No. 013H23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "013H23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.321	39.513	11.738	2.428	0.389	0.394	0.084	0.018	0.841	0.997	0.719	0.727
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	52.049	35.308	10.353	2.290	0.121	0.155	0.080	0.015	0.232	0.438	0.770	0.674
Fraction 6	50.672	36.142	10.768	2.418	0.563	0.526	0.040	0.020	1.110	1.454	0.371	0.831
Fraction 7	48.256	37.733	11.365	2.645	0.159	0.129	0.017	0.032	0.331	0.341	0.145	1.197
Fraction 8	44.282	40.603	12.380	2.735	0.302	0.450	0.129	0.031	0.682	1.109	1.045	1.146
Fraction 9	41.963	41.818	13.421	2.798	0.309	0.353	0.078	0.014	0.737	0.844	0.581	0.510
Fraction 10	42.409	41.514	13.803	2.273	0.264	0.279	0.086	0.019	0.621	0.671	0.621	0.855

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "013H23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	130.37	3.44	0.20	0.11	2.121	0.030	9.33E+11

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 1	172.50	5.78	0.18	0.07	< QL	< QL	5.26E+10
Fraction 2	157.43	4.24	0.18	0.07	< QL	< QL	2.90E+10
Fraction 3	136.13	3.23	0.22	0.07	< QL	< QL	2.68E+10
Fraction 4	129.34	2.94	0.21	0.04	< QL	< QL	3.62E+10
Fraction 5	103.17	2.99	0.18	0.08	0.160	0.003	4.55E+10
Fraction 6	104.38	1.71	0.16	0.06	0.301	0.020	1.13E+11
Fraction 7	109.89	2.93	0.17	0.06	0.725	0.040	2.57E+11
Fraction 8	124.47	3.34	0.19	0.07	1.366	0.020	4.79E+11
Fraction 9	150.10	5.81	0.17	0.08	0.912	0.036	3.23E+11
Fraction 10	198.18	3.79	0.21	0.10	0.513	0.027	1.57E+11

F. Sample No. A-6 (PN 50186 / Moderna Lot No. 7036623013 / Sample Lot No. 006H23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "006H23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.704	39.365	11.636	2.294	0.233	0.289	0.051	0.007	0.499	0.734	0.437	0.293
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 5	51.842	35.739	10.259	2.160	0.186	0.251	0.059	0.020	0.358	0.703	0.575	0.937
Fraction 6	50.884	36.302	10.489	2.324	0.156	0.171	0.029	0.018	0.307	0.472	0.272	0.760
Fraction 7	48.444	37.958	11.151	2.447	0.285	0.277	0.020	0.009	0.588	0.730	0.178	0.365
Fraction 8	45.303	40.225	12.037	2.436	0.138	0.172	0.036	0.024	0.305	0.428	0.295	0.987
Fraction 9	43.036	41.658	12.837	2.469	0.191	0.197	0.014	0.012	0.444	0.472	0.111	0.471
Fraction 10	41.412	42.568	13.715	2.305	0.087	0.159	0.115	0.009	0.210	0.375	0.841	0.396

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "006H23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	131.58	3.78	0.23	0.07	2.187	0.037	8.32E+11
Fraction 1	177.47	2.72	0.16	0.05	< QL	< QL	7.02E+10
Fraction 2	156.47	3.68	0.19	0.06	< QL	< QL	3.55E+10
Fraction 3	137.94	4.32	0.20	0.07	< QL	< QL	3.30E+10
Fraction 4	111.88	2.63	0.16	0.06	< QL	< QL	2.29E+10
Fraction 5	101.45	1.85	0.20	0.04	0.078	0.034	4.15E+10
Fraction 6	99.53	2.35	0.17	0.04	0.208	0.018	1.05E+11
Fraction 7	108.84	2.35	0.18	0.07	0.613	0.017	2.15E+11
Fraction 8	124.86	3.03	0.14	0.05	1.054	0.034	3.33E+11
Fraction 9	150.13	2.89	0.15	0.04	0.892	0.019	2.45E+11
Fraction 10	192.20	8.67	0.22	0.08	0.564	0.032	1.35E+11

G. Sample No. B-7 (PN 50211 / Moderna Lot No. 7036623035 / Sample Lot No. 021J23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "021J23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.816	39.012	11.884	2.289	0.396	0.329	0.207	0.043	0.846	0.843	1.746	1.865
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.954	35.894	10.334	1.817	0.456	0.426	0.061	0.026	0.878	1.185	0.589	1.436
Fraction 5	51.952	35.556	10.467	2.026	0.279	0.323	0.065	0.010	0.536	0.907	0.617	0.472
Fraction 6	51.001	35.944	10.788	2.267	0.362	0.342	0.025	0.006	0.710	0.950	0.231	0.273
Fraction 7	48.775	37.266	11.371	2.589	0.516	0.502	0.121	0.046	1.059	1.347	1.068	1.792
Fraction 8	45.878	38.948	12.520	2.654	0.209	0.167	0.124	0.013	0.456	0.428	0.990	0.503
Fraction 9	42.552	40.945	13.856	2.648	0.315	0.241	0.114	0.024	0.740	0.589	0.823	0.900
Fraction 10	41.823	41.810	14.069	2.298	0.381	0.330	0.057	0.025	0.911	0.790	0.405	1.086

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "021J23A".

	DLS				UV		NTA
Sample No.	**Z-ave (nm)**	**± SD (nm)**	**PdI (a.u.)**	**± SD (a.u.)**	**Mean O.D. at 260 nm [A.U.] scatter corrected**	**± SD (a.u.)**	**[particles/mL] (corrected for dilution)**
Not-fractionated	130.73	4.02	0.23	0.08	1.952	0.022	6.28E+11
Fraction 1	169.13	4.02	0.14	0.08	< QL	< QL	3.07E+10
Fraction 2	162.61	3.40	0.15	0.07	< QL	< QL	2.20E+10
Fraction 3	141.24	4.25	0.19	0.05	< QL	< QL	3.23E+10
Fraction 4	127.98	4.18	0.20	0.06	< QL	< QL	3.93E+10
Fraction 5	113.17	2.88	0.19	0.06	< QL	< QL	4.95E+10
Fraction 6	105.17	2.29	0.17	0.06	0.227	0.024	9.03E+10
Fraction 7	111.30	1.85	0.16	0.04	0.569	0.021	1.66E+11
Fraction 8	125.12	4.48	0.19	0.06	0.858	0.021	2.46E+11
Fraction 9	156.01	3.59	0.18	0.06	0.724	0.022	1.83E+11
Fraction 10	191.25	7.61	0.23	0.08	0.196	0.093	7.88E+10

H. Sample No. B-8 (PN 50211 / Moderna Lot No. 7036623033 / Sample Lot No. 033H23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "033H23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.958	39.062	11.741	2.239	0.156	0.059	0.092	0.025	0.332	0.151	0.782	1.113
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.161	35.826	10.214	1.799	0.456	0.464	0.077	0.016	0.873	1.295	0.752	0.864
Fraction 5	52.396	35.377	10.173	2.053	0.155	0.251	0.108	0.014	0.296	0.710	1.060	0.704
Fraction 6	51.235	35.816	10.623	2.326	0.344	0.257	0.109	0.032	0.671	0.718	1.023	1.384
Fraction 7	48.814	37.197	11.388	2.601	0.107	0.146	0.096	0.027	0.220	0.392	0.839	1.056
Fraction 8	45.513	39.359	12.485	2.642	0.269	0.255	0.113	0.017	0.591	0.649	0.906	0.658
Fraction 9	42.199	41.484	13.669	2.648	0.147	0.133	0.070	0.013	0.349	0.322	0.512	0.488
Fraction 10	42.040	41.783	13.785	2.392	0.131	0.188	0.151	0.014	0.313	0.450	1.094	0.579

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "033H23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.13	3.26	0.26	0.07	1.969	0.058	6.53E+11
Fraction 1	176.98	5.17	0.16	0.05	< QL	< QL	3.30E+10
Fraction 2	179.73	5.99	0.13	0.06	< QL	< QL	2.87E+10
Fraction 3	168.36	4.48	0.26	0.09	< QL	< QL	2.92E+10
Fraction 4	122.45	2.40	0.17	0.04	< QL	< QL	3.48E+10
Fraction 5	107.89	3.32	0.17	0.06	0.101	0.027	6.72E+10
Fraction 6	104.80	2.08	0.16	0.04	0.255	0.018	1.00E+11
Fraction 7	108.98	2.25	0.20	0.05	0.453	0.011	1.63E+11
Fraction 8	125.61	1.75	0.21	0.05	0.776	0.018	2.61E+11
Fraction 9	161.00	3.53	0.21	0.06	0.650	0.009	2.09E+11
Fraction 10	190.28	6.67	0.24	0.08	0.426	0.016	9.97E+10

I. Sample No. B-9 (PN 50092 / Moderna Lot No. 7009622014 / Sample Lot No. 048D22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "048D22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.085	39.635	11.931	2.348	0.149	0.118	0.041	0.005	0.322	0.297	0.344	0.226
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.825	35.020	11.163	1.993	0.230	0.223	0.052	0.004	0.443	0.636	0.470	0.204
Fraction 5	51.223	35.655	10.960	2.162	0.085	0.055	0.080	0.009	0.165	0.154	0.734	0.430
Fraction 6	50.252	36.242	11.152	2.354	0.134	0.104	0.033	0.004	0.266	0.288	0.293	0.178
Fraction 7	48.490	37.420	11.487	2.603	0.168	0.177	0.035	0.012	0.347	0.474	0.302	0.476
Fraction 8	45.411	39.627	12.229	2.734	0.252	0.263	0.046	0.010	0.555	0.664	0.373	0.376
Fraction 9	42.327	41.522	13.323	2.828	0.187	0.174	0.039	0.006	0.443	0.420	0.293	0.224
Fraction 10	42.530	41.418	13.686	2.366	0.129	0.094	0.045	0.002	0.303	0.227	0.330	0.097

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "048D22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	135.89	2.63	0.23	0.05	2.129	0.037	8.24E+11
Fraction 1	174.98	7.80	0.15	0.06	< QL	< QL	4.47E+10
Fraction 2	155.77	6.27	0.19	0.05	< QL	< QL	2.80E+10
Fraction 3	138.75	3.18	0.18	0.05	< QL	< QL	2.60E+10
Fraction 4	125.18	2.22	0.21	0.06	< QL	< QL	2.44E+10
Fraction 5	110.94	1.88	0.19	0.05	< QL	< QL	5.12E+10
Fraction 6	106.82	2.08	0.16	0.07	0.178	0.022	1.04E+11
Fraction 7	116.59	3.04	0.15	0.05	0.474	0.026	2.32E+11
Fraction 8	129.76	3.91	0.15	0.09	0.894	0.030	3.89E+11
Fraction 9	153.80	5.67	0.18	0.06	0.751	0.019	2.72E+11
Fraction 10	187.72	5.35	0.19	0.07	0.431	0.074	1.52E+11

J. Sample No. B-10 (PN 50092 / Moderna Lot No. 7009422031 / Sample Lot No. AR5186C)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "AR5186C".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.649	39.249	11.750	2.352	0.196	0.219	0.095	0.013	0.420	0.559	0.813	0.563
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	52.329	34.842	10.754	2.075	0.167	0.114	0.062	0.027	0.319	0.326	0.575	1.292
Fraction 6	51.248	35.363	10.976	2.413	0.401	0.322	0.117	0.018	0.783	0.912	1.063	0.726
Fraction 7	49.472	36.503	11.336	2.688	0.158	0.159	0.035	0.025	0.319	0.434	0.309	0.919
Fraction 8	46.091	38.866	12.220	2.823	0.156	0.186	0.050	0.015	0.338	0.478	0.406	0.524
Fraction 9	42.538	41.473	13.218	2.771	0.290	0.329	0.096	0.015	0.682	0.793	0.723	0.538
Fraction 10	41.445	41.954	14.097	2.504	0.142	0.165	0.126	0.038	0.343	0.394	0.890	1.505

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "AR5186C".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	139.56	4.20	0.20	0.10	2.212	0.042	9.81E+11
Fraction 1	181.72	8.41	0.15	0.07	< QL	< QL	4.45E+10
Fraction 2	169.76	5.93	0.20	0.04	< QL	< QL	3.41E+10
Fraction 3	153.04	5.54	0.22	0.12	< QL	< QL	3.14E+10
Fraction 4	138.75	2.40	0.17	0.04	0.099	0.011	3.98E+10
Fraction 5	120.16	3.33	0.19	0.06	0.137	0.014	5.60E+10
Fraction 6	104.49	2.25	0.19	0.07	0.271	0.004	8.06E+10
Fraction 7	114.04	2.52	0.19	0.04	0.505	0.018	1.76E+11
Fraction 8	133.29	2.80	0.19	0.08	1.091	0.025	2.99E+11
Fraction 9	163.98	5.08	0.17	0.08	0.840	0.037	2.91E+11
Fraction 10	184.32	6.12	0.28	0.05	0.408	0.036	1.05E+11

K. Sample No. B-11 (PN 50092 / Moderna Lot No. 7009422053 / Sample Lot No. 010L21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "010L21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.484	39.475	11.799	2.242	0.123	0.132	0.012	0.004	0.264	0.335	0.100	0.167
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.776	35.796	10.691	1.737	0.185	0.145	0.092	0.026	0.357	0.405	0.861	1.495
Fraction 5	51.983	35.317	10.714	1.986	0.145	0.198	0.060	0.011	0.278	0.561	0.563	0.575
Fraction 6	50.723	35.970	10.995	2.311	0.096	0.108	0.045	0.018	0.188	0.300	0.407	0.798
Fraction 7	48.741	37.211	11.518	2.530	0.159	0.226	0.062	0.008	0.326	0.608	0.536	0.317
Fraction 8	44.932	40.394	12.116	2.558	0.098	0.044	0.065	0.028	0.219	0.108	0.534	1.096
Fraction 9	42.537	42.130	12.732	2.602	0.098	0.048	0.070	0.017	0.230	0.115	0.553	0.637
Fraction 10	41.501	42.667	13.665	2.167	0.273	0.192	0.090	0.019	0.657	0.451	0.658	0.899

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "010L21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	140.52	3.85	0.18	0.08	2.378	0.024	9.61E+11
Fraction 1	181.13	2.91	0.18	0.10	< QL	< QL	5.42E+10
Fraction 2	166.52	3.69	0.18	0.09	< QL	< QL	3.63E+10
Fraction 3	160.73	4.23	0.21	0.08	< QL	< QL	3.69E+10
Fraction 4	124.45	2.39	0.15	0.05	< QL	< QL	4.16E+10
Fraction 5	111.10	2.37	0.19	0.04	< QL	< QL	5.12E+10
Fraction 6	98.01	2.67	0.18	0.05	0.237	0.038	6.77E+10
Fraction 7	109.54	2.32	0.19	0.06	0.616	0.022	1.65E+11
Fraction 8	136.34	2.56	0.21	0.05	1.180	0.021	3.86E+11
Fraction 9	157.41	3.21	0.16	0.05	0.852	0.030	2.94E+11
Fraction 10	209.51	4.82	0.29	0.10	0.476	0.013	1.10E+11

L. Sample No. B-12 (PN 50092/50141 / Moderna Lot No. 7015323057 / Sample Lot No. 019M22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "019M22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.286	38.580	11.796	2.338	0.506	0.541	0.102	0.030	1.069	1.401	0.866	1.270
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	53.000	34.042	10.842	2.116	0.284	0.297	0.033	0.016	0.535	0.872	0.309	0.756
Fraction 5	52.086	34.838	10.823	2.254	0.359	0.363	0.097	0.015	0.690	1.041	0.898	0.672
Fraction 6	51.248	35.316	11.051	2.386	0.148	0.133	0.088	0.010	0.288	0.377	0.795	0.419
Fraction 7	48.627	37.225	11.476	2.672	0.139	0.154	0.043	0.008	0.286	0.414	0.371	0.315
Fraction 8	45.176	39.342	12.579	2.903	0.169	0.262	0.116	0.043	0.374	0.665	0.923	1.479
Fraction 9	42.657	40.698	13.829	2.815	0.450	0.540	0.101	0.020	1.054	1.327	0.732	0.707
Fraction 10	38.599	43.083	15.592	2.725	0.167	0.148	0.157	0.032	0.433	0.343	1.004	1.189

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "019M22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.88	3.12	0.21	0.09	2.322	0.049	1.05E+12
Fraction 1	179.49	6.38	0.18	0.07	< QL	< QL	4.34E+10
Fraction 2	172.89	6.01	0.18	0.07	< QL	< QL	3.39E+10
Fraction 3	146.27	4.06	0.18	0.04	< QL	< QL	3.58E+10
Fraction 4	120.84	2.15	0.15	0.05	0.103	0.005	3.95E+10
Fraction 5	111.51	2.50	0.21	0.05	0.190	0.010	8.05E+10
Fraction 6	113.63	2.33	0.15	0.06	0.324	0.014	1.41E+11
Fraction 7	117.92	2.21	0.16	0.04	0.654	0.013	2.35E+11
Fraction 8	132.18	2.81	0.19	0.07	1.086	0.028	3.60E+11
Fraction 9	155.38	3.87	0.22	0.05	0.741	0.015	2.37E+11
Fraction 10	182.06	5.26	0.18	0.06	0.404	0.022	1.12E+11

M. Sample No. C-13 (PN 50092/50141 / Moderna Lot No. 7015222058 / Sample Lot No. AS7635B)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "AS7635B".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.930	38.961	11.826	2.283	0.163	0.202	0.060	0.016	0.347	0.518	0.504	0.706

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.769	35.709	10.670	1.852	0.374	0.311	0.107	0.025	0.723	0.871	1.006	1.368
Fraction 5	52.078	35.360	10.642	1.920	0.330	0.431	0.113	0.014	0.634	1.220	1.066	0.742
Fraction 6	51.089	35.929	10.798	2.185	0.263	0.247	0.057	0.025	0.515	0.688	0.529	1.150
Fraction 7	48.692	37.417	11.384	2.507	0.263	0.195	0.066	0.026	0.540	0.521	0.579	1.025
Fraction 8	45.112	39.705	12.481	2.702	0.148	0.152	0.134	0.013	0.329	0.383	1.077	0.465
Fraction 9	42.827	41.075	13.428	2.669	0.356	0.369	0.012	0.018	0.830	0.899	0.092	0.668
Fraction 10	40.511	42.878	14.221	2.390	0.305	0.278	0.060	0.019	0.754	0.648	0.424	0.816

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "AS7635B".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	126.77	3.63	0.21	0.05	2.151	0.031	8.37E+11
Fraction 1	183.08	5.18	0.22	0.10	< QL	< QL	3.96E+10
Fraction 2	177.77	7.28	0.21	0.05	< QL	< QL	3.01E+10
Fraction 3	152.22	5.26	0.24	0.03	0.085	0.008	3.00E+10
Fraction 4	125.71	3.46	0.21	0.06	0.105	0.010	4.97E+10
Fraction 5	115.09	2.50	0.17	0.04	0.150	0.016	7.64E+10
Fraction 6	111.29	2.36	0.12	0.04	0.338	0.050	1.38E+11
Fraction 7	113.92	3.64	0.18	0.08	0.731	0.006	3.15E+11
Fraction 8	124.22	2.92	0.19	0.09	1.099	0.013	3.70E+11
Fraction 9	141.55	2.56	0.24	0.08	0.571	0.012	1.66E+11
Fraction 10	186.13	4.10	0.21	0.05	0.280	0.029	1.06E+11

N. Sample No. C-14 (PN 50111/50092 / Moderna Lot No. 7010722056 / Sample Lot No. AS5059C)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "AS5059C".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.902	39.222	11.625	2.251	0.245	0.397	0.154	0.027	0.521	1.013	1.328	1.180
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.013	35.574	10.565	1.848	0.271	0.347	0.099	0.013	0.520	0.975	0.936	0.714
Fraction 5	51.827	35.461	10.653	2.059	0.235	0.271	0.078	0.006	0.454	0.763	0.734	0.310
Fraction 6	50.918	35.681	11.032	2.370	0.497	0.533	0.058	0.025	0.976	1.494	0.526	1.034
Fraction 7	48.983	37.014	11.407	2.595	0.351	0.312	0.080	0.020	0.716	0.842	0.702	0.754
Fraction 8	45.673	39.069	12.542	2.716	0.387	0.405	0.064	0.023	0.846	1.037	0.509	0.836
Fraction 9	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 10	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed

I understand from Dr. Schuster that there was no check standard bracketing of fractions 9 and 10, and therefore they are not being relied upon.

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "AS5059C".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.30	4.13	0.23	0.07	2.082	0.058	9.38E+11
Fraction 1	179.03	5.70	0.12	0.10	< QL	< QL	6.63E+10
Fraction 2	175.70	3.43	0.15	0.08	< QL	< QL	4.24E+10
Fraction 3	145.33	3.87	0.16	0.05	< QL	< QL	4.32E+10
Fraction 4	121.44	1.94	0.21	0.06	0.079	0.027	4.81E+10
Fraction 5	101.78	2.26	0.21	0.04	0.156	0.003	5.60E+10
Fraction 6	96.49	1.59	0.19	0.07	0.286	0.019	8.52E+10
Fraction 7	104.49	2.63	0.21	0.05	0.481	0.027	1.95E+11
Fraction 8	129.17	1.64	0.21	0.07	0.875	0.041	2.96E+11
Fraction 9	162.75	2.19	0.17	0.08	0.816	0.046	3.72E+11
Fraction 10	200.87	7.34	0.18	0.07	0.516	0.011	1.47E+11

O. Sample No. C-15 (PN 50186 / Moderna Lot No. 7036623005 / Sample Lot No. 023G23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "023G23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.195	39.466	11.951	2.388	0.103	0.134	0.027	0.013	0.224	0.340	0.226	0.527
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.434	35.276	10.383	1.907	0.043	0.036	0.020	0.026	0.082	0.101	0.192	1.353
Fraction 5	51.888	35.218	10.674	2.220	0.112	0.118	0.037	0.013	0.217	0.336	0.344	0.599
Fraction 6	50.600	36.002	10.985	2.412	0.103	0.148	0.054	0.009	0.203	0.412	0.488	0.368
Fraction 7	48.261	37.385	11.612	2.742	0.222	0.196	0.047	0.005	0.461	0.523	0.403	0.198
Fraction 8	44.875	39.756	12.598	2.771	0.247	0.333	0.072	0.015	0.551	0.838	0.575	0.547
Fraction 9	41.699	41.739	13.831	2.732	0.167	0.150	0.050	0.005	0.401	0.359	0.363	0.169
Fraction 10	40.012	43.066	14.446	2.476	0.212	0.119	0.138	0.010	0.530	0.276	0.959	0.400

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "023G23A".

Sample No.	DLS				UV		NTA
	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	127.65	3.16	0.27	0.06	2.028	0.040	7.76E+11
Fraction 1	168.36	2.82	0.16	0.08	< QL	< QL	3.86E+10
Fraction 2	167.80	5.53	0.18	0.05	< QL	< QL	2.96E+10
Fraction 3	134.42	3.33	0.20	0.06	< QL	< QL	2.61E+10
Fraction 4	124.61	4.09	0.19	0.05	0.083	0.010	3.86E+10
Fraction 5	102.09	2.29	0.16	0.04	0.127	0.030	5.48E+10
Fraction 6	101.15	1.87	0.19	0.06	0.235	0.008	9.86E+10
Fraction 7	107.32	1.69	0.14	0.04	0.565	0.007	2.18E+11
Fraction 8	123.99	3.47	0.17	0.10	0.879	0.011	3.20E+11
Fraction 9	155.83	2.07	0.18	0.05	0.670	0.058	2.27E+11
Fraction 10	186.89	3.79	0.21	0.06	0.367	0.009	1.31E+11

P. Sample No. C-16 (PN 50111/50092 / Moderna Lot No. 7010722059 / Sample Lot No. 032E22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "032E22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.133	38.856	11.653	2.359	0.097	0.135	0.096	0.025	0.205	0.347	0.824	1.079
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.353	35.330	10.428	1.889	0.296	0.236	0.091	0.018	0.564	0.668	0.869	0.947
Fraction 5	52.247	35.120	10.461	2.172	0.282	0.263	0.124	0.017	0.540	0.749	1.185	0.783
Fraction 6	51.190	35.630	10.753	2.427	0.291	0.249	0.055	0.020	0.569	0.698	0.514	0.817
Fraction 7	48.789	37.075	11.324	2.812	0.173	0.172	0.111	0.063	0.354	0.464	0.981	2.231
Fraction 8	45.424	39.386	12.223	2.966	0.420	0.455	0.102	0.027	0.925	1.156	0.834	0.896
Fraction 9	42.665	40.942	13.494	2.899	0.394	0.400	0.130	0.005	0.924	0.977	0.964	0.187
Fraction 10	41.538	41.931	14.091	2.440	0.268	0.206	0.116	0.016	0.644	0.490	0.823	0.673

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "032E22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	125.79	3.08	0.22	0.07	2.175	0.042	7.24E+11
Fraction 1	173.73	4.62	0.19	0.07	< QL	< QL	3.37E+10
Fraction 2	168.46	3.31	0.18	0.06	< QL	< QL	2.11E+10
Fraction 3	151.77	2.68	0.20	0.11	< QL	< QL	2.31E+10
Fraction 4	130.17	4.04	0.21	0.07	< QL	< QL	3.03E+10
Fraction 5	105.17	2.81	0.17	0.08	< QL	< QL	4.37E+10
Fraction 6	101.13	2.98	0.14	0.06	0.169	0.039	8.87E+10
Fraction 7	106.74	1.82	0.16	0.05	0.620	0.017	1.57E+11
Fraction 8	119.65	2.70	0.20	0.07	0.945	0.016	1.72E+11
Fraction 9	154.26	5.00	0.15	0.07	0.714	0.008	1.17E+11
Fraction 10	190.85	5.27	0.16	0.05	0.346	0.010	8.57E+10

Q. Sample No. C-17 (PN 50111/50092 / Moderna Lot No. 7010722054 / Sample Lot No. AS5052C)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "AS5052C".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.545	39.471	11.675	2.309	0.069	0.076	0.087	0.008	0.147	0.192	0.742	0.360
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.941	35.408	9.834	1.817	0.171	0.118	0.081	0.016	0.323	0.334	0.824	0.888

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 5	52.793	35.108	10.071	2.029	0.182	0.157	0.071	0.010	0.345	0.447	0.703	0.514
Fraction 6	51.724	35.431	10.473	2.371	0.168	0.131	0.061	0.008	0.325	0.370	0.582	0.319
Fraction 7	49.250	36.734	11.360	2.656	0.284	0.411	0.101	0.030	0.576	1.120	0.889	1.144
Fraction 8	45.438	39.457	12.392	2.714	0.244	0.309	0.089	0.021	0.537	0.782	0.715	0.777
Fraction 9	41.842	42.096	13.365	2.697	0.105	0.081	0.086	0.020	0.252	0.194	0.642	0.730
Fraction 10	40.657	42.876	14.013	2.454	0.198	0.203	0.026	0.010	0.486	0.473	0.186	0.388

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "AS5052C".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.05	3.27	0.20	0.04	2.030	0.028	5.37E+11
Fraction 1	173.36	5.14	0.17	0.08	< QL	< QL	4.33E+10
Fraction 2	165.77	4.87	0.17	0.06	< QL	< QL	2.38E+10
Fraction 3	155.69	3.35	0.17	0.07	< QL	< QL	3.01E+10
Fraction 4	133.16	3.26	0.19	0.07	< QL	< QL	3.03E+10
Fraction 5	113.24	2.24	0.17	0.07	< QL	< QL	3.85E+10
Fraction 6	97.26	1.99	0.17	0.05	0.086	0.019	6.13E+10
Fraction 7	107.72	1.96	0.17	0.04	0.431	0.008	8.24E+10
Fraction 8	132.11	3.18	0.20	0.07	0.894	0.010	2.12E+11
Fraction 9	165.77	5.00	0.22	0.07	0.771	0.048	2.15E+11
Fraction 10	188.21	3.95	0.19	0.08	0.366	0.076	5.03E+10

R. Sample No. C-18 (PN 50092/50141 / Moderna Lot No. 7015323058 / Sample Lot No. 019M22A-2A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "019M22A-2A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.272	39.686	11.732	2.311	0.307	0.347	0.065	0.025	0.665	0.875	0.558	1.066
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	51.975	35.609	10.388	2.028	0.165	0.093	0.122	0.010	0.317	0.262	1.174	0.503
Fraction 6	50.965	36.080	10.674	2.281	0.111	0.185	0.067	0.023	0.218	0.513	0.626	0.989

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 7	48.764	37.438	11.248	2.549	0.214	0.247	0.074	0.010	0.440	0.661	0.657	0.393
Fraction 8	45.124	39.829	12.291	2.755	0.197	0.269	0.073	0.016	0.436	0.676	0.598	0.576
Fraction 9	42.025	41.956	13.312	2.707	0.243	0.364	0.108	0.021	0.578	0.866	0.809	0.774
Fraction 10	37.984	44.415	15.053	2.548	0.238	0.233	0.043	0.017	0.627	0.526	0.289	0.683

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "019M22A-2A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	127.96	3.55	0.25	0.11	1.939	0.011	5.78E+11
Fraction 1	177.83	6.63	0.16	0.08	< QL	< QL	1.79E+10
Fraction 2	163.06	4.49	0.20	0.07	< QL	< QL	1.65E+10
Fraction 3	158.31	6.91	0.18	0.06	< QL	< QL	1.88E+10
Fraction 4	131.03	2.68	0.21	0.06	< QL	< QL	2.49E+10
Fraction 5	120.37	3.14	0.20	0.07	< QL	< QL	3.37E+10
Fraction 6	107.11	3.72	0.19	0.05	0.106	0.045	7.14E+10
Fraction 7	107.83	2.60	0.14	0.05	0.372	0.029	1.33E+11
Fraction 8	125.53	2.44	0.24	0.08	0.877	0.014	1.31E+11
Fraction 9	146.66	4.53	0.24	0.07	0.639	0.026	1.21E+11
Fraction 10	179.52	5.61	0.17	0.08	0.241	0.027	4.03E+10

S. Sample No. D-19 (PN 50108/50115 / Moderna Lot No. 7010722191 / Sample Lot No. MV1022A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV1022A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.508	39.394	11.724	2.374	0.150	0.132	0.062	0.016	0.322	0.335	0.528	0.661
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	52.782	34.538	10.383	2.297	0.337	0.372	0.045	0.011	0.638	1.078	0.432	0.491
Fraction 6	51.199	35.725	10.593	2.483	0.113	0.128	0.098	0.022	0.220	0.358	0.927	0.890
Fraction 7	48.828	37.379	11.103	2.689	0.052	0.112	0.091	0.022	0.106	0.299	0.821	0.824
Fraction 8	44.879	39.882	12.461	2.777	0.162	0.146	0.017	0.030	0.362	0.365	0.134	1.096

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 9	42.575	41.503	13.199	2.723	0.246	0.224	0.086	0.026	0.578	0.540	0.654	0.953
Fraction 10	42.059	42.206	13.357	2.378	0.371	0.291	0.114	0.016	0.882	0.689	0.855	0.692

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV1022A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	130.01	3.20	0.24	0.08	2.098	0.089	5.96E+11
Fraction 1	175.68	3.59	0.15	0.05	0.073	0.005	4.41E+10
Fraction 2	153.43	3.48	0.19	0.06	< QL	< QL	2.35E+10
Fraction 3	141.75	5.21	0.20	0.09	< QL	< QL	2.12E+10
Fraction 4	110.54	2.85	0.23	0.07	< QL	< QL	1.33E+10
Fraction 5	92.47	1.69	0.20	0.04	0.094	0.022	1.63E+10
Fraction 6	92.49	1.46	0.21	0.05	0.175	0.017	3.90E+10
Fraction 7	104.05	2.66	0.18	0.03	0.449	0.018	8.93E+10
Fraction 8	128.73	2.40	0.17	0.08	0.920	0.022	2.32E+11
Fraction 9	158.14	3.41	0.17	0.04	0.859	0.009	2.17E+11
Fraction 10	192.83	6.10	0.20	0.10	0.641	0.007	1.13E+11

T. Sample No. D-20 (PN 50108/50140 / Moderna Lot No. 7015322024 / Sample Lot No. MV1025A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV1025A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.949	39.114	11.662	2.275	0.349	0.401	0.062	0.023	0.742	1.025	0.528	1.002
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.849	35.679	10.661	1.811	0.095	0.166	0.077	0.027	0.184	0.465	0.718	1.472
Fraction 5	52.332	35.172	10.456	2.039	0.318	0.426	0.131	0.021	0.608	1.211	1.253	1.007
Fraction 6	51.110	35.785	10.715	2.390	0.170	0.133	0.100	0.015	0.333	0.371	0.929	0.648
Fraction 7	49.295	36.887	11.235	2.583	0.159	0.139	0.067	0.007	0.322	0.376	0.593	0.275
Fraction 8	45.620	39.423	12.325	2.633	0.353	0.464	0.129	0.030	0.774	1.176	1.043	1.148
Fraction 9	42.795	41.381	13.228	2.596	0.619	0.683	0.138	0.006	1.445	1.650	1.043	0.235
Fraction 10	40.566	42.563	14.452	2.419	0.346	0.399	0.149	0.011	0.852	0.938	1.034	0.468

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV1025A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	140.70	3.85	0.22	0.05	2.201	0.045	6.72E+11
Fraction 1	192.90	6.41	0.19	0.08	< QL	< QL	3.63E+10
Fraction 2	158.03	3.46	0.26	0.06	< QL	< QL	1.95E+10
Fraction 3	160.18	4.04	0.25	0.07	< QL	< QL	1.98E+10
Fraction 4	146.09	3.56	0.30	0.08	< QL	< QL	2.57E+10
Fraction 5	119.51	1.84	0.28	0.07	0.202	0.028	3.13E+10
Fraction 6	100.81	1.39	0.18	0.06	0.191	0.011	6.24E+10
Fraction 7	109.25	1.71	0.19	0.06	0.596	0.030	1.26E+11
Fraction 8	131.93	2.70	0.21	0.05	1.155	0.041	2.77E+11
Fraction 9	165.67	2.95	0.20	0.10	0.803	0.033	1.85E+11
Fraction 10	199.29	6.56	0.21	0.06	0.540	0.055	5.08E+10

U. Sample No. D-21 (PN 50073 / Moderna Lot No. 7006520008 / Sample Lot No. 029K20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "029K20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.803	39.322	11.469	1.407	0.269	0.246	0.086	0.010	0.563	0.626	0.747	0.691
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	52.768	34.770	11.003	1.459	0.131	0.195	0.095	0.008	0.249	0.561	0.866	0.519
Fraction 6	51.981	34.970	11.403	1.646	0.283	0.260	0.048	0.013	0.545	0.745	0.418	0.798
Fraction 7	48.806	37.419	12.122	1.652	0.295	0.312	0.048	0.012	0.605	0.833	0.397	0.744
Fraction 8	44.886	41.113	12.503	1.498	0.204	0.191	0.053	0.007	0.455	0.466	0.422	0.467
Fraction 9	43.044	42.097	13.336	1.524	0.316	0.322	0.027	0.016	0.735	0.764	0.205	1.037
Fraction 10	44.481	41.570	12.917	1.032	0.216	0.289	0.105	0.007	0.485	0.696	0.809	0.660

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "029K20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	190.48	8.21	0.26	0.06	4.231	0.075	2.94E+12
Fraction 1	214.73	8.51	0.22	0.07	< QL	< QL	5.63E+10
Fraction 2	210.79	6.24	0.29	0.08	< QL	< QL	5.10E+10
Fraction 3	187.10	7.96	0.34	0.06	< QL	< QL	5.13E+10
Fraction 4	157.61	5.99	0.38	0.10	< QL	< QL	5.81E+10
Fraction 5	121.57	5.74	0.32	0.06	0.110	0.012	6.73E+10
Fraction 6	115.59	2.28	0.24	0.06	0.207	0.006	1.08E+11
Fraction 7	145.69	4.58	0.17	0.06	0.559	0.039	4.21E+11
Fraction 8	187.23	6.69	0.16	0.09	1.081	0.013	8.96E+11
Fraction 9	208.66	5.12	0.15	0.07	0.356	0.024	2.58E+11
Fraction 10	281.43	12.63	0.29	0.10	0.345	0.062	1.45E+11

V. Sample No. D-22 (PN 50089 / Moderna Lot No. 7007521017 / Sample Lot No. 940916)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "940916".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.557	40.233	11.813	1.397	0.350	0.260	0.115	0.009	0.751	0.646	0.972	0.614
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	48.891	37.992	11.933	1.185	0.207	0.188	0.134	0.006	0.423	0.495	1.119	0.541
Fraction 5	50.708	36.212	11.600	1.481	0.122	0.091	0.063	0.012	0.241	0.252	0.542	0.829
Fraction 6	50.055	36.426	11.829	1.690	0.247	0.280	0.082	0.011	0.494	0.769	0.697	0.640
Fraction 7	47.134	38.847	12.364	1.656	0.321	0.279	0.084	0.016	0.681	0.719	0.679	0.939
Fraction 8	43.803	41.891	12.738	1.568	0.094	0.244	0.169	0.009	0.214	0.583	1.330	0.590
Fraction 9	42.653	42.774	13.056	1.517	0.228	0.240	0.034	0.003	0.534	0.561	0.262	0.229
Fraction 10	43.671	42.835	12.530	0.964	0.111	0.146	0.041	0.003	0.254	0.342	0.326	0.361

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "940916".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	176.04	4.25	0.31	0.12	4.456	0.109	2.13E+12
Fraction 1	200.37	7.16	0.28	0.06	< QL	< QL	1.06E+11
Fraction 2	188.86	7.93	0.28	0.08	< QL	< QL	7.41E+10
Fraction 3	152.56	3.40	0.27	0.09	< QL	< QL	6.89E+10
Fraction 4	128.49	5.38	0.32	0.05	< QL	< QL	6.74E+10
Fraction 5	114.73	2.61	0.31	0.08	0.126	0.014	7.18E+10
Fraction 6	108.25	2.52	0.26	0.09	0.343	0.023	1.39E+11
Fraction 7	133.51	2.72	0.22	0.06	0.777	0.020	3.21E+11
Fraction 8	155.01	2.88	0.19	0.04	0.991	0.015	4.15E+11
Fraction 9	189.91	5.69	0.21	0.08	0.557	0.026	2.52E+11
Fraction 10	282.53	6.07	0.33	0.05	0.472	0.044	1.98E+11

W. Sample No. E-23 (PN 50075 / Moderna Lot No. 7007522019 / Sample Lot No. 088M21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "088M21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.834	39.902	11.754	1.511	0.425	0.310	0.170	0.017	0.907	0.778	1.449	1.102
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	51.366	35.944	11.195	1.495	0.062	0.058	0.020	0.008	0.120	0.161	0.183	0.546
Fraction 6	50.502	36.475	11.383	1.640	0.243	0.266	0.026	0.007	0.482	0.729	0.226	0.446
Fraction 7	47.986	38.647	11.705	1.661	0.089	0.057	0.107	0.002	0.185	0.148	0.910	0.100
Fraction 8	45.150	40.925	12.331	1.594	0.207	0.190	0.044	0.006	0.459	0.463	0.360	0.395
Fraction 9	43.317	42.202	12.914	1.567	0.023	0.091	0.090	0.009	0.053	0.215	0.696	0.550
Fraction 10	42.851	41.827	13.923	1.399	0.169	0.260	0.082	0.024	0.396	0.621	0.590	1.732

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "088M21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	171.49	4.18	0.20	0.07	4.202	0.101	9.83E+11
Fraction 1	197.30	7.05	0.24	0.09	< QL	< QL	1.48E+10
Fraction 2	193.14	5.60	0.26	0.08	< QL	< QL	2.05E+10
Fraction 3	183.54	7.36	0.29	0.06	< QL	< QL	2.09E+10
Fraction 4	138.47	3.49	0.26	0.07	< QL	< QL	1.77E+10
Fraction 5	124.63	3.70	0.28	0.06	0.131	0.012	4.71E+10
Fraction 6	125.29	2.88	0.19	0.08	0.331	0.030	8.68E+10
Fraction 7	144.51	4.62	0.16	0.05	0.984	0.007	3.37E+11
Fraction 8	173.26	3.96	0.14	0.05	1.327	0.011	1.49E+11
Fraction 9	203.40	5.59	0.16	0.08	0.458	0.018	7.29E+10
Fraction 10	224.02	8.98	0.29	0.09	0.349	0.013	5.43E+10

X. Sample No. E-24 (PN 50075 / Moderna Lot No. 7007621002 / Sample Lot No. 033B21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "033B21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.096	39.972	11.547	1.385	0.253	0.209	0.043	0.009	0.536	0.524	0.373	0.615
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.792	35.804	11.193	1.212	0.339	0.326	0.075	0.013	0.654	0.910	0.670	1.047
Fraction 5	51.961	35.456	11.192	1.391	0.296	0.352	0.071	0.016	0.569	0.992	0.631	1.168
Fraction 6	50.784	36.027	11.626	1.563	0.329	0.362	0.060	0.013	0.648	1.005	0.513	0.860
Fraction 7	47.415	38.719	12.279	1.587	0.216	0.236	0.096	0.015	0.456	0.610	0.786	0.927
Fraction 8	44.054	41.476	12.869	1.601	0.124	0.249	0.125	0.003	0.282	0.601	0.972	0.185
Fraction 9	41.495	42.684	14.163	1.658	0.423	0.443	0.063	0.014	1.019	1.039	0.445	0.855
Fraction 10	43.061	44.030	12.054	0.854	0.122	0.243	0.186	0.011	0.283	0.552	1.543	1.294

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "033B21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	159.78	3.54	0.33	0.06	4.409	0.015	1.16E+12
Fraction 1	205.91	4.67	0.38	0.08	< QL	< QL	2.86E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 2	211.22	7.65	0.40	0.12	< QL	< QL	2.30E+10
Fraction 3	157.47	5.99	0.27	0.05	< QL	< QL	3.07E+10
Fraction 4	127.73	3.53	0.22	0.08	0.104	0.022	3.17E+10
Fraction 5	121.29	2.00	0.18	0.07	0.161	0.012	5.18E+10
Fraction 6	120.13	2.98	0.17	0.05	0.522	0.019	1.10E+11
Fraction 7	130.37	2.40	0.16	0.04	0.940	0.027	1.23E+11
Fraction 8	149.68	4.40	0.16	0.07	0.813	0.004	1.27E+11
Fraction 9	167.67	4.23	0.26	0.08	0.228	0.028	2.90E+10
Fraction 10	301.00	16.89	0.38	0.09	0.266	0.035	3.37E+10

Y. Sample No. E-25 (PN 50075 / Moderna Lot No. 7007621149 / Sample Lot No. 068F21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "068F21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.060	40.128	11.396	1.416	0.098	0.155	0.069	0.003	0.209	0.386	0.604	0.192
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.656	35.148	10.932	1.265	0.172	0.188	0.074	0.011	0.327	0.535	0.681	0.838
Fraction 5	52.084	35.357	11.080	1.480	0.094	0.060	0.044	0.008	0.181	0.170	0.401	0.521
Fraction 6	50.390	36.465	11.522	1.624	0.128	0.138	0.043	0.007	0.254	0.379	0.375	0.431
Fraction 7	46.735	39.404	12.255	1.607	0.121	0.148	0.040	0.002	0.258	0.377	0.328	0.128
Fraction 8	43.211	42.319	12.866	1.604	0.055	0.018	0.054	0.007	0.126	0.043	0.421	0.418
Fraction 9	39.865	43.848	14.649	1.639	0.064	0.068	0.062	0.008	0.160	0.155	0.424	0.479
Fraction 10	44.089	42.210	12.722	0.979	0.188	0.275	0.083	0.011	0.426	0.651	0.650	1.084

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "068F21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	170.86	7.03	0.31	0.07	4.215	0.018	6.28E+11
Fraction 1	178.90	6.52	0.28	0.13	< QL	< QL	1.32E+10
Fraction 2	189.45	10.05	0.40	0.08	< QL	< QL	1.99E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 3	142.63	4.80	0.24	0.07	< QL	< QL	1.84E+10
Fraction 4	130.01	3.13	0.29	0.05	0.099	0.021	3.39E+10
Fraction 5	118.90	3.27	0.21	0.05	0.196	0.009	6.14E+10
Fraction 6	128.65	2.97	0.15	0.07	0.518	0.016	8.14E+10
Fraction 7	143.06	2.12	0.17	0.06	0.930	0.003	3.13E+11
Fraction 8	164.99	5.05	0.19	0.07	0.844	0.041	1.76E+11
Fraction 9	182.25	4.81	0.25	0.05	0.258	0.031	3.99E+10
Fraction 10	269.32	7.31	0.41	0.08	0.382	0.011	7.19E+10

Z. Sample No. E-26 (PN 50108/50115 / Moderna Lot No. 7010722121 / Sample Lot No. 200085A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "200085A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.103	38.581	11.796	2.520	0.435	0.336	0.164	0.016	0.922	0.870	1.389	0.619
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	53.179	34.099	10.346	2.376	0.189	0.171	0.039	0.015	0.355	0.501	0.381	0.651
Fraction 6	51.948	34.853	10.576	2.623	0.085	0.117	0.093	0.038	0.164	0.335	0.876	1.462
Fraction 7	49.885	36.117	11.136	2.862	0.332	0.312	0.031	0.005	0.665	0.864	0.282	0.185
Fraction 8	45.614	39.189	12.279	2.919	0.349	0.343	0.049	0.014	0.765	0.875	0.395	0.471
Fraction 9	42.899	40.978	13.240	2.882	0.226	0.362	0.113	0.038	0.527	0.884	0.850	1.316
Fraction 10	42.566	41.382	13.547	2.505	0.300	0.397	0.100	0.010	0.705	0.959	0.735	0.403

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "200085A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	134.07	4.68	0.28	0.09	2.029	0.044	8.87E+11
Fraction 1	159.45	4.44	0.10	0.05	< QL	< QL	5.81E+10
Fraction 2	150.10	3.18	0.18	0.05	< QL	< QL	5.01E+10
Fraction 3	141.85	4.11	0.19	0.05	< QL	< QL	4.08E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 4	124.96	2.55	0.16	0.05	< QL	< QL	3.79E+10
Fraction 5	96.91	2.09	0.18	0.05	0.078	0.018	3.78E+10
Fraction 6	94.51	1.56	0.17	0.03	0.160	0.021	6.75E+10
Fraction 7	102.71	2.05	0.21	0.06	0.323	0.012	1.47E+11
Fraction 8	128.46	3.26	0.20	0.03	0.848	0.028	3.15E+11
Fraction 9	164.22	5.97	0.18	0.05	0.754	0.055	3.36E+11
Fraction 10	192.96	5.13	0.12	0.09	0.439	0.025	2.08E+11

AA. Sample No. E-27 (PN 50068 / Moderna Lot No. 7006520004 / Sample Lot No. 032H20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "032H20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.505	39.656	11.353	1.486	0.155	0.201	0.183	0.012	0.326	0.507	1.616	0.791
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.207	37.423	11.167	1.202	0.079	0.025	0.089	0.009	0.157	0.066	0.797	0.714
Fraction 5	51.530	35.865	11.120	1.484	0.151	0.158	0.072	0.003	0.293	0.440	0.648	0.193
Fraction 6	50.735	36.205	11.426	1.634	0.207	0.177	0.073	0.008	0.407	0.488	0.637	0.488
Fraction 7	47.937	38.466	11.962	1.635	0.154	0.227	0.065	0.010	0.322	0.589	0.547	0.628
Fraction 8	45.355	40.623	12.420	1.603	0.327	0.397	0.083	0.008	0.720	0.978	0.669	0.527
Fraction 9	42.618	42.279	13.342	1.761	0.247	0.303	0.137	0.009	0.580	0.716	1.029	0.509
Fraction 10	41.531	43.628	13.616	1.225	0.194	0.204	0.084	0.004	0.468	0.467	0.618	0.293

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "032H20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	167.12	5.16	0.30	0.08	4.657	0.095	3.56E+12
Fraction 1	222.15	7.19	0.18	0.11	< QL	< QL	7.71E+10
Fraction 2	191.33	5.36	0.22	0.09	< QL	< QL	6.38E+10
Fraction 3	171.71	4.45	0.18	0.08	< QL	< QL	7.49E+10
Fraction 4	154.32	3.36	0.23	0.06	0.077	0.068	1.02E+11

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 5	138.56	2.44	0.21	0.04	0.231	0.025	1.88E+11
Fraction 6	138.80	4.09	0.18	0.08	0.483	0.010	3.31E+11
Fraction 7	156.52	2.24	0.18	0.05	0.720	0.033	4.66E+11
Fraction 8	177.30	3.98	0.17	0.08	0.794	0.027	3.89E+11
Fraction 9	180.55	5.55	0.20	0.09	0.279	0.040	1.09E+11
Fraction 10	233.93	10.70	0.30	0.09	0.287	0.027	1.28E+11

BB. Sample No. E-28 (PN 50108/50140 / Moderna Lot No. 7015922012 / Sample Lot No. MV20028A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV20028A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.281	39.653	11.788	2.277	0.080	0.095	0.060	0.003	0.174	0.240	0.511	0.151
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	53.395	34.314	10.249	2.042	0.246	0.195	0.055	0.025	0.460	0.569	0.536	1.213
Fraction 5	52.712	34.499	10.494	2.296	0.256	0.222	0.073	0.021	0.486	0.643	0.696	0.932
Fraction 6	51.098	35.516	10.921	2.464	0.261	0.280	0.108	0.008	0.510	0.789	0.992	0.339
Fraction 7	48.675	37.160	11.615	2.550	0.130	0.191	0.092	0.023	0.267	0.514	0.796	0.911
Fraction 8	44.121	40.673	12.598	2.607	0.274	0.380	0.146	0.029	0.620	0.933	1.156	1.124
Fraction 9	41.657	42.967	12.794	2.582	0.124	0.105	0.074	0.014	0.298	0.245	0.578	0.537
Fraction 10	41.015	42.715	13.851	2.420	0.117	0.080	0.083	0.016	0.286	0.188	0.596	0.679

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV20028A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	142.31	2.23	0.26	0.07	2.084	0.060	1.28E+12
Fraction 1	173.75	6.96	0.21	0.07	< QL	< QL	3.91E+10
Fraction 2	167.79	4.23	0.24	0.08	< QL	< QL	3.94E+10
Fraction 3	149.63	4.95	0.21	0.04	< QL	< QL	3.50E+10
Fraction 4	122.56	1.87	0.25	0.05	< QL	< QL	3.27E+10
Fraction 5	91.10	1.28	0.20	0.09	0.110	0.007	3.33E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 6	94.30	2.79	0.22	0.07	0.199	0.010	6.64E+10
Fraction 7	115.44	3.29	0.23	0.05	0.303	0.053	1.59E+11
Fraction 8	146.49	4.26	0.13	0.06	0.920	0.026	4.91E+11
Fraction 9	166.74	3.55	0.14	0.08	0.801	0.019	4.34E+11
Fraction 10	180.87	4.24	0.20	0.04	0.515	0.003	1.97E+11

CC. Sample No. F-29 (PN 50099 / Moderna Lot No. 7006822139 / Sample Lot No. 000372A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "000372A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.153	39.734	11.620	1.493	0.371	0.355	0.173	0.011	0.787	0.894	1.491	0.721
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.812	35.863	10.958	1.368	0.325	0.349	0.028	0.005	0.628	0.973	0.257	0.337
Fraction 5	51.478	36.133	10.816	1.573	0.304	0.215	0.084	0.006	0.590	0.596	0.777	0.384
Fraction 6	50.457	36.537	11.264	1.742	0.300	0.351	0.059	0.009	0.594	0.961	0.528	0.491
Fraction 7	46.981	39.174	12.123	1.723	0.156	0.133	0.034	0.010	0.332	0.339	0.282	0.577
Fraction 8	44.201	41.192	12.970	1.637	0.278	0.271	0.098	0.016	0.630	0.658	0.753	0.953
Fraction 9	43.784	41.288	13.321	1.607	0.121	0.129	0.089	0.011	0.277	0.313	0.669	0.692
Fraction 10	44.563	41.337	12.966	1.135	0.164	0.183	0.060	0.008	0.367	0.444	0.463	0.665

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "000372A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	159.74	4.63	0.28	0.08	4.007	0.030	9.91E+11
Fraction 1	199.10	7.12	0.31	0.12	< QL	< QL	1.42E+10
Fraction 2	195.73	8.46	0.28	0.07	< QL	< QL	2.12E+10
Fraction 3	171.80	5.31	0.32	0.07	< QL	< QL	1.65E+10
Fraction 4	127.41	3.12	0.22	0.08	0.080	0.022	2.58E+10
Fraction 5	116.12	2.72	0.24	0.07	0.178	0.010	3.44E+10
Fraction 6	114.90	1.92	0.19	0.06	0.479	0.014	7.17E+10
Fraction 7	133.89	2.26	0.19	0.05	0.949	0.024	6.90E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 8	172.37	3.32	0.23	0.07	0.759	0.017	5.74E+10
Fraction 9	194.92	5.50	0.21	0.06	0.325	0.022	5.37E+10
Fraction 10	233.74	10.64	0.29	0.09	0.330	0.013	3.74E+10

DD. Sample No. F-30 (PN 50092 / Moderna Lot No. 7009623003 / Sample Lot No. 016B23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "016B23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.374	39.006	11.425	2.196	0.476	0.497	0.105	0.011	1.004	1.273	0.923	0.493
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	53.487	34.765	9.998	1.749	0.217	0.226	0.091	0.012	0.407	0.650	0.910	0.673
Fraction 5	52.474	35.197	10.319	2.010	0.238	0.347	0.151	0.014	0.453	0.985	1.467	0.716
Fraction 6	51.110	36.166	10.529	2.195	0.300	0.315	0.067	0.016	0.587	0.872	0.632	0.735
Fraction 7	48.995	37.190	11.404	2.410	0.257	0.254	0.032	0.027	0.525	0.683	0.285	1.108
Fraction 8	44.928	40.084	12.466	2.522	0.329	0.384	0.065	0.020	0.733	0.957	0.521	0.810
Fraction 9	42.060	41.647	13.759	2.533	0.441	0.387	0.062	0.020	1.049	0.928	0.449	0.780
Fraction 10	41.885	41.595	14.127	2.393	0.434	0.530	0.244	0.019	1.036	1.274	1.724	0.789

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "016B23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	140.16	5.59	0.21	0.12	2.106	0.082	6.65E+11
Fraction 1	176.28	4.25	0.15	0.07	< QL	< QL	1.80E+10
Fraction 2	162.47	6.21	0.19	0.07	< QL	< QL	1.81E+10
Fraction 3	143.25	4.56	0.21	0.05	< QL	< QL	2.54E+10
Fraction 4	132.89	3.37	0.19	0.07	0.092	0.020	3.14E+10
Fraction 5	117.63	1.67	0.18	0.05	0.160	0.032	4.95E+10
Fraction 6	118.21	1.80	0.20	0.05	0.385	0.006	1.08E+11
Fraction 7	124.66	3.14	0.15	0.03	0.825	0.011	1.33E+11
Fraction 8	146.76	3.62	0.14	0.08	1.008	0.025	1.69E+11

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 9	168.49	5.78	0.20	0.08	0.401	0.030	5.43E+10
Fraction 10	168.19	4.65	0.21	0.05	0.205	0.031	3.86E+10

EE. Sample No. F-31 (PN 50186 / Moderna Lot No. 7029123015 / Sample Lot No. 3030585)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "3030585".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.372	38.657	11.621	2.350	0.111	0.106	0.026	0.006	0.234	0.274	0.223	0.268
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	54.038	33.943	10.038	1.981	0.184	0.145	0.045	0.008	0.341	0.428	0.449	0.379
Fraction 5	53.354	34.336	10.110	2.199	0.059	0.061	0.005	0.004	0.110	0.177	0.046	0.188
Fraction 6	51.918	35.090	10.519	2.473	0.109	0.124	0.017	0.006	0.211	0.354	0.158	0.257
Fraction 7	48.813	37.104	11.421	2.662	0.135	0.072	0.083	0.005	0.276	0.193	0.725	0.187
Fraction 8	45.217	39.511	12.613	2.658	0.073	0.150	0.073	0.015	0.161	0.379	0.583	0.563
Fraction 9	43.450	40.778	13.135	2.638	0.063	0.058	0.050	0.011	0.145	0.143	0.379	0.414
Fraction 10	43.842	40.660	13.159	2.338	0.104	0.140	0.050	0.007	0.236	0.345	0.380	0.313

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "3030585".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	128.89	3.58	0.19	0.07	2.047	0.027	5.61E+11
Fraction 1	159.21	5.56	0.15	0.10	< QL	< QL	3.04E+10
Fraction 2	144.85	3.49	0.16	0.09	< QL	< QL	2.14E+10
Fraction 3	130.35	2.56	0.17	0.08	< QL	< QL	1.66E+10
Fraction 4	114.70	2.29	0.17	0.07	< QL	< QL	1.71E+10
Fraction 5	99.86	1.73	0.19	0.06	< QL	< QL	2.48E+10
Fraction 6	92.47	1.88	0.16	0.06	0.162	0.057	4.07E+10
Fraction 7	112.39	2.67	0.20	0.05	0.561	0.015	8.69E+10
Fraction 8	139.19	2.35	0.20	0.05	0.925	0.024	1.65E+11
Fraction 9	166.67	4.52	0.18	0.09	0.615	0.028	1.14E+11

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 10	177.21	5.01	0.17	0.08	0.495	0.034	7.51E+10

FF. Sample No. F-32 (PN 50186 / Moderna Lot No. 7029123011 / Sample Lot No. 3030592)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "3030592".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.542	38.625	11.531	2.301	0.207	0.297	0.077	0.019	0.436	0.768	0.670	0.836
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.586	35.090	10.272	2.052	0.409	0.438	0.085	0.028	0.777	1.249	0.828	1.357
Fraction 5	52.454	35.148	10.202	2.196	0.253	0.198	0.070	0.012	0.482	0.565	0.690	0.542
Fraction 6	51.279	35.629	10.605	2.487	0.164	0.122	0.044	0.014	0.319	0.341	0.412	0.580
Fraction 7	49.415	36.549	11.335	2.701	0.364	0.341	0.077	0.026	0.737	0.932	0.677	0.959
Fraction 8	45.746	39.013	12.517	2.723	0.149	0.138	0.062	0.013	0.326	0.353	0.496	0.488
Fraction 9	43.538	40.432	13.339	2.691	0.065	0.160	0.112	0.016	0.149	0.395	0.841	0.605
Fraction 10	43.909	40.647	13.144	2.300	0.264	0.253	0.154	0.013	0.602	0.624	1.173	0.577

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "3030592".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	131.66	3.54	0.20	0.07	2.121	0.036	9.12E+11
Fraction 1	162.84	5.62	0.17	0.06	< QL	< QL	5.03E+10
Fraction 2	156.33	6.14	0.16	0.04	< QL	< QL	4.89E+10
Fraction 3	142.21	4.28	0.16	0.07	< QL	< QL	4.80E+10
Fraction 4	114.00	1.91	0.15	0.05	0.074	0.013	3.52E+10
Fraction 5	104.44	2.24	0.18	0.07	0.118	0.021	5.18E+10
Fraction 6	100.69	1.98	0.18	0.05	0.265	0.011	9.54E+10
Fraction 7	112.23	2.01	0.21	0.05	0.557	0.016	1.73E+11
Fraction 8	135.12	2.11	0.19	0.04	0.940	0.030	3.26E+11
Fraction 9	164.42	4.53	0.18	0.06	0.662	0.025	2.26E+11
Fraction 10	178.32	5.59	0.14	0.05	0.483	0.033	1.57E+11

GG. Sample No. F-33 (PN 50111/50092 / Moderna Lot No. 7010722069 / Sample Lot No. 049F22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "049F22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.411	38.855	11.462	2.271	0.148	0.123	0.030	0.008	0.313	0.316	0.263	0.354
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.791	35.242	10.017	1.950	0.100	0.059	0.072	0.007	0.190	0.167	0.717	0.352
Fraction 5	51.806	35.554	10.501	2.140	0.312	0.268	0.111	0.008	0.601	0.755	1.053	0.385
Fraction 6	50.354	36.608	10.742	2.296	0.142	0.110	0.048	0.019	0.282	0.301	0.443	0.841
Fraction 7	47.376	38.453	11.613	2.558	0.101	0.078	0.029	0.005	0.214	0.204	0.253	0.214
Fraction 8	45.813	39.341	12.260	2.586	0.220	0.216	0.082	0.026	0.480	0.550	0.670	0.999
Fraction 9	43.703	40.484	13.230	2.583	0.300	0.127	0.195	0.021	0.687	0.314	1.478	0.819
Fraction 10	43.008	41.155	13.469	2.368	0.199	0.223	0.034	0.007	0.463	0.543	0.251	0.277

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "049F22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	127.65	2.44	0.23	0.05	2.165	0.007	1.11E+12
Fraction 1	172.70	6.04	0.16	0.07	< QL	< QL	3.67E+10
Fraction 2	164.82	6.42	0.27	0.07	< QL	< QL	3.56E+10
Fraction 3	150.80	4.53	0.19	0.09	< QL	< QL	4.09E+10
Fraction 4	111.86	1.49	0.17	0.04	0.079	0.016	5.09E+10
Fraction 5	106.17	2.54	0.15	0.05	0.183	0.029	1.09E+11
Fraction 6	108.24	3.17	0.16	0.05	0.376	0.034	1.35E+11
Fraction 7	116.98	2.04	0.20	0.05	0.910	0.017	3.08E+11
Fraction 8	127.60	2.02	0.17	0.06	0.891	0.028	2.90E+11
Fraction 9	160.19	4.27	0.21	0.07	0.465	0.014	1.63E+11
Fraction 10	169.76	4.34	0.24	0.08	0.329	0.007	9.59E+10

HH. Sample No. F-34 (PN 50092/50141 / Moderna Lot No. 7015222071 / Sample Lot No. 044H22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "044H22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.129	39.135	11.421	2.315	0.162	0.184	0.089	0.011	0.343	0.469	0.776	0.482
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	54.375	33.790	10.100	1.735	0.148	0.089	0.067	0.009	0.272	0.263	0.658	0.547
Fraction 5	52.645	34.997	10.185	2.173	0.055	0.049	0.022	0.012	0.105	0.139	0.211	0.574
Fraction 6	51.406	35.793	10.471	2.331	0.275	0.308	0.074	0.015	0.535	0.861	0.704	0.653
Fraction 7	48.442	37.782	11.246	2.529	0.235	0.113	0.152	0.033	0.484	0.298	1.355	1.297
Fraction 8	45.187	40.049	12.200	2.563	0.249	0.232	0.062	0.020	0.551	0.578	0.509	0.762
Fraction 9	42.837	41.425	13.118	2.620	0.179	0.198	0.113	0.015	0.418	0.477	0.862	0.569
Fraction 10	43.175	41.085	13.306	2.435	0.101	0.123	0.027	0.017	0.233	0.299	0.200	0.701

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "044H22A".

Sample No.	DLS				UV		NTA
	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	129.53	3.21	0.19	0.07	2.157	0.035	5.64E+11
Fraction 1	167.14	4.21	0.11	0.07	< QL	< QL	4.63E+10
Fraction 2	143.96	4.51	0.14	0.09	< QL	< QL	3.02E+10
Fraction 3	138.47	5.08	0.19	0.06	< QL	< QL	3.12E+10
Fraction 4	127.84	4.23	0.24	0.06	0.084	0.012	4.15E+10
Fraction 5	99.68	2.52	0.13	0.05	0.150	0.006	5.56E+10
Fraction 6	99.29	1.27	0.18	0.04	0.256	0.030	9.22E+10
Fraction 7	109.52	2.38	0.16	0.05	0.711	0.012	2.35E+11
Fraction 8	129.14	2.79	0.16	0.07	1.183	0.027	3.64E+11
Fraction 9	159.81	4.25	0.19	0.09	0.646	0.024	2.35E+11
Fraction 10	161.44	4.14	0.24	0.09	0.453	0.016	1.41E+11

II. Sample No. G-35 (PN 50108/50115 / Moderna Lot No. 7010722092 / Sample Lot No. 200028A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "200028A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.387	38.766	11.423	2.424	0.291	0.306	0.041	0.013	0.614	0.788	0.363	0.533
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	53.832	34.130	9.872	2.166	0.120	0.144	0.064	0.010	0.223	0.423	0.648	0.463
Fraction 6	52.263	35.158	10.140	2.438	0.144	0.159	0.056	0.021	0.276	0.451	0.554	0.870
Fraction 7	49.938	36.521	10.871	2.671	0.138	0.115	0.036	0.008	0.276	0.315	0.332	0.285
Fraction 8	45.767	39.407	12.101	2.725	0.141	0.250	0.117	0.008	0.308	0.634	0.964	0.290
Fraction 9	43.163	40.939	13.170	2.728	0.117	0.086	0.045	0.006	0.272	0.209	0.344	0.225
Fraction 10	43.314	41.156	13.114	2.416	0.138	0.151	0.089	0.011	0.318	0.367	0.681	0.460

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "200028A".

Sample No.	DLS				UV		NTA
	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	129.08	3.13	0.23	0.06	2.088	0.018	5.61E+11
Fraction 1	159.60	4.29	0.14	0.07	< QL	< QL	3.37E+10
Fraction 2	163.97	3.38	0.12	0.04	< QL	< QL	3.53E+10
Fraction 3	140.52	2.70	0.18	0.06	< QL	< QL	1.58E+10
Fraction 4	114.26	2.74	0.19	0.05	< QL	< QL	1.58E+10
Fraction 5	105.06	3.19	0.21	0.06	0.116	0.013	2.70E+10
Fraction 6	95.07	2.99	0.20	0.06	0.219	0.026	3.27E+10
Fraction 7	98.68	2.64	0.17	0.06	0.391	0.040	5.31E+10
Fraction 8	121.41	2.04	0.19	0.08	0.903	0.021	1.30E+11
Fraction 9	154.36	4.11	0.14	0.05	0.789	0.019	1.62E+11
Fraction 10	187.78	5.36	0.19	0.05	0.667	0.030	1.23E+11

JJ. Sample No. G-36 (PN 50108/50140 / Moderna Lot No. 7015322077 / Sample Lot No. 400038A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "400038A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.417	38.877	11.387	2.318	0.362	0.320	0.048	0.035	0.763	0.822	0.421	1.497
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.862	34.928	10.101	2.109	0.592	0.492	0.094	0.014	1.120	1.408	0.932	0.663
Fraction 5	52.654	34.993	10.133	2.219	0.359	0.479	0.125	0.008	0.681	1.369	1.235	0.355

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 6	51.517	35.697	10.419	2.368	0.222	0.270	0.089	0.015	0.430	0.757	0.855	0.651
Fraction 7	49.448	37.106	10.951	2.495	0.180	0.083	0.131	0.013	0.365	0.224	1.198	0.509
Fraction 8	46.530	39.135	11.796	2.538	0.735	0.675	0.084	0.031	1.580	1.725	0.716	1.238
Fraction 9	43.632	40.630	13.188	2.550	0.264	0.367	0.171	0.024	0.605	0.903	1.297	0.949
Fraction 10	43.890	40.663	13.224	2.223	0.216	0.163	0.197	0.030	0.493	0.401	1.490	1.360

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "400038A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	127.83	4.09	0.20	0.06	2.112	0.038	5.36E+11
Fraction 1	169.29	5.94	0.14	0.09	< QL	< QL	2.59E+10
Fraction 2	144.30	4.93	0.20	0.06	< QL	< QL	1.95E+10
Fraction 3	123.46	2.41	0.22	0.07	< QL	< QL	1.46E+10
Fraction 4	107.23	2.62	0.21	0.08	< QL	< QL	1.49E+10
Fraction 5	102.10	1.89	0.24	0.09	0.150	0.023	3.08E+10
Fraction 6	104.35	1.85	0.17	0.06	0.273	0.027	7.18E+10
Fraction 7	110.11	2.70	0.19	0.06	0.587	0.048	1.40E+11
Fraction 8	125.95	3.36	0.20	0.06	0.939	0.039	2.42E+11
Fraction 9	157.79	3.49	0.21	0.06	0.707	0.042	1.79E+11
Fraction 10	189.02	6.95	0.17	0.06	0.457	0.029	1.15E+11

KK. Sample No. G-37 (PN 50075 / Moderna Lot No. 7006822286 / Sample Lot No. 019D22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "019D22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.709	39.670	11.212	1.409	0.185	0.206	0.056	0.006	0.388	0.518	0.501	0.401
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.991	36.644	11.120	1.244	0.194	0.198	0.016	0.011	0.380	0.541	0.144	0.862
Fraction 5	51.073	36.578	10.909	1.440	0.204	0.160	0.106	0.014	0.400	0.438	0.967	0.988
Fraction 6	50.321	36.996	11.101	1.581	0.208	0.177	0.069	0.016	0.413	0.478	0.626	0.993
Fraction 7	48.207	38.719	11.506	1.568	0.263	0.240	0.058	0.014	0.546	0.620	0.503	0.866
Fraction 8	45.522	40.978	12.055	1.446	0.139	0.136	0.058	0.010	0.306	0.333	0.485	0.658

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Fraction 9	43.877	41.969	12.769	1.385	0.089	0.157	0.080	0.013	0.204	0.375	0.627	0.943
Fraction 10	43.764	41.709	13.423	1.104	0.149	0.100	0.116	0.012	0.341	0.239	0.866	1.046

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "019D22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	179.45	5.33	0.21	0.04	4.634	0.070	2.31E+12
Fraction 1	213.01	9.99	0.25	0.07	< QL	< QL	4.72E+10
Fraction 2	187.27	4.42	0.26	0.12	< QL	< QL	3.47E+10
Fraction 3	162.83	4.03	0.26	0.09	< QL	< QL	4.76E+10
Fraction 4	137.62	4.54	0.23	0.07	0.083	0.032	5.10E+10
Fraction 5	128.10	2.77	0.22	0.06	0.125	0.045	8.75E+10
Fraction 6	133.01	2.78	0.23	0.05	0.369	0.017	1.39E+11
Fraction 7	152.76	4.55	0.16	0.10	0.888	0.043	3.31E+11
Fraction 8	186.85	6.02	0.15	0.07	1.190	0.029	4.82E+11
Fraction 9	219.01	7.96	0.17	0.11	0.485	0.024	1.78E+11
Fraction 10	257.45	8.18	0.30	0.07	0.322	0.014	9.79E+10

LL. Sample No. G-38 (PN 50075 / Moderna Lot No. 7006822285 / Sample Lot No. 18D22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "018D22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.085	39.354	11.164	1.396	0.187	0.278	0.123	0.006	0.390	0.706	1.102	0.449
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 5	52.245	35.236	11.098	1.420	0.135	0.133	0.025	0.010	0.259	0.378	0.228	0.718
Fraction 6	51.276	35.944	11.222	1.559	0.193	0.123	0.137	0.009	0.376	0.341	1.222	0.573
Fraction 7	48.651	38.139	11.683	1.526	0.229	0.224	0.062	0.004	0.471	0.589	0.529	0.242
Fraction 8	45.572	40.986	12.065	1.377	0.295	0.349	0.068	0.005	0.647	0.851	0.560	0.385
Fraction 9	43.727	42.403	12.504	1.366	0.122	0.166	0.091	0.010	0.279	0.391	0.731	0.756
Fraction 10	44.094	41.658	13.202	1.045	0.156	0.175	0.046	0.007	0.353	0.419	0.348	0.676

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "018D22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	181.08	5.50	0.25	0.08	4.341	0.006	2.24E+12
Fraction 1	194.96	10.31	0.31	0.08	< QL	< QL	3.43E+10
Fraction 2	175.38	6.72	0.33	0.09	< QL	< QL	2.64E+10
Fraction 3	154.47	4.96	0.29	0.07	< QL	< QL	3.11E+10
Fraction 4	123.92	4.73	0.27	0.07	< QL	< QL	3.58E+10
Fraction 5	114.91	0.85	0.24	0.07	0.073	0.005	5.35E+10
Fraction 6	120.91	3.62	0.22	0.07	0.269	0.015	1.25E+11
Fraction 7	148.04	3.86	0.17	0.06	0.819	0.011	2.78E+11
Fraction 8	188.92	4.88	0.12	0.07	1.231	0.036	5.98E+11
Fraction 9	205.25	8.51	0.19	0.12	0.448	0.004	2.35E+11
Fraction 10	249.09	8.55	0.34	0.12	0.285	0.021	1.06E+11

MM. Sample No. H-39 (PN 50073 / Moderna Lot No. 7006520006 / Sample Lot No. 025J20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "025J20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.809	38.970	10.830	1.392	0.204	0.232	0.058	0.012	0.417	0.594	0.535	0.851
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.872	35.160	10.716	1.252	0.269	0.269	0.067	0.014	0.509	0.764	0.622	1.104
Fraction 5	53.647	34.193	10.707	1.452	0.149	0.052	0.120	0.009	0.278	0.153	1.124	0.632
Fraction 6	52.975	34.434	11.017	1.574	0.101	0.143	0.046	0.015	0.190	0.415	0.419	0.925
Fraction 7	49.764	36.905	11.775	1.556	0.234	0.230	0.063	0.011	0.470	0.623	0.531	0.678
Fraction 8	47.030	39.342	12.131	1.497	0.177	0.165	0.138	0.014	0.377	0.419	1.136	0.946
Fraction 9	45.154	40.655	12.655	1.536	0.284	0.296	0.097	0.002	0.628	0.728	0.768	0.159
Fraction 10	45.383	41.755	11.904	0.957	0.178	0.240	0.106	0.011	0.392	0.574	0.891	1.193

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "062G20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	183.27	4.44	0.32	0.10	4.396	0.023	1.00E+12
Fraction 1	206.72	11.38	0.22	0.08	< QL	< QL	3.24E+10
Fraction 2	194.35	3.83	0.29	0.06	< QL	< QL	2.10E+10
Fraction 3	176.97	4.85	0.27	0.05	< QL	< QL	2.43E+10
Fraction 4	136.32	4.32	0.32	0.09	0.076	0.011	2.33E+10
Fraction 5	122.79	2.91	0.25	0.06	0.128	0.032	2.72E+10
Fraction 6	119.00	2.93	0.29	0.05	0.232	0.011	5.22E+10
Fraction 7	152.90	3.64	0.14	0.06	0.609	0.077	1.73E+11
Fraction 8	174.08	4.44	0.09	0.08	1.078	0.029	2.32E+11
Fraction 9	196.96	3.67	0.15	0.08	0.648	0.033	1.09E+11
Fraction 10	270.29	12.62	0.22	0.06	0.456	0.006	8.67E+10

NN. Sample No. H-40 (PN 50068 / Moderna Lot No. 7006520002 / Sample Lot No. 062G20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "062G20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.060	39.129	11.334	1.477	0.526	0.497	0.068	0.007	1.095	1.270	0.599	0.455
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.617	37.471	10.762	1.150	0.278	0.309	0.062	0.008	0.550	0.826	0.576	0.660
Fraction 5	51.883	35.831	10.872	1.414	0.290	0.220	0.148	0.006	0.558	0.615	1.359	0.443
Fraction 6	51.750	35.546	11.089	1.615	0.165	0.060	0.153	0.010	0.320	0.169	1.382	0.612
Fraction 7	49.233	37.459	11.652	1.656	0.225	0.293	0.140	0.004	0.457	0.781	1.202	0.267
Fraction 8	46.305	39.894	12.153	1.648	0.223	0.224	0.066	0.016	0.482	0.561	0.542	0.989
Fraction 9	45.476	40.401	12.393	1.729	0.148	0.098	0.111	0.003	0.326	0.244	0.895	0.167
Fraction 10	40.772	43.729	14.153	1.346	0.227	0.134	0.114	0.006	0.556	0.306	0.806	0.420

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "062G20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	172.94	3.75	0.25	0.11	4.479	0.059	9.44E+11
Fraction 1	223.45	9.32	0.19	0.06	0.078	0.010	3.41E+10
Fraction 2	204.68	5.18	0.19	0.06	< QL	< QL	2.00E+10
Fraction 3	193.15	8.29	0.21	0.08	< QL	< QL	3.27E+10
Fraction 4	163.37	6.01	0.25	0.08	0.120	0.010	3.91E+10
Fraction 5	134.78	3.46	0.25	0.06	0.193	0.010	5.79E+10
Fraction 6	128.90	1.93	0.21	0.05	0.355	0.036	6.49E+10
Fraction 7	141.38	1.73	0.24	0.06	0.574	0.054	7.62E+10
Fraction 8	168.19	3.72	0.17	0.04	0.799	0.006	1.29E+11
Fraction 9	174.73	4.78	0.14	0.05	0.454	0.020	8.09E+10
Fraction 10	238.88	6.78	0.22	0.04	0.286	0.023	4.69E+10

OO. Sample No. H-41 (PN 50089 / Moderna Lot No. 7007521015 / Sample Lot No. 940914)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "940914".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.615	39.284	11.760	1.341	0.137	0.177	0.038	0.006	0.288	0.451	0.322	0.466
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.040	36.211	11.579	1.170	0.167	0.132	0.043	0.004	0.327	0.363	0.372	0.318
Fraction 5	52.436	34.715	11.408	1.441	0.086	0.085	0.036	0.006	0.164	0.244	0.320	0.424
Fraction 6	52.298	34.682	11.430	1.591	0.188	0.160	0.030	0.014	0.359	0.460	0.262	0.903
Fraction 7	49.355	37.061	11.984	1.601	0.103	0.106	0.027	0.005	0.209	0.286	0.222	0.341
Fraction 8	45.819	40.461	12.237	1.484	0.066	0.066	0.080	0.008	0.144	0.162	0.653	0.535
Fraction 9	43.610	42.266	12.681	1.443	0.195	0.213	0.058	0.005	0.447	0.504	0.458	0.316
Fraction 10	44.561	41.560	12.889	0.990	0.176	0.178	0.020	0.004	0.395	0.429	0.153	0.438

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "940914".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	186.91	5.97	0.28	0.08	4.028	0.174	9.25E+11
Fraction 1	181.67	4.38	0.19	0.09	< QL	< QL	3.35E+10
Fraction 2	183.08	5.84	0.27	0.08	< QL	< QL	3.15E+10
Fraction 3	161.72	4.10	0.23	0.06	< QL	< QL	2.97E+10
Fraction 4	125.42	2.05	0.30	0.04	< QL	< QL	2.64E+10
Fraction 5	117.10	2.36	0.28	0.03	0.084	0.023	3.24E+10
Fraction 6	119.60	2.90	0.32	0.04	0.192	0.019	4.47E+10
Fraction 7	141.33	3.56	0.23	0.11	0.548	0.040	8.08E+10
Fraction 8	171.11	5.98	0.18	0.07	0.891	0.033	1.66E+11
Fraction 9	202.72	7.15	0.16	0.11	0.468	0.045	9.34E+10
Fraction 10	276.95	6.79	0.34	0.15	0.542	0.007	1.09E+11

PP. Sample No. H-42 (PN 50099 / Moderna Lot No. 7006822145 / Sample Lot No. 000383A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "000383A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.996	38.971	11.491	1.543	0.337	0.360	0.101	0.019	0.703	0.924	0.877	1.204
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.881	35.738	11.018	1.362	0.245	0.227	0.029	0.007	0.473	0.636	0.263	0.550
Fraction 5	52.506	35.070	10.789	1.634	0.232	0.238	0.028	0.008	0.442	0.680	0.259	0.513
Fraction 6	51.746	35.502	10.989	1.763	0.153	0.150	0.119	0.008	0.295	0.422	1.078	0.431
Fraction 7	48.974	37.442	11.755	1.829	0.174	0.256	0.113	0.026	0.356	0.683	0.958	1.396
Fraction 8	45.578	40.121	12.623	1.678	0.197	0.214	0.123	0.010	0.433	0.534	0.973	0.589
Fraction 9	44.173	41.074	13.138	1.616	0.145	0.256	0.126	0.012	0.329	0.624	0.958	0.725
Fraction 10	45.376	40.661	12.781	1.182	0.096	0.197	0.142	0.005	0.211	0.485	1.108	0.435

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "000383A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	166.16	7.25	0.26	0.09	4.656	0.005	2.14E+12
Fraction 1	190.72	6.10	0.26	0.08	< QL	< QL	7.22E+10
Fraction 2	170.50	3.57	0.23	0.07	< QL	< QL	5.38E+10
Fraction 3	136.96	3.45	0.28	0.08	< QL	< QL	4.34E+10
Fraction 4	121.30	3.39	0.31	0.06	< QL	< QL	4.84E+10
Fraction 5	107.82	1.98	0.18	0.08	0.195	0.010	7.90E+10
Fraction 6	107.22	2.85	0.24	0.04	0.415	0.043	1.27E+11
Fraction 7	126.45	3.17	0.23	0.05	0.832	0.034	3.02E+11
Fraction 8	167.74	4.82	0.14	0.07	1.004	0.067	4.17E+11
Fraction 9	213.54	5.51	0.10	0.09	0.603	0.013	2.35E+11
Fraction 10	252.99	7.15	0.30	0.07	0.553	0.099	1.74E+11

QQ. Sample No. H-43 (PN 50073 / Moderna Lot No. 7006520005 / Sample Lot No. 011J20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "011J20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.240	39.106	11.306	1.349	0.105	0.253	0.189	0.005	0.217	0.646	1.675	0.376
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.858	34.630	11.233	1.279	0.339	0.360	0.053	0.007	0.641	1.039	0.471	0.563
Fraction 5	52.883	34.734	10.991	1.392	0.188	0.155	0.053	0.008	0.355	0.445	0.480	0.594
Fraction 6	52.375	34.923	11.192	1.510	0.134	0.100	0.058	0.002	0.256	0.287	0.518	0.153
Fraction 7	49.598	37.074	11.785	1.543	0.215	0.254	0.077	0.005	0.433	0.684	0.652	0.306
Fraction 8	46.126	39.882	12.420	1.573	0.145	0.142	0.073	0.007	0.315	0.356	0.584	0.426
Fraction 9	45.185	40.289	12.936	1.590	0.151	0.155	0.171	0.015	0.333	0.385	1.320	0.914
Fraction 10	45.434	41.825	11.804	0.938	0.149	0.190	0.058	0.009	0.329	0.455	0.496	0.996

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "011J20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	179.89	6.61	0.34	0.06	5.091	0.216	2.60E+12
Fraction 1	186.77	4.07	0.25	0.07	< QL	< QL	5.04E+10
Fraction 2	178.68	6.02	0.22	0.08	< QL	< QL	4.36E+10
Fraction 3	146.97	3.75	0.28	0.04	< QL	< QL	4.04E+10
Fraction 4	130.49	2.91	0.22	0.06	0.107	0.017	2.04E+10
Fraction 5	125.65	4.70	0.24	0.05	0.161	0.024	8.06E+10
Fraction 6	127.68	3.60	0.25	0.06	0.371	0.028	2.03E+11
Fraction 7	149.15	4.30	0.17	0.08	0.790	0.007	4.95E+11
Fraction 8	165.32	4.37	0.15	0.07	0.790	0.017	4.27E+11
Fraction 9	176.50	4.00	0.18	0.06	0.277	0.067	1.52E+11
Fraction 10	269.94	15.11	0.30	0.14	0.371	0.015	1.62E+11

RR. Sample No. H-44 (PN 50089 / Moderna Lot No. 7006821486 / Sample Lot No. 091K21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "091K21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.763	39.561	11.279	1.396	0.215	0.197	0.087	0.008	0.450	0.499	0.771	0.569
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.589	35.917	11.228	1.266	0.195	0.258	0.099	0.010	0.378	0.719	0.879	0.758
Fraction 5	52.222	35.189	11.091	1.498	0.321	0.307	0.052	0.013	0.614	0.873	0.465	0.866
Fraction 6	51.548	35.520	11.301	1.631	0.224	0.237	0.056	0.004	0.435	0.668	0.497	0.238
Fraction 7	48.709	37.708	11.944	1.639	0.100	0.132	0.063	0.005	0.205	0.349	0.530	0.289
Fraction 8	45.135	40.933	12.427	1.506	0.259	0.217	0.050	0.007	0.574	0.531	0.401	0.459
Fraction 9	43.727	42.003	12.808	1.462	0.196	0.262	0.068	0.013	0.448	0.623	0.530	0.912
Fraction 10	44.582	41.610	12.742	1.065	0.115	0.133	0.052	0.007	0.257	0.321	0.409	0.659

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "091K21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	172.43	6.63	0.27	0.08	4.203	0.097	2.15E+12
Fraction 1	210.91	6.18	0.35	0.06	0.115	0.027	6.92E+10
Fraction 2	171.76	6.46	0.32	0.10	< QL	< QL	4.90E+10
Fraction 3	153.26	5.90	0.35	0.07	< QL	< QL	5.28E+10
Fraction 4	125.28	5.41	0.27	0.09	0.096	0.001	5.35E+10
Fraction 5	107.73	2.00	0.26	0.09	0.168	0.009	7.76E+10
Fraction 6	112.62	1.79	0.22	0.06	0.350	0.010	1.58E+11
Fraction 7	137.12	3.75	0.20	0.04	0.707	0.037	3.18E+11
Fraction 8	167.06	3.63	0.20	0.06	0.954	0.067	4.67E+11
Fraction 9	209.43	9.84	0.20	0.09	0.506	0.058	2.18E+11
Fraction 10	249.96	8.03	0.31	0.06	0.468	0.031	1.72E+11

SS. Sample No. I-45 (PN 50099 / Moderna Lot No. 7006822119 / Sample Lot No. 000371A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "000371A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.327	39.438	11.746	1.489	0.262	0.213	0.049	0.008	0.554	0.541	0.414	0.543
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.158	36.485	11.099	1.258	0.159	0.217	0.107	0.008	0.310	0.595	0.960	0.624
Fraction 5	52.254	35.404	10.819	1.524	0.288	0.266	0.071	0.003	0.552	0.752	0.660	0.194
Fraction 6	51.303	35.801	11.203	1.692	0.228	0.234	0.050	0.012	0.445	0.654	0.451	0.701
Fraction 7	48.483	37.888	11.985	1.643	0.478	0.506	0.084	0.013	0.985	1.336	0.702	0.793
Fraction 8	45.725	40.078	12.634	1.563	0.314	0.283	0.104	0.015	0.688	0.706	0.824	0.957
Fraction 9	44.425	41.255	12.845	1.474	0.337	0.329	0.027	0.014	0.758	0.797	0.212	0.944
Fraction 10	41.405	42.591	14.706	1.298	0.200	0.239	0.083	0.012	0.483	0.561	0.567	0.945

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "000371A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	160.40	5.97	0.27	0.07	4.171	0.013	8.08E+11
Fraction 1	206.72	11.38	0.22	0.08	< QL	< QL	4.18E+10
Fraction 2	164.32	3.66	0.26	0.07	< QL	< QL	2.90E+10
Fraction 3	156.82	3.98	0.26	0.07	< QL	< QL	2.73E+10
Fraction 4	144.02	3.85	0.30	0.07	0.084	0.029	2.30E+10
Fraction 5	116.69	2.64	0.31	0.05	0.137	0.041	4.16E+10
Fraction 6	113.29	4.11	0.25	0.07	0.333	0.028	7.30E+10
Fraction 7	138.49	1.28	0.26	0.05	0.675	0.018	1.51E+11
Fraction 8	171.55	5.56	0.20	0.05	0.928	0.024	2.01E+11
Fraction 9	212.87	3.42	0.10	0.08	0.528	0.058	9.86E+10
Fraction 10	225.58	9.37	0.18	0.10	0.286	0.062	6.33E+10

TT. Sample No. I-46 (PN 50075 / Moderna Lot No. 7007521033 / Sample Lot No. 940922)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "940922".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.665	39.218	11.731	1.385	0.169	0.271	0.118	0.003	0.355	0.692	1.007	0.216
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.300	37.082	11.447	1.172	0.331	0.393	0.094	0.018	0.658	1.059	0.817	1.533
Fraction 5	51.754	35.416	11.422	1.407	0.253	0.293	0.097	0.010	0.488	0.827	0.848	0.729
Fraction 6	51.594	35.346	11.476	1.584	0.318	0.327	0.058	0.015	0.616	0.925	0.506	0.928
Fraction 7	48.541	37.780	12.053	1.626	0.326	0.411	0.117	0.015	0.673	1.088	0.968	0.919
Fraction 8	45.580	40.404	12.481	1.536	0.225	0.307	0.125	0.020	0.495	0.761	0.999	1.332
Fraction 9	44.977	40.845	12.680	1.498	0.154	0.140	0.057	0.010	0.342	0.343	0.452	0.672
Fraction 10	43.517	41.827	13.592	1.064	0.362	0.408	0.148	0.012	0.832	0.976	1.092	1.123

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "940922".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	175.07	7.85	0.29	0.08	4.151	0.121	7.40E+11
Fraction 1	229.53	10.03	0.31	0.10	< QL	< QL	4.22E+10
Fraction 2	200.18	7.79	0.32	0.11	< QL	< QL	3.37E+10
Fraction 3	200.57	6.55	0.35	0.11	0.079	0.004	3.25E+10
Fraction 4	143.92	3.44	0.28	0.06	< QL	< QL	3.09E+10
Fraction 5	122.82	2.94	0.23	0.05	0.141	0.015	3.17E+10
Fraction 6	120.53	3.22	0.22	0.05	0.324	0.029	6.22E+10
Fraction 7	145.89	3.52	0.15	0.06	0.697	0.023	1.28E+11
Fraction 8	179.04	3.63	0.17	0.05	0.911	0.034	1.07E+11
Fraction 9	195.31	4.17	0.17	0.06	0.417	0.014	8.34E+10
Fraction 10	239.00	6.26	0.44	0.11	0.361	0.035	5.48E+10

UU. Sample No. I-47 (PN 50075 / Moderna Lot No. 7007621110 / Sample Lot No. 001F21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "001F21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.774	39.234	11.619	1.373	0.215	0.230	0.075	0.002	0.449	0.587	0.643	0.176
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.316	36.667	10.944	1.074	0.154	0.125	0.035	0.006	0.300	0.340	0.315	0.593
Fraction 5	51.948	35.360	11.264	1.428	0.188	0.136	0.065	0.004	0.363	0.384	0.573	0.249
Fraction 6	50.535	36.301	11.608	1.556	0.151	0.166	0.027	0.002	0.299	0.456	0.233	0.105
Fraction 7	48.086	38.389	11.986	1.539	0.136	0.203	0.078	0.004	0.282	0.529	0.652	0.229
Fraction 8	45.663	40.407	12.440	1.490	0.192	0.154	0.042	0.002	0.420	0.382	0.341	0.103
Fraction 9	44.493	41.406	12.705	1.396	0.066	0.043	0.038	0.004	0.149	0.104	0.303	0.319
Fraction 10	44.326	41.716	13.009	0.949	0.092	0.116	0.063	0.007	0.207	0.279	0.483	0.742

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "001F21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	177.86	3.62	0.26	0.07	4.255	0.068	8.87E+11
Fraction 1	210.40	12.57	0.34	0.09	< QL	< QL	1.41E+10
Fraction 2	200.11	6.39	0.36	0.07	< QL	< QL	2.03E+10
Fraction 3	169.04	7.01	0.40	0.09	< QL	< QL	3.06E+10
Fraction 4	154.81	2.91	0.37	0.10	0.083	0.015	3.19E+10
Fraction 5	123.10	3.19	0.22	0.06	0.153	0.026	4.74E+10
Fraction 6	135.48	2.21	0.18	0.05	0.483	0.027	9.65E+10
Fraction 7	152.30	4.34	0.18	0.05	0.828	0.018	1.68E+11
Fraction 8	177.85	4.96	0.19	0.08	0.881	0.028	1.70E+11
Fraction 9	204.40	5.92	0.18	0.07	0.302	0.018	6.41E+10
Fraction 10	206.72	11.38	0.22	0.08	0.246	0.002	4.83E+10

VV. Sample No. I-48 (PN 50075 / Moderna Lot No. 7006520026 / Sample Lot No. 029L20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "029L20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.390	38.539	11.544	1.526	0.390	0.349	0.086	0.012	0.805	0.906	0.742	0.791
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.182	35.385	11.026	1.406	0.134	0.194	0.092	0.013	0.257	0.549	0.833	0.941
Fraction 5	53.273	34.211	10.939	1.577	0.282	0.195	0.133	0.021	0.529	0.569	1.214	1.337
Fraction 6	51.545	35.386	11.343	1.726	0.237	0.265	0.029	0.012	0.460	0.749	0.252	0.699
Fraction 7	49.705	37.086	11.602	1.607	0.332	0.267	0.071	0.011	0.667	0.720	0.608	0.706
Fraction 8	46.967	39.101	12.318	1.615	0.389	0.391	0.077	0.008	0.829	1.001	0.628	0.516
Fraction 9	46.336	39.943	12.163	1.558	0.251	0.218	0.079	0.007	0.543	0.545	0.651	0.435
Fraction 10	43.518	41.778	13.395	1.309	0.145	0.189	0.096	0.008	0.333	0.454	0.716	0.618

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "029L20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	178.01	4.72	0.19	0.09	4.268	0.057	2.71E+12
Fraction 1	212.99	8.67	0.30	0.04	0.083	0.024	4.17E+10
Fraction 2	194.42	6.82	0.31	0.11	0.091	0.011	4.93E+10
Fraction 3	168.99	3.48	0.26	0.09	0.112	0.020	4.90E+10
Fraction 4	130.25	3.40	0.26	0.06	0.122	0.001	6.19E+10
Fraction 5	122.25	2.55	0.24	0.06	0.166	0.039	7.40E+10
Fraction 6	136.59	3.69	0.22	0.05	0.422	0.035	1.17E+11
Fraction 7	156.65	2.11	0.16	0.05	0.597	0.052	2.43E+11
Fraction 8	180.72	4.51	0.13	0.05	1.287	0.015	7.17E+11
Fraction 9	197.06	4.63	0.16	0.08	0.583	0.008	3.05E+11
Fraction 10	235.35	10.27	0.26	0.09	0.407	0.009	1.57E+11

WW. Sample No. I-49 (PN 50092 / Moderna Lot No. 7009622018 / Sample Lot No. 053F22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "053F22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.364	38.917	11.524	2.195	0.168	0.148	0.055	0.007	0.356	0.381	0.476	0.306
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.712	34.933	10.425	1.930	0.118	0.108	0.015	0.013	0.224	0.310	0.143	0.665
Fraction 5	52.039	35.304	10.587	2.071	0.278	0.258	0.043	0.016	0.534	0.731	0.409	0.783
Fraction 6	51.303	35.637	10.836	2.224	0.273	0.247	0.044	0.003	0.533	0.694	0.403	0.149
Fraction 7	48.654	37.563	11.372	2.411	0.158	0.098	0.104	0.007	0.324	0.261	0.919	0.287
Fraction 8	45.577	39.566	12.398	2.460	0.250	0.256	0.030	0.007	0.547	0.646	0.242	0.295
Fraction 9	42.489	41.378	13.663	2.470	0.278	0.287	0.089	0.019	0.654	0.694	0.653	0.766
Fraction 10	44.896	39.742	13.157	2.206	0.122	0.220	0.092	0.014	0.272	0.553	0.700	0.647

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "053F22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	137.64	3.11	0.22	0.07	2.472	0.022	9.41E+11
Fraction 1	178.96	7.51	0.20	0.09	< QL	< QL	3.89E+10
Fraction 2	149.33	3.66	0.26	0.11	< QL	< QL	3.32E+10
Fraction 3	145.42	4.03	0.22	0.08	0.073	0.021	3.69E+10
Fraction 4	120.63	3.83	0.21	0.05	0.118	0.032	4.60E+10
Fraction 5	115.63	3.17	0.20	0.06	0.164	0.010	8.20E+10
Fraction 6	112.14	2.57	0.17	0.05	0.337	0.020	1.04E+11
Fraction 7	123.44	2.88	0.14	0.05	0.859	0.037	2.95E+11
Fraction 8	139.31	1.06	0.23	0.07	1.223	0.018	4.71E+11
Fraction 9	174.62	5.46	0.21	0.06	0.667	0.017	2.07E+11
Fraction 10	179.74	6.07	0.23	0.13	0.486	0.046	1.56E+11

XX. Sample No. I-50 (PN 50092/50141 / Moderna Lot No. 7015322082 / Sample Lot No. 001K22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "001K22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	46.917	39.282	11.657	2.144	0.048	0.061	0.082	0.014	0.103	0.156	0.703	0.655
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.552	36.348	10.285	1.815	0.127	0.169	0.061	0.011	0.246	0.465	0.596	0.600
Fraction 5	51.500	36.004	10.559	1.936	0.402	0.532	0.118	0.015	0.781	1.477	1.119	0.754
Fraction 6	50.717	36.403	10.788	2.092	0.038	0.141	0.088	0.026	0.075	0.387	0.815	1.221
Fraction 7	48.136	38.160	11.416	2.288	0.250	0.226	0.043	0.009	0.520	0.593	0.378	0.401
Fraction 8	45.620	39.756	12.264	2.360	0.042	0.066	0.040	0.029	0.093	0.167	0.324	1.217
Fraction 9	42.876	41.475	13.277	2.372	0.244	0.219	0.058	0.014	0.569	0.528	0.437	0.603
Fraction 10	42.203	41.423	14.059	2.314	0.251	0.329	0.130	0.009	0.594	0.795	0.924	0.393

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "001K22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	137.02	2.69	0.18	0.05	2.224	0.021	9.12E+11
Fraction 1	189.97	5.95	0.20	0.13	< QL	< QL	3.84E+10
Fraction 2	150.17	4.77	0.21	0.08	< QL	< QL	2.66E+10
Fraction 3	150.03	2.07	0.22	0.09	< QL	< QL	3.16E+10
Fraction 4	125.63	4.21	0.19	0.05	< QL	< QL	4.86E+10
Fraction 5	115.01	2.50	0.18	0.07	0.091	0.004	8.66E+10
Fraction 6	115.78	1.95	0.13	0.06	0.299	0.028	1.07E+11
Fraction 7	123.11	3.01	0.18	0.04	0.935	0.011	2.75E+11
Fraction 8	133.94	2.44	0.17	0.03	1.051	0.028	3.68E+11
Fraction 9	153.24	3.78	0.22	0.05	0.485	0.041	1.54E+11
Fraction 10	160.16	4.65	0.22	0.07	0.292	0.024	5.38E+10

YY. Sample No. J-51 (PN 50108/50115 / Moderna Lot No. 7013822019 / Sample Lot No. MV20013B)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV20013B".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.638	38.490	11.629	2.243	0.089	0.137	0.047	0.010	0.188	0.355	0.407	0.431
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	54.896	32.977	10.055	2.072	0.390	0.367	0.127	0.013	0.710	1.112	1.261	0.633
Fraction 5	53.357	34.189	10.272	2.182	0.092	0.075	0.042	0.036	0.173	0.219	0.405	1.667
Fraction 6	51.944	34.805	10.844	2.407	0.251	0.223	0.064	0.009	0.483	0.642	0.588	0.383
Fraction 7	48.836	37.144	11.511	2.508	0.170	0.131	0.121	0.006	0.347	0.353	1.050	0.224
Fraction 8	45.681	39.470	12.361	2.487	0.145	0.102	0.034	0.011	0.318	0.258	0.274	0.448
Fraction 9	44.394	40.561	12.669	2.376	0.242	0.283	0.100	0.018	0.545	0.698	0.790	0.770
Fraction 10	39.115	42.983	15.395	2.507	0.209	0.237	0.075	0.006	0.534	0.552	0.489	0.250

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV20013B".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	147.84	5.34	0.27	0.10	2.140	0.029	5.25E+11
Fraction 1	185.25	5.20	0.18	0.10	< QL	< QL	3.79E+10
Fraction 2	162.49	4.95	0.23	0.05	< QL	< QL	1.78E+10
Fraction 3	156.54	5.25	0.29	0.06	< QL	< QL	1.39E+10
Fraction 4	113.14	2.89	0.22	0.04	< QL	< QL	8.91E+09
Fraction 5	107.81	2.15	0.27	0.07	0.105	0.018	1.98E+10
Fraction 6	105.12	2.54	0.24	0.06	0.192	0.049	3.75E+10
Fraction 7	126.90	4.16	0.26	0.06	0.478	0.018	1.26E+11
Fraction 8	155.20	4.50	0.15	0.07	0.910	0.001	2.87E+11
Fraction 9	179.39	4.09	0.21	0.07	0.748	0.030	1.67E+11
Fraction 10	208.34	7.88	0.19	0.09	0.654	0.037	1.01E+11

ZZ. Sample No. J-52 (PN 50108/50140 / Moderna Lot No. 7015923016 / Sample Lot No. MV1050A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV1050A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.373	38.773	11.550	2.305	0.269	0.262	0.033	0.019	0.568	0.676	0.286	0.832
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	53.653	34.072	10.211	2.064	0.283	0.398	0.130	0.023	0.527	1.167	1.276	1.111
Fraction 5	52.527	34.937	10.351	2.186	0.371	0.283	0.138	0.030	0.707	0.810	1.333	1.358
Fraction 6	51.889	35.184	10.589	2.338	0.593	0.555	0.084	0.019	1.143	1.577	0.796	0.824
Fraction 7	49.413	36.877	11.170	2.539	0.359	0.295	0.095	0.010	0.727	0.801	0.851	0.403
Fraction 8	46.493	38.816	12.076	2.614	0.167	0.133	0.080	0.020	0.358	0.342	0.665	0.776
Fraction 9	43.943	40.519	12.944	2.595	0.111	0.116	0.050	0.024	0.252	0.286	0.385	0.915
Fraction 10	41.915	41.887	13.750	2.449	0.332	0.388	0.051	0.027	0.792	0.926	0.370	1.099

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV1050A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	131.68	4.23	0.18	0.07	2.088	0.018	4.80E+11
Fraction 1	175.71	4.33	0.15	0.06	< QL	< QL	2.62E+10
Fraction 2	164.80	2.81	0.24	0.05	< QL	< QL	1.77E+10
Fraction 3	150.94	3.33	0.25	0.08	< QL	< QL	1.51E+10
Fraction 4	120.21	3.27	0.22	0.08	0.108	0.010	1.59E+10
Fraction 5	106.58	2.32	0.20	0.07	0.110	0.018	3.31E+10
Fraction 6	101.28	2.95	0.17	0.04	0.244	0.013	6.67E+10
Fraction 7	109.35	2.68	0.19	0.07	0.505	0.023	1.39E+11
Fraction 8	127.65	3.89	0.12	0.06	0.884	0.024	2.17E+11
Fraction 9	159.80	5.19	0.16	0.08	0.747	0.017	1.70E+11
Fraction 10	180.84	5.01	0.17	0.06	0.473	0.024	8.32E+10

AAA. Sample No. J-53 (PN 50073 / Moderna Lot No. 7006520007 / Sample Lot No. 025J20-2A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "025J20-2A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.422	38.846	11.375	1.357	0.105	0.079	0.144	0.011	0.216	0.204	1.265	0.825
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.975	37.339	10.525	1.161	0.092	0.062	0.092	0.013	0.181	0.165	0.878	1.136
Fraction 5	52.555	35.132	10.869	1.444	0.236	0.281	0.060	0.006	0.449	0.799	0.550	0.450
Fraction 6	51.402	35.781	11.289	1.528	0.191	0.250	0.056	0.010	0.372	0.700	0.493	0.685
Fraction 7	48.626	37.870	11.965	1.539	0.250	0.237	0.086	0.010	0.513	0.625	0.718	0.651
Fraction 8	45.976	39.895	12.602	1.527	0.207	0.273	0.073	0.013	0.451	0.683	0.578	0.853
Fraction 9	43.060	41.842	13.577	1.521	0.211	0.083	0.150	0.006	0.489	0.199	1.105	0.366
Fraction 10	44.549	42.058	12.306	1.087	0.171	0.193	0.066	0.008	0.385	0.458	0.536	0.709

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "025J20-2A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	173.24	8.00	0.27	0.08	4.535	0.048	1.15E+12
Fraction 1	216.06	4.46	0.36	0.08	0.101	0.020	3.48E+10
Fraction 2	195.48	11.05	0.28	0.08	< QL	< QL	4.73E+10
Fraction 3	168.07	7.38	0.35	0.11	0.116	0.014	4.99E+10
Fraction 4	157.64	4.26	0.29	0.05	0.142	0.035	5.83E+10
Fraction 5	125.36	2.08	0.22	0.09	0.264	0.010	1.10E+11
Fraction 6	131.21	4.13	0.12	0.09	0.482	0.020	1.10E+11
Fraction 7	145.96	3.88	0.15	0.06	0.813	0.001	2.90E+11
Fraction 8	163.78	2.79	0.15	0.05	0.892	0.021	3.67E+11
Fraction 9	198.35	3.28	0.23	0.06	0.321	0.024	1.34E+11
Fraction 10	260.87	9.11	0.35	0.12	0.482	0.015	1.50E+11

BBB. Sample No. J-54 (PN 50068 / Moderna Lot No. 7006520001 / Sample Lot No. 057G20A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "057G20A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.204	39.070	11.288	1.437	0.600	0.554	0.204	0.019	1.245	1.418	1.810	1.332
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	48.550	39.455	11.090	0.905	0.266	0.248	0.123	0.008	0.549	0.629	1.106	0.934
Fraction 4	50.337	37.405	11.105	1.153	0.306	0.304	0.127	0.009	0.609	0.813	1.145	0.797
Fraction 5	51.819	35.850	10.970	1.360	0.093	0.126	0.071	0.007	0.180	0.351	0.644	0.523
Fraction 6	51.065	36.050	11.277	1.607	0.270	0.233	0.037	0.007	0.529	0.647	0.327	0.449
Fraction 7	49.022	37.685	11.712	1.581	0.228	0.119	0.144	0.017	0.464	0.315	1.226	1.097
Fraction 8	46.718	39.520	12.182	1.579	0.163	0.194	0.107	0.001	0.348	0.491	0.881	0.087
Fraction 9	45.755	40.254	12.400	1.591	0.207	0.322	0.119	0.006	0.453	0.799	0.958	0.407
Fraction 10	39.288	43.952	15.328	1.432	0.222	0.232	0.027	0.008	0.565	0.527	0.174	0.588

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "057G20A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	184.09	5.25	0.27	0.11	4.589	0.032	1.21E+12
Fraction 1	219.07	7.37	0.19	0.08	0.103	0.031	7.26E+10
Fraction 2	202.96	5.24	0.27	0.06	0.096	0.016	6.15E+10
Fraction 3	193.07	8.14	0.25	0.07	0.129	0.006	8.84E+10
Fraction 4	157.10	2.80	0.27	0.07	0.165	0.017	6.09E+10
Fraction 5	140.33	4.12	0.30	0.05	0.219	0.035	9.13E+10
Fraction 6	121.45	2.40	0.28	0.04	0.379	0.021	8.95E+10
Fraction 7	146.89	2.41	0.21	0.08	0.493	0.011	2.09E+11
Fraction 8	178.41	2.07	0.12	0.06	0.793	0.009	4.52E+11
Fraction 9	186.08	5.60	0.18	0.06	0.383	0.040	2.63E+11
Fraction 10	222.46	4.85	0.23	0.11	0.248	0.005	1.31E+11

CCC. Sample No. K-55 (PN 50073 / Moderna Lot No. 7006520009 / Sample Lot No. 029K20-2A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "029K20-2A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.887	38.562	11.168	1.384	0.263	0.117	0.196	0.010	0.538	0.303	1.756	0.720
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	53.683	34.124	10.933	1.260	0.154	0.088	0.091	0.011	0.286	0.257	0.832	0.835
Fraction 5	53.411	33.936	11.166	1.487	0.133	0.186	0.120	0.016	0.249	0.548	1.073	1.106
Fraction 6	52.114	34.713	11.569	1.604	0.218	0.186	0.057	0.010	0.418	0.537	0.489	0.608
Fraction 7	49.469	36.650	12.196	1.685	0.344	0.324	0.114	0.004	0.696	0.885	0.935	0.223
Fraction 8	44.631	41.062	12.645	1.662	0.084	0.145	0.086	0.014	0.187	0.353	0.680	0.835
Fraction 9	41.920	42.287	13.882	1.911	0.191	0.154	0.091	0.018	0.456	0.365	0.657	0.966
Fraction 10	46.543	39.368	13.076	1.013	0.181	0.170	0.098	0.004	0.388	0.433	0.750	0.439

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "029K20-2A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	196.83	8.65	0.29	0.13	3.651	0.079	1.25E+12
Fraction 1	203.62	3.99	0.24	0.10	0.078	0.024	3.93E+10
Fraction 2	194.50	4.91	0.23	0.07	0.074	0.017	3.20E+10
Fraction 3	166.71	5.77	0.29	0.06	0.079	0.023	2.71E+10
Fraction 4	150.16	6.16	0.33	0.11	0.119	0.012	4.01E+10
Fraction 5	134.09	2.63	0.26	0.04	0.176	0.014	5.57E+10
Fraction 6	137.52	3.83	0.22	0.07	0.303	0.029	8.36E+10
Fraction 7	150.65	3.67	0.17	0.06	0.447	0.003	1.58E+11
Fraction 8	173.40	3.48	0.24	0.07	0.629	0.010	1.69E+11
Fraction 9	186.81	5.93	0.19	0.10	0.403	0.014	7.03E+10
Fraction 10	283.74	15.84	0.25	0.11	0.628	0.031	1.58E+11

DDD. Sample No. K-56 (PN 50111/50092 / Moderna Lot No. 7010722044 / Sample Lot No. 029E22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "029E33A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.082	39.256	11.383	2.279	0.295	0.414	0.139	0.010	0.627	1.054	1.223	0.454
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.509	34.869	10.567	2.055	0.287	0.385	0.124	0.017	0.546	1.105	1.176	0.835
Fraction 5	52.709	34.785	10.344	2.162	0.252	0.368	0.156	0.024	0.478	1.058	1.508	1.099
Fraction 6	51.570	35.539	10.533	2.357	0.216	0.170	0.142	0.010	0.418	0.479	1.351	0.444
Fraction 7	49.909	36.381	11.187	2.524	0.422	0.462	0.084	0.023	0.846	1.271	0.754	0.910
Fraction 8	46.287	38.987	12.148	2.578	0.123	0.157	0.071	0.012	0.266	0.404	0.586	0.459
Fraction 9	44.265	40.022	13.143	2.570	0.200	0.274	0.104	0.010	0.451	0.683	0.792	0.387
Fraction 10	43.472	40.977	13.335	2.216	0.374	0.453	0.177	0.010	0.860	1.105	1.331	0.450

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "029E33A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	141.77	3.32	0.20	0.08	2.131	0.007	6.13E+11
Fraction 1	167.11	3.80	0.20	0.07	< QL	< QL	2.93E+10
Fraction 2	143.26	4.81	0.25	0.09	< QL	< QL	1.81E+10
Fraction 3	133.83	3.94	0.25	0.07	< QL	< QL	2.14E+10
Fraction 4	114.76	2.13	0.19	0.04	< QL	< QL	1.99E+10
Fraction 5	104.65	2.27	0.21	0.04	0.074	0.006	2.25E+10
Fraction 6	102.51	2.19	0.20	0.03	0.135	0.015	4.82E+10
Fraction 7	112.85	2.70	0.22	0.05	0.334	0.015	1.02E+11
Fraction 8	138.29	4.65	0.16	0.07	0.804	0.032	2.56E+11
Fraction 9	158.59	3.23	0.18	0.07	0.870	0.005	2.93E+11
Fraction 10	195.24	7.71	0.18	0.06	0.614	0.011	1.80E+11

EEE. Sample No. K-57 (PN 50089 / Moderna Lot No. 7006821495 / Sample Lot No. 011L21A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "011L21A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.401	39.520	11.714	1.366	0.104	0.190	0.106	0.004	0.218	0.481	0.905	0.300
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.848	36.755	11.249	1.148	0.123	0.105	0.045	0.007	0.242	0.285	0.396	0.573
Fraction 5	51.100	36.343	11.229	1.328	0.145	0.138	0.017	0.002	0.284	0.380	0.154	0.162
Fraction 6	50.747	36.495	11.283	1.475	0.065	0.064	0.006	0.011	0.128	0.175	0.055	0.743
Fraction 7	48.743	38.148	11.588	1.521	0.183	0.139	0.051	0.006	0.375	0.363	0.441	0.405
Fraction 8	46.147	40.194	12.210	1.448	0.163	0.200	0.047	0.005	0.354	0.498	0.386	0.336
Fraction 9	44.091	41.932	12.634	1.343	0.119	0.150	0.052	0.007	0.269	0.358	0.409	0.541
Fraction 10	41.876	43.039	14.005	1.080	0.065	0.086	0.050	0.007	0.156	0.200	0.360	0.606

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "011L21A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	176.90	3.63	0.25	0.06	4.035	0.051	1.46E+12
Fraction 1	190.88	8.58	0.34	0.07	< QL	< QL	2.68E+10
Fraction 2	188.15	8.16	0.29	0.10	< QL	< QL	2.67E+10
Fraction 3	162.94	5.56	0.30	0.08	0.076	0.013	3.15E+10
Fraction 4	145.27	3.88	0.35	0.08	0.098	0.021	4.39E+10
Fraction 5	131.58	3.00	0.27	0.08	0.167	0.023	6.03E+10
Fraction 6	126.85	3.55	0.24	0.06	0.348	0.025	1.31E+11
Fraction 7	137.86	3.57	0.18	0.07	0.701	0.033	2.79E+11
Fraction 8	159.49	2.90	0.22	0.08	0.893	0.027	3.65E+11
Fraction 9	194.28	4.61	0.15	0.09	0.556	0.029	1.71E+11
Fraction 10	248.50	8.79	0.30	0.07	0.226	0.011	5.67E+10

FFF. Sample No. K-58 (PN 50092 / Moderna Lot No. 7009623002 / Sample Lot No. 044A23A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "044A23A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.830	38.380	11.545	2.245	0.221	0.248	0.055	0.013	0.462	0.647	0.479	0.592
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.501	35.326	10.327	1.847	0.274	0.265	0.036	0.007	0.522	0.751	0.351	0.363
Fraction 5	52.230	35.311	10.443	2.016	0.216	0.231	0.064	0.009	0.413	0.654	0.616	0.454
Fraction 6	51.097	35.973	10.684	2.246	0.114	0.182	0.142	0.020	0.224	0.506	1.334	0.875
Fraction 7	49.690	36.831	11.013	2.466	0.392	0.374	0.093	0.023	0.788	1.016	0.841	0.926
Fraction 8	46.815	38.597	12.015	2.573	0.316	0.328	0.112	0.019	0.676	0.850	0.931	0.747
Fraction 9	43.262	40.816	13.323	2.599	0.234	0.215	0.135	0.022	0.541	0.527	1.013	0.833
Fraction 10	42.430	41.336	13.823	2.411	0.166	0.213	0.106	0.012	0.392	0.516	0.767	0.489

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "044A23A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.25	5.12	0.23	0.08	2.447	0.023	1.16E+12
Fraction 1	169.27	4.99	0.20	0.06	0.108	0.034	4.27E+10
Fraction 2	157.36	2.69	0.20	0.10	0.107	0.007	4.22E+10
Fraction 3	145.98	4.41	0.15	0.08	0.115	0.016	5.07E+10
Fraction 4	127.34	2.70	0.16	0.04	0.175	0.007	7.69E+10
Fraction 5	120.03	2.45	0.16	0.04	0.254	0.009	1.33E+11
Fraction 6	116.87	2.43	0.13	0.04	0.489	0.011	2.63E+11
Fraction 7	117.96	2.67	0.18	0.06	0.761	0.025	3.89E+11
Fraction 8	133.42	2.40	0.18	0.05	1.148	0.037	4.97E+11
Fraction 9	164.27	4.66	0.23	0.08	0.778	0.008	2.64E+11
Fraction 10	189.15	5.33	0.21	0.06	0.360	0.043	1.13E+11

GGG. Sample No. K-59 (PN 50099 / Moderna Lot No. 7006822102 / Sample Lot No. 000345A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "000345A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.885	39.067	11.610	1.438	0.080	0.100	0.054	0.014	0.167	0.257	0.465	0.946
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.150	36.500	11.114	1.236	0.146	0.135	0.085	0.006	0.286	0.371	0.767	0.487
Fraction 5	51.387	36.013	11.136	1.464	0.122	0.145	0.079	0.010	0.237	0.404	0.707	0.704
Fraction 6	51.090	36.045	11.276	1.589	0.202	0.188	0.062	0.010	0.395	0.520	0.551	0.645
Fraction 7	49.185	37.371	11.773	1.670	0.101	0.165	0.114	0.009	0.204	0.441	0.964	0.537
Fraction 8	46.016	40.036	12.337	1.611	0.217	0.294	0.094	0.009	0.471	0.735	0.764	0.533
Fraction 9	44.152	41.256	13.012	1.580	0.234	0.195	0.084	0.005	0.530	0.473	0.645	0.309
Fraction 10	45.167	40.387	13.211	1.235	0.207	0.250	0.046	0.004	0.459	0.620	0.347	0.304

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "000345A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	162.93	4.09	0.28	0.07	4.341	0.065	2.57E+12
Fraction 1	186.79	4.51	0.18	0.09	0.099	0.007	7.82E+10
Fraction 2	176.34	4.52	0.19	0.04	0.111	0.016	6.42E+10
Fraction 3	156.75	3.36	0.23	0.05	0.114	0.029	7.55E+10
Fraction 4	145.17	3.61	0.24	0.07	0.152	0.017	8.96E+10
Fraction 5	123.04	4.28	0.22	0.07	0.226	0.019	1.19E+11
Fraction 6	123.42	3.53	0.21	0.06	0.362	0.022	2.09E+11
Fraction 7	133.83	3.93	0.19	0.06	0.598	0.037	3.44E+11
Fraction 8	158.94	4.65	0.18	0.07	0.901	0.027	4.55E+11
Fraction 9	199.91	1.72	0.14	0.04	0.620	0.040	2.57E+11
Fraction 10	226.83	8.56	0.12	0.05	0.502	0.032	2.20E+11

HHH. Sample No. K-60 (PN 50075 / Moderna Lot No. 7006822277 / Sample Lot No. 012D22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "012D22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.729	39.840	11.025	1.406	0.029	0.090	0.103	0.005	0.060	0.226	0.936	0.380
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.717	35.748	11.223	1.311	0.263	0.234	0.035	0.008	0.508	0.653	0.310	0.633
Fraction 5	51.606	35.819	11.140	1.434	0.183	0.168	0.073	0.015	0.355	0.470	0.652	1.074
Fraction 6	51.502	35.714	11.204	1.580	0.410	0.381	0.072	0.004	0.797	1.066	0.641	0.256
Fraction 7	48.841	37.806	11.735	1.618	0.159	0.241	0.089	0.009	0.326	0.638	0.761	0.565
Fraction 8	45.930	40.492	12.128	1.450	0.197	0.224	0.049	0.019	0.428	0.554	0.407	1.278
Fraction 9	43.684	42.487	12.355	1.474	0.102	0.156	0.067	0.003	0.233	0.367	0.539	0.186
Fraction 10	43.761	41.753	13.350	1.136	0.208	0.409	0.195	0.018	0.476	0.980	1.461	1.593

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "012D22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	187.02	4.45	0.22	0.07	4.471	0.027	2.69E+12
Fraction 1	194.43	8.75	0.32	0.08	< QL	< QL	4.90E+10
Fraction 2	173.44	6.27	0.37	0.12	< QL	< QL	3.59E+10
Fraction 3	146.93	3.20	0.29	0.08	< QL	< QL	4.15E+10
Fraction 4	121.00	2.37	0.34	0.13	< QL	< QL	4.99E+10
Fraction 5	115.64	2.79	0.23	0.08	0.102	0.022	6.92E+10
Fraction 6	117.59	1.05	0.24	0.06	0.212	0.011	1.12E+11
Fraction 7	146.47	2.66	0.19	0.04	0.614	0.012	3.53E+11
Fraction 8	183.28	3.88	0.15	0.07	1.103	0.026	6.60E+11
Fraction 9	205.39	9.37	0.14	0.09	0.669	0.014	3.30E+11
Fraction 10	239.33	10.44	0.33	0.09	0.303	0.021	1.16E+11

III. Sample No. L-61 (PN 50108/50115 / Moderna Lot No. 7010722104 / Sample Lot No. 200080A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "200080A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.455	38.794	11.333	2.418	0.081	0.147	0.068	0.016	0.171	0.379	0.602	0.649
Fraction 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed	SAT failed
Fraction 5	53.064	34.522	10.228	2.186	0.264	0.240	0.022	0.009	0.497	0.696	0.216	0.399
Fraction 6	52.116	35.201	10.221	2.462	0.165	0.186	0.029	0.011	0.316	0.529	0.282	0.463
Fraction 7	50.217	36.348	10.782	2.654	0.239	0.223	0.038	0.008	0.476	0.613	0.356	0.284
Fraction 8	46.186	38.984	12.073	2.758	0.232	0.251	0.030	0.019	0.503	0.643	0.249	0.695
Fraction 9	42.860	41.172	13.193	2.775	0.175	0.235	0.071	0.010	0.408	0.571	0.539	0.358
Fraction 10	43.551	41.019	12.920	2.510	0.301	0.402	0.145	0.007	0.690	0.980	1.119	0.268

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "200080A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	132.37	2.52	0.23	0.08	2.162	0.027	4.49E+11
Fraction 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Fraction 2	141.00	3.01	0.13	0.04	< QL	< QL	1.35E+10
Fraction 3	141.02	3.79	0.18	0.06	< QL	< QL	1.15E+10
Fraction 4	127.22	2.33	0.24	0.07	< QL	< QL	9.89E+09
Fraction 5	109.39	4.24	0.19	0.05	< QL	< QL	1.27E+10
Fraction 6	96.70	2.05	0.20	0.05	0.154	0.008	2.14E+10
Fraction 7	104.96	1.56	0.21	0.04	0.437	0.027	4.47E+10
Fraction 8	125.52	3.62	0.20	0.06	0.894	0.033	1.44E+11
Fraction 9	161.33	5.36	0.18	0.06	0.842	0.027	1.36E+11
Fraction 10	182.07	3.64	0.21	0.06	0.618	0.026	9.16E+10

I understand from Dr. Schuster that fraction 1 of this sample was not available for any testing due to an operator mix-up.

JJJ. Sample No. L-62 (PN 50108/50115 / Moderna Lot No. 7010722177 / Sample Lot No. 200133A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "200133A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.163	39.033	11.548	2.257	0.163	0.230	0.072	0.010	0.347	0.588	0.625	0.434
Fraction 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.323	35.353	10.366	1.957	0.149	0.183	0.092	0.002	0.285	0.517	0.883	0.082
Fraction 5	52.390	35.304	10.241	2.065	0.263	0.307	0.064	0.020	0.502	0.869	0.628	0.981
Fraction 6	51.424	35.718	10.525	2.334	0.215	0.200	0.032	0.012	0.417	0.559	0.305	0.507
Fraction 7	50.046	36.421	11.003	2.530	0.387	0.412	0.076	0.003	0.773	1.131	0.693	0.110
Fraction 8	46.994	38.659	11.760	2.586	0.141	0.111	0.116	0.014	0.300	0.288	0.987	0.543
Fraction 9	43.525	41.075	12.838	2.563	0.315	0.312	0.049	0.005	0.724	0.760	0.380	0.176
Fraction 10	42.512	41.840	13.356	2.292	0.155	0.188	0.158	0.015	0.364	0.450	1.182	0.657

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "200133A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	136.04	4.19	0.21	0.06	2.131	0.041	2.98E+11
Fraction 1	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.	n.a.
Fraction 2	134.76	3.82	0.19	0.08	< QL	< QL	1.79E+10
Fraction 3	124.31	2.19	0.19	0.05	< QL	< QL	1.40E+10
Fraction 4	110.73	1.81	0.20	0.06	< QL	< QL	1.09E+10
Fraction 5	108.25	1.73	0.21	0.07	< QL	< QL	1.66E+10
Fraction 6	97.33	2.39	0.20	0.06	0.193	0.022	2.20E+10
Fraction 7	105.09	1.94	0.23	0.04	0.440	0.037	6.04E+10
Fraction 8	124.31	3.13	0.19	0.06	0.829	0.004	1.24E+11
Fraction 9	153.75	3.29	0.18	0.05	0.867	0.030	1.28E+11
Fraction 10	192.24	4.90	0.14	0.07	0.616	0.021	8.87E+10

I understand from Dr. Schuster that fraction 1 of this sample was not available for any testing due to an operator mix-up.

KKK. Sample No. L-63 (PN 50108/50140 / Moderna Lot No. 7015322058 / Sample Lot No. MV1028A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV1028A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.426	38.969	11.322	2.283	0.037	0.055	0.058	0.006	0.077	0.140	0.514	0.246
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	53.411	34.661	9.978	1.950	0.131	0.110	0.045	0.007	0.244	0.316	0.455	0.358
Fraction 5	53.168	34.877	9.899	2.056	0.058	0.077	0.046	0.012	0.110	0.220	0.468	0.603
Fraction 6	52.067	35.491	10.154	2.288	0.103	0.118	0.043	0.006	0.198	0.332	0.427	0.253
Fraction 7	50.110	36.732	10.716	2.442	0.097	0.132	0.049	0.013	0.193	0.360	0.456	0.538
Fraction 8	46.943	38.858	11.727	2.471	0.119	0.081	0.066	0.006	0.254	0.208	0.563	0.247
Fraction 9	43.504	41.249	12.825	2.422	0.087	0.127	0.037	0.010	0.201	0.308	0.291	0.427
Fraction 10	42.674	41.831	13.255	2.239	0.135	0.177	0.035	0.013	0.317	0.422	0.266	0.568

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV1028A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	137.47	2.14	0.24	0.09	2.121	0.011	3.57E+11
Fraction 1	164.78	6.48	0.19	0.07	0.076	0.016	1.72E+10
Fraction 2	148.08	5.46	0.19	0.04	< QL	< QL	5.28E+09
Fraction 3	136.68	2.02	0.23	0.10	< QL	< QL	9.31E+09
Fraction 4	122.37	2.22	0.27	0.06	< QL	< QL	1.28E+10
Fraction 5	109.46	2.81	0.22	0.07	0.090	0.012	1.16E+10
Fraction 6	100.87	2.77	0.18	0.05	0.182	0.026	3.03E+10
Fraction 7	112.03	2.31	0.21	0.06	0.481	0.007	7.43E+10
Fraction 8	131.34	3.51	0.19	0.04	0.916	0.045	1.02E+11
Fraction 9	166.26	4.01	0.20	0.06	0.909	0.004	1.24E+11
Fraction 10	198.48	5.36	0.24	0.07	0.462	0.019	4.98E+10

LLL. Sample No. L-64 (PN 50099 / Moderna Lot No. 7006822281 / Sample Lot No. 000482A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "000482A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.869	38.951	11.650	1.529	0.233	0.254	0.080	0.014	0.486	0.651	0.687	0.907
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	50.420	36.637	11.701	1.243	0.304	0.385	0.160	0.003	0.602	1.050	1.369	0.281
Fraction 5	51.146	35.921	11.449	1.484	0.241	0.216	0.069	0.006	0.472	0.601	0.606	0.409
Fraction 6	51.041	35.909	11.371	1.680	0.248	0.272	0.092	0.005	0.485	0.758	0.808	0.293
Fraction 7	49.663	36.975	11.643	1.720	0.153	0.140	0.094	0.012	0.308	0.380	0.807	0.684
Fraction 8	46.460	39.619	12.257	1.665	0.184	0.096	0.121	0.015	0.395	0.243	0.987	0.873
Fraction 9	45.676	40.062	12.641	1.621	0.161	0.238	0.123	0.018	0.353	0.595	0.976	1.134
Fraction 10	43.847	41.077	13.637	1.439	0.222	0.162	0.095	0.019	0.506	0.394	0.699	1.288

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "000482A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	159.52	4.64	0.24	0.09	4.690	0.029	2.37E+12

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 1	172.29	4.63	0.18	0.10	< QL	< QL	7.95E+10
Fraction 2	157.60	3.90	0.18	0.08	< QL	< QL	6.12E+10
Fraction 3	148.09	3.60	0.19	0.05	< QL	< QL	8.57E+10
Fraction 4	132.56	5.44	0.24	0.08	0.075	0.018	9.11E+10
Fraction 5	123.55	2.35	0.21	0.06	0.161	0.010	1.11E+11
Fraction 6	120.90	2.61	0.21	0.04	0.300	0.012	1.50E+11
Fraction 7	135.66	2.82	0.21	0.08	0.593	0.011	3.44E+11
Fraction 8	157.74	2.70	0.15	0.05	0.904	0.023	4.61E+11
Fraction 9	186.08	5.42	0.12	0.06	0.598	0.036	3.47E+11
Fraction 10	212.43	6.13	0.13	0.05	0.492	0.045	2.07E+11

MMM. Sample No. L-65 (PN 50108/50140 / Moderna Lot No. 7015322057 / Sample Lot No. MV1027A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "MV1027A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.529	38.735	11.456	2.280	0.190	0.232	0.120	0.014	0.399	0.600	1.051	0.601
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	54.391	33.591	10.130	1.888	0.141	0.133	0.076	0.004	0.259	0.395	0.754	0.202
Fraction 5	53.380	34.334	10.220	2.066	0.067	0.072	0.039	0.006	0.125	0.209	0.378	0.268
Fraction 6	52.166	35.111	10.478	2.245	0.210	0.259	0.058	0.012	0.402	0.738	0.558	0.517
Fraction 7	49.860	36.616	11.111	2.413	0.373	0.369	0.036	0.006	0.747	1.007	0.326	0.264
Fraction 8	46.756	38.669	12.044	2.532	0.105	0.165	0.074	0.019	0.225	0.428	0.615	0.764
Fraction 9	43.628	40.530	13.259	2.584	0.103	0.153	0.060	0.011	0.237	0.378	0.456	0.422
Fraction 10	41.563	41.834	14.141	2.463	0.169	0.070	0.160	0.010	0.407	0.166	1.132	0.410

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "MV1027A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	133.05	3.57	0.27	0.08	2.064	0.018	9.62E+11
Fraction 1	166.87	5.60	0.21	0.07	< QL	< QL	4.47E+10
Fraction 2	150.56	4.39	0.19	0.02	< QL	< QL	3.29E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 3	135.04	5.42	0.20	0.06	< QL	< QL	2.96E+10
Fraction 4	129.07	1.97	0.24	0.08	< QL	< QL	3.72E+10
Fraction 5	114.26	1.77	0.22	0.06	0.102	0.011	6.02E+10
Fraction 6	110.45	3.28	0.20	0.05	0.186	0.003	9.67E+10
Fraction 7	119.96	1.68	0.18	0.06	0.454	0.022	2.77E+11
Fraction 8	131.07	3.63	0.24	0.03	0.900	0.021	4.45E+11
Fraction 9	154.68	1.60	0.16	0.08	0.778	0.018	3.00E+11
Fraction 10	184.77	5.13	0.20	0.07	0.374	0.016	1.27E+11

NNN. Sample No. L-66 (PN 50111/50092 / Moderna Lot No. 7010722046 / Sample Lot No. 031E22A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "031E22A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	47.286	39.047	11.369	2.298	0.145	0.180	0.044	0.009	0.307	0.461	0.385	0.380
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	52.678	35.175	10.126	2.022	0.346	0.348	0.053	0.011	0.656	0.988	0.528	0.559
Fraction 5	52.326	35.217	10.305	2.153	0.121	0.120	0.034	0.010	0.232	0.340	0.333	0.455
Fraction 6	51.355	35.813	10.517	2.315	0.274	0.325	0.064	0.019	0.534	0.907	0.609	0.814
Fraction 7	49.734	36.756	11.038	2.472	0.149	0.114	0.052	0.024	0.300	0.310	0.471	0.985
Fraction 8	46.538	38.960	11.938	2.564	0.188	0.155	0.063	0.012	0.404	0.398	0.525	0.451
Fraction 9	43.371	40.936	13.072	2.622	0.060	0.089	0.027	0.014	0.139	0.217	0.210	0.527
Fraction 10	41.707	42.156	13.786	2.351	0.228	0.297	0.061	0.015	0.547	0.704	0.445	0.625

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "031E22A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	131.03	3.59	0.23	0.08	2.066	0.013	1.03E+12
Fraction 1	169.75	3.00	0.13	0.07	< QL	< QL	6.30E+10
Fraction 2	140.47	5.21	0.23	0.07	< QL	< QL	3.30E+10
Fraction 3	130.01	3.16	0.20	0.06	< QL	< QL	3.42E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 4	118.38	2.14	0.23	0.05	< QL	< QL	4.21E+10
Fraction 5	112.65	2.43	0.17	0.07	0.119	0.025	5.34E+10
Fraction 6	109.76	1.56	0.18	0.06	0.259	0.003	1.28E+11
Fraction 7	116.28	3.11	0.19	0.05	0.438	0.002	2.44E+11
Fraction 8	126.80	1.74	0.16	0.05	0.803	0.018	3.52E+11
Fraction 9	146.45	2.55	0.18	0.05	0.668	0.038	2.90E+11
Fraction 10	193.10	6.61	0.19	0.07	0.276	0.027	1.24E+11

OOO. Sample No. M-67 (PN 50099 / Moderna Lot No. 7006822236 / Sample Lot No. 000449A)

Tabulated results of molar ratios by LC-CAD for CMO LOT number "000449A".

Sample No.	Average molar ratio (%)				SD molar ratio (%)				RSD% molar ratio (%)			
	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG	SM-102	Cholesterol	DSPC	PEG-DMG
Not-fractionated	48.414	38.809	11.272	1.504	0.141	0.153	0.060	0.014	0.291	0.394	0.536	0.935
Fraction 1	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 2	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 3	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL	< QL
Fraction 4	51.456	36.113	11.127	1.304	0.356	0.267	0.096	0.006	0.692	0.741	0.863	0.434
Fraction 5	52.611	35.097	10.785	1.508	0.145	0.193	0.099	0.008	0.276	0.549	0.915	0.525
Fraction 6	52.527	34.908	10.854	1.711	0.071	0.114	0.045	0.013	0.136	0.326	0.418	0.778
Fraction 7	50.038	36.695	11.522	1.745	0.207	0.199	0.094	0.007	0.414	0.543	0.820	0.375
Fraction 8	46.673	39.491	12.214	1.622	0.233	0.274	0.082	0.011	0.499	0.694	0.672	0.698
Fraction 9	44.700	40.914	12.824	1.562	0.123	0.134	0.027	0.007	0.274	0.328	0.209	0.449
Fraction 10	44.540	40.701	13.552	1.207	0.172	0.289	0.122	0.005	0.386	0.710	0.903	0.378

Tabulated results of DLS, UV spectroscopy, and NTA for CMO LOT number "000449A".

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Not-fractionated	156.85	4.40	0.24	0.10	4.566	0.004	1.62E+12
Fraction 1	194.99	5.50	0.21	0.11	< QL	< QL	4.78E+10
Fraction 2	174.68	3.97	0.22	0.06	< QL	< QL	3.53E+10
Fraction 3	168.38	9.00	0.26	0.06	< QL	< QL	4.34E+10
Fraction 4	130.92	4.20	0.28	0.07	< QL	< QL	2.90E+10
Fraction 5	119.91	2.96	0.26	0.05	0.137	0.021	4.25E+10

	DLS				UV		NTA
Sample No.	Z-ave (nm)	± SD (nm)	PdI (a.u.)	± SD (a.u.)	Mean O.D. at 260 nm [A.U.] scatter corrected	± SD (a.u.)	[particles/mL] (corrected for dilution)
Fraction 6	114.05	2.49	0.24	0.04	0.340	0.024	7.33E+10
Fraction 7	128.12	3.13	0.20	0.07	0.694	0.023	1.96E+11
Fraction 8	154.31	4.18	0.17	0.06	1.031	0.030	3.08E+11
Fraction 9	194.72	5.29	0.19	0.07	0.605	0.020	1.51E+11
Fraction 10	228.94	5.26	0.23	0.06	0.400	0.049	9.91E+10

a. Moderna's Testing Data Demonstrate Infringement

1) Drug Product

609. As explained above, I understand that Moderna has reported lipid content testing for lots of Moderna's drug product in COAs that correspond to each released drug product lot. *See supra* Section X.E.1. I understand that Moderna's COAs report the concentration of each lipid component, which, as explained above, can be converted into molar ratios. *See supra* Section X.A. Moderna's release testing for lipid content measures the concentrations of SM-102, cholesterol, DSPC, and PEG2000-DMG on the basis of bulk, unfractionated samples of the lots tested, and reports the results in its COAs. As I explain above, *supra* Section VI.C, ¶¶ 90-92, such testing still informs whether nucleic acid-lipid particles satisfy the recited lipid content limitations are present in the lots. That is because: (1) the measurement ascertains the average lipid content across the very large number of particles that would be present; (2) the lipid content of those particles would be distributed around an average value for each lipid; and (3) at least some of the particles in that distribution would fall at or very close to the measured average values. *Supra* Section VI.C; ¶¶ 90-92. Moderna's witnesses further agreed that the lipid molar ratio of the Accused Product can be determined from the lipid content measurements reported in Moderna's COAs, and it is appropriate to use Moderna's COAs to assess infringement. *See, e.g.*, Parsons 6/7/2024 Tr. 133:12-134:3; Kramarcyzk 4/30/2024 Tr. 73:6-9.

610. I understand that Moderna has also produced limited sets of "raw data" related to its lipid content measurements. The analysis in the present report relies on the lipid content data reported in Moderna's COAs, rather than these raw data, for several reasons. First, Moderna and its witnesses have taken the position that infringement can be determined from Moderna's COAs. *See, e.g.*, D.I. 183 at 1 (Letter to the Honorable Mitchell S. Goldberg in Opposition to Plaintiffs' Motion to Compel Samples); Parsons 6/7/2024 Tr. 133:12-134:3. Second, it is my

understanding that Moderna has not produced a complete set of raw data upon which I could conduct the analysis—in particular, I understand that Moderna has not produced raw data from at least some third-party manufacturers. Third, it is my understanding that Moderna has not produced information that identifies the nature of each test in its raw data spreadsheets (for example, whether it is a release test, a stability test, or a different type of test). Fourth, as I explain above, *supra* Section X.E.1, Moderna submitted its COA data to the FDA, not the raw data itself, and the accuracy and precision of the data that it reported [redacted] *See, e.g.*, MRNA-GEN-00038383 at -390; *see also supra* ¶ 460. I reserve the right to rely on Moderna's "raw data" in the future, including if Moderna should take the position—which it has not yet taken in this litigation to my knowledge and is contrary to the evidence above, including its statements to FDA—that its COAs are insufficiently reliable to use to calculate lipid molar percentages.

611. Based on the COAs that Moderna has produced, I have calculated the lipid molar ratio of Moderna's labeled drug product lots to determine whether they meet the lipid content limitations of the foregoing claims. For each claim, I have provided a listing of the lots that fall within the claimed ranges in accordance with the Court's claim construction of "___ mol % of the total lipid present in the particle" as following the standard rules of rounding based on significant figures; the concentrations for SM-102, cholesterol, DSPC, and PEG2000-DMG reported by Moderna (or its third-party manufacturer); and the calculated lipid molar ratio. The following table summarizes the numerical limits that I have applied for each claim and the corresponding Appendix where the listing of lots infringing that claim can be found. For this and all similar tables in this report, I have only listed the claims that recite lipid compositions;

however, the same lots would likewise infringe the asserted claims that depend from the listed claims.

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'069 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 3
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 4
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 20	49.5	≤ SM-102 <	65.5	Appendix 5
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	9.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 21	49.5	≤ SM-102 <	65.5	Appendix 6
	31.5	≤ Cholesterol <	36.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 7
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 7	49.5	≤ SM-102 <	60.5	Appendix 8
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 9	49.5	≤ SM-102 <	65.5	Appendix 9
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 10
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 11	49.5	≤ SM-102 <	65.5	Appendix 11
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'359 Patent, Claim 12	49.5	≤ SM-102 <	65.5	Appendix 12
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 13	49.5	≤ SM-102 <	65.5	Appendix 13
	29.5	≤ Cholesterol <	35.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 18	49.5	≤ SM-102 <	65.5	Appendix 14
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 15
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	49.5	≤ SM-102 <	60.5	Appendix 16
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 17
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	35.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 18
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	49.5	≤ SM-102 <	85.5	Appendix 19
	12.5	≤ Non-Cationic <	49.55	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	49.5	≤ SM-102 <	85.5	Appendix 20
	12.5	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'378 Patent, Claim 1	N/A	≤ SM-102 <	N/A	Appendix 21
	29.5	≤ Non-Cationic <	55.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claims 2 and 13	N/A	≤ SM-102 <	N/A	Appendix 22
	29.5	≤ Non-Cationic <	55.5	
	24.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claims 7, 18, and 24	N/A	≤ SM-102 <	N/A	Appendix 23
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claim 25	N/A	≤ SM-102 <	N/A	Appendix 24
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

612. Moderna's COAs and the lipid content testing data they report do not account for the variation in lipid content between particles that would be present in the drug product. That is because Moderna's technique for analyzing lipid content relies on unfractionated, bulk samples of the drug product. However, such variation is undoubtedly present, as confirmed by [redacted] testing discussed above, the well-accepted understanding in the field, and Moderna's statements to tribunals in connection with its challenges to certain of the patents asserted in this case. *See supra* Sections VI.C.3, IX.E, X.E.2; *see also, e.g.*, Moderna '435 IPR CAFC Appeal Reply Brief at 42 (explaining that "in formulated particles, one would expect a bell curve for the lipid percentages"), 43 (discussing "resulting particle variation from the input percentages," emphasizing Dr. Thompson's testimony that "[i]n a population of particles . . . there's likely to be . . . a range of compositions on a particle-by-particle basis");

'435 IPR CAFC Opinion at 1363-64 (agreeing with the PTAB that "there would be some variation in the final compositions of the lipid particles fabricated").

613. [redacted] As I explain above, *supra* Section VI.C.3, in measuring the lipid content of a fraction (or even a bulk formulation), the composition of some particles within the fraction would reflect the measured mean value, with other particles distributed around that mean—a point that Moderna has acknowledged before the Federal Circuit, *see* Moderna '435 IPR CAFC Appeal Reply Brief at

48 ("Moderna is pointing out that the industry, prior art, '435 patent and both experts expect the particle formulation to reflect a point in the resulting particle distribution.").

614. Notably, Moderna refrained from conducting fractionation testing of the "compositional heterogeneity" of the Accused Product, even though one of its scientists on the team suggested doing so, due to the possibility that such testing could "pose uncomfortable questions." MRNA-GEN-01274243 at -243; [redacted]

That conclusion is also consistent with the recognition by Moderna's President, Dr. Hoge "that there are incredibly strong business reasons why a composition with 40% amino lipid is more attractive." MRNA-GEN-02619870 at -870. [redacted]

2) [redacted]

615. [redacted]

[redacted]

616. [redacted]

[redacted]

617. I have been asked to identify the lots of [redacted] that would give rise to a literally infringing process intermediate [redacted] based on the lipid content reported in COAs that Moderna has produced for [redacted], applying the same analysis that I performed with respect to Moderna's labeled drug product. *Supra* ¶ 611. For each claim, I have provided a listing of the [redacted] lots that fall within the claimed ranges in accordance with the Court's claim construction of "___ mol % of the total lipid present in the particle" as following the standard rules of rounding based on significant figures; the concentrations for SM-102, cholesterol, DSPC, and PEG2000-DMG reported by Moderna (or its third-party manufacturer); and the calculated lipid molar ratio. The following table summarizes the numerical limits that I have applied for each claim and the corresponding Appendix where the listing of lots with molar ratios falling within that claim can be found.

[redacted]

Patent Claim	Lipid Molar Ratio Range (%)			[redacted]
'069 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 25
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 26
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 27
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 7	49.5	≤ SM-102 <	60.5	Appendix 28
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 9	49.5	≤ SM-102 <	65.5	Appendix 29
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

Patent Claim	Lipid Molar Ratio Range (%)			[redacted]
'359 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 30
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 11	49.5	≤ SM-102 <	65.5	Appendix 31
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 12	49.5	≤ SM-102 <	65.5	Appendix 32
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 18	49.5	≤ SM-102 <	65.5	Appendix 33
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 34
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	49.5	≤ SM-102 <	60.5	Appendix 35
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 36
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	49.5	≤ SM-102 <	85.5	Appendix 37
	12.5	≤ Non-Cationic <	49.55	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	49.5	≤ SM-102 <	85.5	Appendix 38
	12.5	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

Patent Claim	Lipid Molar Ratio Range (%)			[redacted]
'378 Patent, Claim 1	N/A	≤ SM-102 <	N/A	Appendix 39
	29.5	≤ Non-Cationic <	55.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claims 2 and 13	N/A	≤ SM-102 <	N/A	Appendix 40
	29.5	≤ Non-Cationic <	55.5	
	24.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claims 7, 18, and 24	N/A	≤ SM-102 <	N/A	Appendix 41
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claim 25	N/A	≤ SM-102 <	N/A	Appendix 42
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

b. Plaintiffs' Fractionation Testing Data Demonstrate Infringement

618. The ultracentrifugation fractionation testing conducted by Dr. Schuster and his colleagues at Coriolis further establishes that Moderna's Accused Product infringes the lipid content limitations set forth in the claims of the Lipid Composition Patents above. *See supra* Section XI.

619. As discussed throughout this report, ultracentrifugation ("UC") is an established and reliable technique for fractionating LNPs. *See supra* Sections VI.C.3, IX.E., X.E.2. UC is well-suited for fractionating LNPs, as it is sensitive to the density differences among LNPs and is a gentle, "non-destructive" technique. Vaidya 2024 at 5571. These advantages are the reason why, in my lab, we use UC to analyze polydispersity in LNP batches and to isolate and analyze subpopulations of particles.

620. As I have explained, *see supra* Section VI.C.3, the identification of a fraction with an infringing composition demonstrates that particles within the fraction also have an infringing composition, because the measured composition of the fraction (with respect to the mol% of each lipid) reflects the measured mean value of all the particles that are distributed normally about this mean. Given the very large number of particles that are present, there would exist particles at or essentially at the mean. *See also* Moderna '435 IPR CAFC Appeal Reply Brief at 48 ("Moderna is pointing out that the industry, prior art, '435 patent and both experts expect the particle formulation to reflect a point in the resulting particle distribution."); [redacted] MRNA-GEN-01274243 at -243 (Dr. Schariter proposing to run SEC fractionation analysis, hydrophobic interaction chromatography fraction analysis, and density gradient ultracentrifugation fraction analysis, each of which would include the analysis of "Compositional Heterogeneity: RNA Content and Lipid Content," in order to "run a comprehensive study on the compositional heterogeneity of [] mRNA-1273 batches"); [redacted]

621. For each claim, I have provided a listing of the fractions (and corresponding lots) that fall within the claimed ranges in accordance with the Court's claim construction of "___ mol

% of the total lipid present in the particle," following the standard rules of rounding based on significant figures, per Claim Construction Opinion at 24-25, in view of the lipid molar ratios determined by Dr. Schuster. The following table summarizes the numerical limits that I have applied for each claim and the corresponding Appendix where the listing of fractions infringing that claim can be found. In my analysis, I did not include any fractions for which the optical density (O.D.) of mRNA was below the limit of quantification (reported by Dr. Schuster as "< LQ"), the lipid concentration was below the limit of quantification (reported by Dr. Schuster as "< LQ"), or any system acceptability testing criteria was not met (reported as "SAT failed"), such that I am confident that only trustworthy, accurate, and precise measurements of mRNA-LNP fractions were included. For clarity, that does not mean that those other fractions are non-infringing, but simply that I did not rely on them in my analysis below.

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**Infringing Fractions**
'069 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 133
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 134
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 21	49.5	≤ SM-102 <	65.5	Appendix 135
	31.5	≤ Cholesterol <	36.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 136
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 7	49.5	≤ SM-102 <	60.5	Appendix 137
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**Infringing Fractions**
'359 Patent, Claim 9	49.5	≤ SM-102 <	65.5	Appendix 138
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 139
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 11	49.5	≤ SM-102 <	65.5	Appendix 140
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 12	49.5	≤ SM-102 <	65.5	Appendix 141
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 13	49.5	≤ SM-102 <	65.5	Appendix 142
	29.5	≤ Cholesterol <	35.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 18	49.5	≤ SM-102 <	65.5	Appendix 143
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 144
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	49.5	≤ SM-102 <	60.5	Appendix 145
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 146
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	35.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**Infringing Fractions**
'668 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 147
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	49.5	≤ SM-102 <	85.5	Appendix 148
	12.5	≤ Non-Cationic <	49.55	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	49.5	≤ SM-102 <	85.5	Appendix 149
	12.5	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'378 Patent, Claim 1	N/A	≤ SM-102 <	N/A	Appendix 150
	29.5	≤ Non-Cationic <	55.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claims 2 and 13	N/A	≤ SM-102 <	N/A	Appendix 151
	29.5	≤ Non-Cationic <	55.5	
	24.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claims 7, 18, and 24	N/A	≤ SM-102 <	N/A	Appendix 152
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	2.5	
'378 Patent, Claim 25	N/A	≤ SM-102 <	N/A	Appendix 153
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

622. I understand that Moderna may rely on its own lipid content testing to dispute testing data produced by Plaintiffs, but I am not aware of any Moderna fractionation data of the Accused Product that would inform whether particles satisfying the lipid content limitations of the Lipid Composition Patents are present, [redacted]

F9	Unexpired	42.6	41.2	13.6	2.6
	Expired	42.9	41.2	13.2	2.6
F10	Unexpired	41.9	42.0	13.9	2.3
	expired	41.9	41.9	13.8	2.4

The above data demonstrate that the Coriolis method is suitable for use on expired samples and that the mere fact of sample expiration does not substantially alter the lipid composition of the mRNA-LNPs in the sample.

647. In addition, as noted in the graphs displayed earlier, the general trends and distributions of each lipid type across fractions are consistent between v1 lots and v2 lots that were tested. *Supra* ¶ 634. The data strongly indicate that the test results from the unexpired samples, are, in fact, representative of the expired samples and that fractionation testing results from the expired lots are equivalent to the fractionation testing results that one would have obtained from those same lots had they been tested prior to expiry. I am therefore confident that infringement of an expired lot means that the same lot infringed prior to expiry.

648. I understand that Moderna has stipulated that Plaintiffs' test results for the samples produced by Moderna are applicable to other lots "containing the same mRNA-LNP part number." Sample Stipulation ¶ 5. That position is consistent with the fact that each of Moderna's part numbers have been qualified to ensure lot-to-lot reproducibility and consistency, as a I have previously discussed. *See, e.g.*, Boyer 5/20/2024 Tr. 27:17-32:14; *supra* Section X.B. With respect to the lots that Moderna did not produce and that Plaintiffs could not test, Dr. Schuster's results are considered indicative of the frequency with which lots within Moderna's corresponding part numbers would contain infringing particles.

649. Accordingly, in the following table, for part numbers 50068, 50075, 50092, 50186, 50211, 50092/50111, and 50092/50141, 50099, 50108/50115, and 50108/50140, and for each of the claims identified above reciting lipid content limitations, I have set forth (1) the

number of lots that were found by Dr. Schuster to contain particles falling with the lipid content limitations for that claim and part number, and (2) the total number of lots Plaintiffs tested from that part number. I then divided the former by the latter to determine the proportion of untested lots within that part number that would infringe the claim. This calculation would determine the percentage of lots within the corresponding part numbers that would infringe the corresponding claim. For part number 50068, the lots tested correspond only to the v1 lots within that number and the percentages apply only to the v1 lots, as Moderna does not dispute that the PVU Formulation lots within part number 50068 infringe the Lipid Composition Patents.

	50068 (3 Lots Tested)		50075 (9 Lots Tested)		50092 (6 Lots Tested)		50186 (5 Lots Tested)		50211 (6 Lots Tested)		50092/50111 (6 Lots Tested)		50092/50141 (5 Lots Tested)		50099 (6 Lots Tested)		50108/50115 (6 Lots Tested)		50108/50140 (6 Lots Tested)	
Pat. Clm.	# Inf.	% Inf.	# Inf.	% Inf.	# Inf.	% Inf	# Inf.	% Inf	# Inf.	% Inf.	# Inf.	% Inf.	# Inf.	% Inf.	# Inf.	% Inf.	# Inf.	% Inf.	# Inf.	% Inf.
069-1	0	0%	0	0%	3	50%	4	80%	3	50%	4	66.7%	1	20%	0	0%	5	83.3%	6	100%
069-15	0	0%	0	0%	3	50%	4	80%	3	50%	4	66.7%	1	20%	0	0%	5	83.3%	6	100%
069-20	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%	0	0%
069-21	0	0%	0	0%	3	50%	4	80%	3	50%	4	66.7%	1	20%	0	0%	5	83.3%	6	100%
359-1	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
359-7	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
359-9	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
359-10	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
359-11	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
359-12	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
359-13	0	0%	6	66.7%	4	66.7%	4	80%	3	50%	5	83.3%	3	60%	3	50%	5	83.3%	6	100%
359-18	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
668-1	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
668-8	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
668-10	0	0%	6	66.7%	4	66.7%	4	80%	3	50%	5	83.3%	3	60%	3	50%	5	83.3%	6	100%
668-15	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
435-7	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
435-8	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
378-1	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
378-2 378-13	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	6	100%	6	100%
378-7 378-18 378-24	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	5	83.3%	6	100%
378-25	3	100%	9	100%	6	100%	5	100%	6	100%	6	100%	5	100%	6	100%	5	83.3%	6	100%

650. It is also the case, however, that Moderna's part numbers within its target v1 Formulation do not meaningfully differ with respect to whether they would generate infringing particles. I understand that beyond the PVMP—which distinguishes part numbers on the basis of scale, manufacturing sites, and the mRNA payload(s) used to generate the COVID-19 vaccine variants—Moderna has not set forth any difference with respect to LNP lipid composition between part numbers within its target v1 Formulation. These differences do not result in any meaningful change in product quality, *see supra* Sections X.B, X.C; *infra* XIII.F.2, and I am not aware of any evidence that indicates that they would affect the lipid molar ratio of particles within the Accused Product. Accordingly, I have applied the same claim-by-claim analysis as above, but with respect to lots within Moderna's target v1 Formulation, to ascertain the proportion of v1 Formulation lots that would infringe the lipid content limitations.

	v1 Formulation (27 Lots Tested)	
Patent Claim	**# Infringing Lots**	**% Infringing Lots**
069-1	0	0%
069-15	0	0%
069-20	0	0%
069-21	0	0%
359-1	27	100%
359-7	27	100%
359-9	27	100%
359-10	27	100%
359-11	27	100%
359-12	27	100%
359-13	16	59.3%
359-18	27	100%
668-1	27	100%
668-8	27	100%
668-10	16	59.3%
668-15	27	100%
435-7	27	100%
435-8	27	100%
378-1	27	100%
378-2 378-13	27	100%
378-7 378-18 378-24	27	100%
378-25	27	100%

651. The same is also true of part numbers that Moderna has designated belonging to its target v2 Formulation. Moderna has not set forth any difference with respect to LNP lipid composition between part numbers within its target v2 Formulation. Any differences across part numbers do not result in any meaningful change in product quality, *see supra* ¶ 355, and I am not aware of any evidence that indicates that they would affect the lipid molar ratio of particles within the Accused Product. Accordingly, I have applied the same claim-by-claim analysis as above, but with respect to lots within Moderna's target v2 Formulation, to ascertain the proportion of v2 Formulation lots that would infringe the lipid content limitations.

	v2 Formulation (40 Lots Tested)	
Patent Claim	**# Infringing Lots**	**% Infringing Lots**
069-1	26	65%
069-15	26	65%
069-20	0	0%
069-21	26	65%
359-1	40	100%
359-7	40	100%
359-9	40	100%
359-10	40	100%
359-11	40	100%
359-12	40	100%
359-13	30	75%
359-18	40	100%
668-1	40	100%
668-8	40	100%
668-10	30	75%
668-15	40	100%
435-7	40	100%
435-8	40	100%
378-1	40	100%
378-2 378-13	40	100%
378-7, 378-18 378-24	39	97.5%
378-25	39	97.5%

652. I have been asked by counsel to prepare a table summarizing my analysis of Plaintiffs' testing data on a claim-by-claim and lot-by-lot basis, applying Plaintiffs' results for the tested lots and the proportional values above on both a part number basis and Moderna's v1 and v2 Formulations for untested lots. I have provided this table in **Appendix 154**.

2. Infringement by the Doctrine of Equivalents

653. In the previous sections, I set forth my opinions as to how the Accused Product literally infringes the lipid content limitations of the Lipid Composition Patents. Separate and apart from that analysis, it is also my opinion that Accused Product infringes the lipid content limitations of the Lipid Composition Patents pursuant to the doctrine of equivalents. I set forth my understanding of the legal test for infringement under the doctrine of equivalents above. *Supra* Section III.B.3. For convenience, I have arranged my opinions below with respect to the limitations related to the particular type of lipid (that is, cationic lipid; non-cationic lipid; and conjugated and/or PEG-lipid).

a. Cationic Lipid

654. Whereas Moderna disputes infringement of the v1 and v2 Formulations on the basis of their target cationic mol %, to my knowledge, Moderna does not dispute that the PVU Formulation meets the claimed cationic lipid mol % limitations of the Lipid Composition Patents.[132] *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57, 65, 122-23; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (No. 13) (June 7, 2024) at 6-9; *see also*, *e.g.*, MRNA-GEN-01374118; MRNA-GEN-01747429 at -431 (stating Moderna's goal to "[a]void licensing (intellectual property regarding 50 mole percent cationic lipid)").

[132] In this section of my report, Section XIII.F.2.a, "claimed cationic lipid mol % limitations" refers to the cationic lipid limitations in the '069 patent claim 1; the '359 patent claims 1 and 7; the '668 patent claims 1 and 8; and the '435 patent claim 1. I recognize that the claims that depend on these claims also incorporate those limitations.

655. Based on Moderna's documents, statements made by Moderna's employees, and representations Moderna has made to the FDA, it is my opinion that the cationic lipid mol % of lots of Moderna's COVID-19 vaccine drug product formulated using the target v1 Formulation (including specifically its 48.5 mol % target for the SM-102 cationic lipid), is insubstantially different from the claimed cationic lipid mol % limitations, which undisputedly encompasses the 50 mol % cationic lipid target of the PVU Formulation that Moderna used to formulate lots of the Accused Product in its Phase 1, Phase 2, and part of its Phase 3 clinical trials. Furthermore, it is my opinion that the cationic lipid mol % of Moderna's v1 Formulation lots performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed cationic lipid mol % limitations. Likewise, it is my opinion that the cationic lipid mol % of lots of Moderna's COVID-19 vaccine drug product formulated using the target v2 Formulation (including specifically its 48 mol % target for the SM-102 cationic lipid), is insubstantially different from the claimed cationic lipid mol % limitations—which again undisputedly encompasses the 50 mol % cationic lipid target of the PVU Formulation—and performs substantially the same function, in substantially the same way, to achieve substantially the same results as the claimed cationic lipid mol % limitations. As I will explain below, the reduction in the target cationic lipid from 50 mol % in the PVU Formulation to 48.5 mol % in the v1 Formulation and 48.0 mol % in the v2 Formulation, and the subsequent formulation of various lots with measured lipid content values of less than 50 mol % cationic lipid, do not render the COVID-19 drug product substantially different from: (a) a product having LNPs with a target composition of 50 mol % cationic lipid, such as in the PVU Formulation (for which Moderna does not dispute infringement on the basis of lipid content) nor (b) lots formulated with

the target PVU, v1, and v2 Formulations that contain 50 mol % (or more) cationic lipid that literally infringe the Patents-in-Suit.

656. **Equivalent Function.** The POSA would understand that the function of the cationic lipid in the claimed cationic lipid mol % limitations is to provide a positive electrostatic charge that subsequently interacts with the negative charge of the nucleic acid to facilitate encapsulation of the nucleic acid. This function is supported by the disclosure of the Lipid Composition Patents as well the contemporaneous scientific literature. *See, e.g.*, '069 patent, 12:51-52 ("The term 'cationic lipid' refers to any of a number of lipid species that carry a net *positive charge* at a selected pH." (emphasis added)); *see also, e.g.*, Semple 2001 at 153 ("The inclusion of cationic lipids in lipid formulations improves the association with polyanionic nucleic acids."); *supra* Sections VI.B, VIII.B.1. In challenging the validity of the '069 and '435 patents in the IPR proceedings before the PTAB, *see supra* Section VIII.C, Moderna relied on the testimony of Dr. Andrew S. Janoff, who explained to the Board that "[c]ationic lipids have been used in the construction of nucleic acid-lipid particles because they interact with the negative charges on nucleic acid payloads facilitating the formation of such particles." *Moderna Therapeutics, Inc. v. Protiva Biotherapeutics, Inc.*, IPR2018-00739, Exhibit 1007 ¶ 62 (P.T.A.B. Mar. 5, 2018) ("Janoff '435 IPR Declaration"); *see also Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554, Exhibit 1008 ¶ 62 (P.T.A.B. Jan. 2, 2019) ("IP '069 IPR Declaration"). Accordingly, I do not understand Moderna to dispute the function of the cationic lipid element, including the mol % thereof, recited in the Asserted Claims of the Patents-in-Suit.

657. The function of the SM-102 cationic lipid and its mol % concentration in drug product lots of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, is substantially the same as the cationic lipid and its mol % in the claimed

invention. As discussed earlier in my report, Moderna describes the function of the SM-102 lipid in its COVID-19 vaccine as "the ionizable lipid component of the [redacted] *See supra* XII.A, ¶ 341; MRNA-GEN-00988589 at -591; MRNA-GEN-00018512 at -513; *see also, e.g.,* MRNA-GEN-02316901 at -922. I have not seen any evidence, nor does Moderna appear to contend, that the SM-102 lipids within the mRNA-LNPs of any of its specification-conforming drug product lots, including lots formulated with a target SM-102 of 48.5 mol % (v1) or 48 mol % (v2), function substantially differently than SM-102 lipids in mRNA-LNPs with 50 mol % cationic lipid, including as used in the PVU Formulation and Moderna's other clinical programs and development programs using a 50 mol % cationic lipid target. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. It is my understanding that across all lots of Moderna's COVID-19 vaccine drug product, the SM-102 lipids and their concentration in the product help drive electrostatic interaction with the mRNA. *See supra* ¶ 341; MRNA-GEN-00988589 at -591; MRNA-GEN-00018512 at -513; *see also* MRNA-GEN-02316901 at -922. Furthermore, to my knowledge, Moderna does not contend that the cationic lipid and its mol % concentration in lots formulated with the PVU, v1, and v2 Formulations performs substantially different functions by virtue of differences in the lots' respective target lipid molar ratios or measured lipid content in the formulated product. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental

Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Indeed, the LNPs of Moderna's COVID-19 vaccine drug product, whether formulated with the PVU, v1, or v2 Formulations, including their respective mol % targets for the SM-102 cationic lipid, perform the same function of [redacted] and enablement of "cellular uptake of the nanoparticle, endosomal escape, and ultimately productive cytosolic display of the mRNA such that protein translation may occur." MRNA-GEN-00988461 at -468; *see also* MRNA-GEN-00306589 -597-600. Moderna's description of the role served by the mRNA-LNPs of the Accused Product—encapsulation of the mRNA, delivery of the mRNA, and eventual facilitation of protein translation—has remained constant throughout Moderna's regulatory submissions, notwithstanding the change in the target cationic lipid mol % in the v1 and v2 Formulations. *See, e.g.*, MRNA-GEN-00999602; MRNA-GEN-00988461 at -467-468; MRNA-GEN-00305704; MRNA-GEN-00302728 at -733; MRNA-GEN-01806150; MRNA-GEN-00177578; MRNA-GEN-00047244 at -248; MRNA-GEN-00046242 at -246; MRNA-GEN-01799476 at -478-479; MRNA-GEN-01799027.

658. I am aware of statements—by Moderna and in the literature—suggesting that the cationic lipid may be serving additional functions in the LNP. *See, e.g.*, Janoff '069 IPR Declaration ¶ 62 ("Since cationic lipids can also interact with negative charges on cell membranes (under appropriate conditions, depending on the specific mixture of lipids in the carrier particles), this has been believed to promote, in some cases, the fusion event necessary for the effective delivery of the nucleic acid."). However, I have not seen any evidence—and I am not aware of Moderna contending—that any such function would differ substantially between lots formulated with a target SM-102 amount of 48.5 mol % (v1) or 48 mol % (v2), as compared

to mRNA-LNPs with 50 mol % cationic lipid, including as used in the PVU Formulation. To the contrary, as I discuss in more detail below, Moderna found that such changes in the amount of SM-102 in its mRNA-LNPs did *not* affect efficacy. *See infra* ¶¶ 661-664. That is consistent with my opinion that the function of the amount of cationic lipid is the same across Moderna's different target formulations and as compared to the claimed cationic lipid mol % amounts.

659. **Function in an Equivalent Way.** The POSA would further understand the SM-102 cationic lipid and its mol % concentration in drug product lots of the of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, to perform substantially the same function of the cationic lipid of the Asserted Claims, including its recited mol %, in substantially the same way. The way in which the SM-102 lipids of the drug product achieve their function is through their structure, chemical composition, and concentration, which enables the lipids to carry a positive charge in acidic conditions and subsequently helps to drive chemical interactions, [redacted] *See supra* ¶ 341. The same chemical mechanism is disclosed in the Lipid Composition Patents. *See, e.g.*, '069 patent, 12:53-13:3 (describing various structural features of cationic lipids that could be used in the invention, such as a protonatable tertiary amine group).

660. It is my understanding that the SM-102 lipids in all lots of Moderna's COVID-19 vaccine drug product, regardless of the target or measured mol % of SM-102 in that lot, are the same structure and possess the same structural features. *See supra* ¶ 341. Moderna does not appear to contend that the SM-102 lipids within the mRNA-LNPs of any of its specification-conforming lots, including lots formulated with a target SM-102 of 48.5 mol % (v1) or 48 mol % (v2) function in a substantially different way than SM-102 lipids in mRNA-LNPs with 50 mol % cationic lipid, including as used in the PVU Formulation and Moderna's other clinical programs

and development programs using a 50 mol % cationic lipid target. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 22-23; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Indeed, the mRNA-LNPs of Moderna's COVID-19 vaccine drug product, including within lots formulated with the PVU, v1, and v2 Formulations, function in substantially the same way. As noted above, the mRNA-LNPs of the Accused Product provide a positive electrostatic charge that subsequently

[redacted]

[redacted] *Supra* ¶ 656; *see also* MRNA-GEN-00988461 at -467-468; MRNA-GEN-02634802 at -811. I have not seen any evidence, nor does Moderna appear to contend, that the mRNA-LNPs of any of its lots of the COVID-19 vaccine drug product, including lots formulated with a target SM-102 of 48.5 mol % (v1), or 48 mol% (v2) function in a substantially different way from mRNA-LNPs with 50 mol % cationic lipid, including as used in the PVU Formulation and Moderna's other clinical programs and development programs using a 50 mol % cationic lipid target. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. The underlying mechanism of action for the LNPs in all lots of Moderna's COVID-19 vaccine drug product, across all of Moderna's target PVU, v1, and v2 Formulations, has consistently been represented by Moderna to the FDA as being the same, and I am aware of no reason why the mechanism of action of these LNPs should differ.

661. **Equivalent Results.** It is further my opinion that the SM-102 cationic lipid and its mol % concentration in drug product lots of the Accused Product, including within lots

formulated with the PVU, v1, and v2 Formulations, achieve substantially the same result as the cationic lipid and its mol % in the claimed invention. As explained in the Lipid Composition Patents, the result of the cationic lipid limitation, including its recited mol % in the claims, in the context of the invention as a whole, is the effective and efficient intracellular delivery of nucleic acid. *See, e.g.*, '069 patent, 2:55-57 (observing the "strong need in the art for novel and more efficient methods and compositions for introducing nucleic acids such as siRNA into cells"), 5:51-61 (disclosing that the inventive nucleic acid-lipid particles, including the claimed cationic lipid mol %, "advantageously impart increased activity of the encapsulated nucleic acid," "improved tolerability of the formulations in vivo" and "are substantially non-toxic to mammals such as humans."), 6:13-19 ("For instance, the '1:57 SNALP' and '1:62 SNALP' formulations described herein are exemplary formulations of the present invention that are particularly advantageous because they provide improved efficacy and tolerability in vivo, are serum-stable, are substantially non-toxic, are capable of accessing extravascular sites, and are capable of reaching target cell populations."); 57:50-55 (noting that the particles of the invention encapsulate and protect from degradation the active or therapeutic agent (i.e., nucleic acid)). As I explain below, Moderna's COVID-19 vaccine drug product, whether formulated with the PVU, v1, or v2 Formulations, including drug product formulations with reported cationic lipid content values of 45 to 50 mol % cationic lipid, achieve substantially the same result, including with respect to efficacy (immunogenicity), safety, and stability compared to formulations using 50 mol % cationic lipid, including the PVU Formulation for which Moderna does not dispute meets the claimed cationic lipid mol % limitations. *See supra* Sections X.D, IX.C; *see also, e.g.*, Parsons 6/7/2024 Tr. 191:2-9 ("We believed that additional safety data would not be required. That's the reason that we made the change in the way that we did. Clearly we did not believe

that there was an impact to immunogenicity, and so the change could be affirmatively made without an impact to the clinical study."), 202:17-203:4 (Q. "Do you know if there are significant differences in safety and efficacy across batches with different lipid compositions?" A. "So we obviously studied many batches of the vaccine as part of clinical development of the product. I am not aware of any variations that were clinically meaningful.").

662. Consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, each specification-conforming lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, exhibit substantially equivalent immunogenicity and efficacy, including as compared to formulations with 50 mol % cationic lipid that fall within the claimed cationic lipid mol % limitations. *See supra* Section X.D; MRNA-GEN-00601091 at -093 (July 29, 2020 email from Jack Kramarczyk, [redacted]

663. In particular, Moderna has repeatedly concluded and represented that the reduced SM-102 mol % accompanying the switch from the PVU to the v1 Formulation and then to the v2 Formulation (from a starting target 50 mol % cationic lipid in the PVU Formulation) had no substantial impact on the immunogenicity of the Accused Product. *See supra* Section X.D; MRNA-GEN-00604539 at -555 [redacted]

[redacted]

664. [redacted]

[redacted]

MRNA-GEN-00734102 at -108; *see also* MRNA-GEN-00482490. In his deposition, Dr. Parsons explained that these PowerPoint slides are a "compilation of data" that outlined the strategy "[Moderna] used for [redacted] Parsons 6/7/2024 Tr. 203:18-208:15. [redacted] Parsons 6/7/2024 Tr. 211:4-212:7. I do not believe that Moderna contends that any of its lots of the Accused Product differ substantially with respect to immunogenicity by virtue of its SM-102 lipid content compared to LNPs having 50 mol % cationic lipid. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. On the contrary, Moderna sold the lots without any indication, to the FDA or the public, that they differed substantially in immunogenicity or any other respect.

665. In addition, consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, each specification-conforming lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, exhibit substantially equivalent safety, including as compared to formulations with 50 mol % cationic lipid that fall within the claimed cationic lipid mol % limitations. *See supra* Section X.D. I do not believe that Moderna contends that any of its lots of the Accused Product

have different tolerability or safety by virtue of its SM-102 lipid content. In particular, Moderna has concluded and represented that variations in the mol % of SM-102 in the Accused Product, including reduced SM-102 caused by the switch to the target v1 and v2 Formulations (from the target PVU Formulation using 50 mol % cationic lipid) have no substantial impact on the safety of its COVID-19 vaccine drug product. *See supra* Section X.D; *see also, e.g.,* Parsons 6/7/2024 Tr. 191:2-9 [redacted] *Supra* Section X.D; *see, e.g.*,

Parsons 6/7/2024 Tr. 181:1-186:2. [redacted]

666. Finally, consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, lots formulated with the PVU, v1, and v2 Formulations exhibit substantially equivalent stability, including as compared to formulations with a measured lipid content of 50 mol % cationic lipid. *See supra* Section X.D; *see also* MRNA-GEN-01802160 at -165 (BLA 125752 Manufacturing Process Development {SM-102 LNP} Manufacturing History) [redacted] MRNA-GEN-00192423 at -423 [redacted] MRNA-GEN-00089073 at -073 [redacted] In particular, Moderna has concluded and represented that variations in the mol % of SM-102 in the Accused Product, including reduced SM-102 caused by the switch to the v1 and v2 Formulations (from the target PVU Formulation using 50 mol % cationic lipid) have no substantial impact on the stability of the Accused Product. *See supra* Section X.D; *see also* MRNA-GEN-00659610 at -610 (August 3, 2020 Email from Don Parsons stating, [redacted]); Kramarczyk 4/30/2024 Tr. 199:15-19 (testifying, after being asked whether he has any basis to believe [redacted]

[redacted] I do not understand Moderna to contend that the different SM-102 mol % values measured across the lots of its drug product cause the mRNA-LNPs within its formulations to differ substantially with respect to stability, including as compared to mRNA-LNPs with 50 mol % cationic lipid. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Supplemental Responses and Objections to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9.

667. **Insubstantial Differences.** It is my further opinion that, in view of the current and historical understandings in the field, the cationic lipid content of each lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, are insubstantially different both from one another and insubstantially different from the claimed cationic lipid mol % limitations. *See supra* Section X.D; *see also* MRNA-GEN-01264023 at -023. [redacted] Parsons 6/7/2024 Tr. 130:3-12. In Moderna's 10-K for the fiscal year ending December 31, 2019 (submitted February 27 2020), Moderna stated that its "Phase 2 study" of CMV mRNA-1647 "is testing the intended Phase 3 formulation, which contains the ***same lipid nanoparticle ("LNP")*** used in the Phase 1 study," MRNA-GEN-01156478 at -527 (emphasis added), despite Moderna's January 2020 internal presentation showing its [redacted] MRNA-GEN-00601067 at -070;

Kramarczyk 4/30/2024 Tr. 148:1-151:20. To my knowledge, Moderna has not corrected its 10-K. *See* EDGAR landing page.[133] I agree with Moderna about the sameness of the LNP contained in formulations using the PVU and v2 target ratios. The variations in the mol % of SM-102 across the lots of Moderna's COVID-19 drug product are insubstantial, and even Moderna itself has described the changes to its target formulation of the Accused Product as "minor,"[134] "subtle,"[135] "slight,"[136] a "small change,"[137] and a "rounding error[]."[138] As I describe at length above in this Section, there is no evidence that Moderna's modifications of its target lipid ratios of SM-102 from 50 mol % to 48.5 mol % to 48 mol % produced any substantial change in any product quality attribute. Indeed, given the heterogeneity of lipid compositions within Moderna's LNP batches, *see supra* Sections IX.E, X.E.2, it is likely that the distribution of SM-102 amounts across particles is highly overlapping between the PVU, v1, and v2 Formulations (in other words, batches made with the PVU, v1, and v2 formulations are likely to have many particles with overlapping amounts of SM-102). Moderna has repeatedly represented that the variations in SM-102 content in its COVID-19 drug product do not yield any difference in the performance of the function of the lipid particles, including with regard to safety, efficacy, and stability of its product.

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[133] SEC, *Edgar Entity Landing Page*, available at https://www.sec.gov/edgar/browse/?CIK=1682852&owner=exclude (accessed Nov. 2024).

[134] *See, e.g.*, MRNA-GEN-00508546 at -562.

[135] *See, e.g.*, MRNA-GEN-00601091 at -094.

[136] *See, e.g.*, MRNA-GEN-00604539 at -555; MRNA-GEN-00657578 at -578 ("[T]he lipid content of this product is being adjusted slightly to reduce the mole% of SM-102 to below 50% for IP purposes.").

[137] *See, e.g.*, MRNA-GEN-00604539 at -549.

[138] *See, e.g.*, MRNA-GEN-00656142.

668. That the target lipid molar ratio originally used for numerous of Moderna's vaccine programs as well as the first lots of the COVID-19 vaccine formulated with the PVU Formulation (*i.e.*, 50:10:38.5:1.5) was taken from Plaintiffs' work and changed due to intellectual-property considerations provides further support that Moderna's COVID-19 drug product is insubstantially different from mRNA-LNPs with 50 mol % cationic lipid that fall within the literal scope of the claims. *See supra* Sections IX.A, X.D; *see also, e.g.*, MRNA-GEN-02635779 at -782-784 (Moderna's BLA noting the literature use of the molar ratio 50:38.5:10:1.5 and also noting how Moderna leveraged "historical knowledge" for the composition of the COVID-19 drug product); MRNA-GEN-00742618 at -621 (describing Moderna's LNP candidate in development as "based on a Phase III program," citing to ALN-TTR-02, and then stating that "[t]he main difference in composition of Moderna's LNP relative to Alnylam's [redacted]"); MRNA-GEN-00741030 at -043-044 (describing how the drug product for its "first clinical" program has a composition of 50:38.5:10:1.5, which it notes is "the same lipid composition used in the Alnylam Phase 3 TTR IV product."); MRNA-GEN-01747429 at -431 [redacted]; MRNA-GEN-00657578 at -578 ("the lipid content of this product is being adjusted slightly to reduce the mole% of SM-102 to below 50% for IP purposes."); Parsons 6/7/2024 Tr. 106:1-6 (testifying, in reference to Exhibit 7, which includes MRNA-GEN-00648789, a PowerPoint presentation in which Moderna discussed the ratio 48.0:38.5:11.0:2.5, "as I mentioned previously, one of the things that we were aware of was that there was intellectual property associated with the molar ratio."); MRNA-GEN-01264023 at -023 (2018 Email correspondence noting that the lipid composition used by Moderna was "virtually identical" to Patisiran).

669. In fact, Moderna's express goal when changing its formulation of various vaccine programs in the 2018-2019 timeframe and again in 2020 for the COVID-19 vaccine drug product was to create a product that was insubstantially different from its formulations with 50 mol % cationic lipid in order to avoid the need to conduct additional clinical trials. *See e.g.*, MRNA-GEN-01747429 at -431 ("We are not setting out to create a more immunogenic product" and "[w]e are not setting out to increase tolerability."); Kramarczyk 4/30/2024 Tr. 173:16-20 ("One of our express goals was that CMV changes should match prior experience for biological endpoints. And I think we achieved that range -- we achieved that goal in the ranges of lipid compositions we explored or identified."); MRNA-GEN-02634802 at -811 (Moderna's BLA Justification of Specifications, noting in the context of the switch to the v2 Formulation, that "[t]he lipid content specifications are adjusted to reflect the formulation modifications of mRNA-1273 DP," stating that the specification limits they selected are "intended to ensure consistency of commercial lots with lots used in clinical trials," and further noting that this selection "incorporate[d] [] clinical knowledge"); Parsons 6/7/2024 Tr. 191:2-9 ("We believed that additional safety data would not be required. That's the reason that we made the change in the way that we did. Clearly we did not believe that there was an impact to immunogenicity, and so the change could be affirmatively made without an impact to the clinical study."). Moderna's goal of creating a sufficiently equivalent product so as to avoid re-conducting Phase I and II testing was particularly critical during the pandemic, for which there was an urgent need to develop the vaccine as quickly as possible and a strong desire to not fall behind other vaccines being developed at that time. *See, e.g.*, MRNA-GEN-02645641 at -644 (May 15, 2020 PowerPoint presentation titled "Board Discussion," stating that "[a]ny further delays in investing risks losing a share of the most valuable early [COVID-19 vaccine] deliveries"); *infra* Section

XVI. As noted earlier, I do not understand Moderna to contend that its lots formulated with the 50:38.5:10:1.5 target PVU Formulation do not meet the cationic mol % claim limitations of the Lipid Composition Patents. *Supra* ¶ 654.

670. Further evidence that each formulation of Moderna's COVID-19 drug product is insubstantially different from drug products with 50 mol % cationic lipid can be found in the fact that [redacted] The lipid content specifications for lots formulated with the PVU, v1, and v2 Formulations are sufficiently broad to encompass and/or overlap substantially with the claimed cationic lipid mol % limitations (as well as other lipid type mol % limitations), as I demonstrated with calculations I made earlier in this report. *See supra* Section X.A. Further, as discussed above, I understand that Moderna previously adopted the same analysis to explain that the [redacted] *See supra* Section X.B; *see also, e.g.*, Hoge 5/22/2024 Tr. 197:8-22; Ryan Declaration ¶ 5 (discussing Moderna's mRNA-1777 RSV vaccine product candidate). Moderna specifically highlighted the fact that the [redacted], *see* MRNA-GEN-01352552 at -554 (BLA Section 3.2.S.2.6) [redacted]

671. Moderna made minor changes to the lipid content specification ranges of the Accused Product when switching from the PVU to v1 to v2 Formulations. *Supra* Section X.D; *see also, e.g.*, MRNA-GEN-00547580 at -583-584; MRNA-GEN-02634802 at -811, -816-819; MRNA-GEN-00556478 at -478. The very purpose of specification ranges and acceptance criteria is to ensure product consistency or comparability as it pertains to quality, safety, and efficacy. *See, e.g.*, FDA Guidance Document Q6A, "Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances" at Section 1.2 ("Specifications are one part of a total control strategy for the drug substance and drug product designed to ensure product quality and consistency."), Section 2.5 ("The basis for the acceptance criteria at the time of filing should necessarily focus on safety and efficacy."). Dr. Parsons, a member of Moderna's COVID-19 Specification Committee, testified that Moderna's "assertion as part of the proposed specification limits was that if those differences were present, they would be present at an acceptable level," and explained that "[o]ur view was that they did not have a significant impact on quality or efficacy of the product . . . [o]r safety." Parsons 6/7/2024 Tr. 301:7-19. Dr. Parsons further testified that Moderna "set specifications based on our clinical experience and the process performance that is relevant to different critical quality attributes." *Id*. at 313:15-18. When setting its specifications, Moderna specifically intended to yield drug product comparable to the drug product used in the clinical trials (with the PVU target lipid molar ratio using 50 mol % cationic lipid), and Moderna did so by [redacted] across its various lots. *See, e.g.*, MRNA-GEN-00998152 (BLA Section 3.2.P.5.6 Justification of Specifications {0.10 mg/mL}) at -204-205 (Figures 24-26 describing distribution of SM-102 lipid content); MRNA-GEN-02634802 at -811. Lots within Moderna's specification could be—and were—sold as Moderna's COVID-19 vaccine and used to vaccinate

the U.S. population, without any indication that the lots differed from each other in any substantial or meaningful way. The reason is simple—they did not differ in any substantial or meaningful way. This opinion is consistent with the opinions offered by Dr. Kimberly Benton. *See* Opening Expert Report of Kimberly A. Benton, Ph.D. Sec. V.

672. Additional evidence of the lack of substantial differences between the formulations of Moderna's specification-conforming COVID-19 drug product lots, including lots that that fall within the claimed cationic lipid mol % limitations, can be found in its lack of testing of within-batch compositional heterogeneity. Moderna had strong reason to suspect that the lipid content of the mRNA-LNPs within its COVID-19 drug product batches varies, [redacted] *See, e.g.*, *supra* Sections X.E.2, IX.E; MRNA-GEN-02644934 at -964-965; MRNA-GEN-00736872 at -875; MRNA-GEN-00589883 at -896; Almarsson 5/31/2024 Tr. 219:2-223:2; MRNA-GEN-01281871. [redacted] Parsons 6/7/2024 Tr. 257:4-14; *supra* ¶ 463; MRNA-GEN-01274243 at -243. [redacted] *Supra* Section IX.E. [redacted]

[redacted]

673. Based on Moderna's own evidence, representations it has made in its own internal reports, to others (including the FDA), in the circumstances of this case, and in view of the technology and state of the art, specification-conforming PVU Formulation lots are insubstantially different from specification-conforming v1 Formulation lots and are further insubstantially different from specification-conforming v2 Formulation lots, and the relative proportion of cationic lipid within the three formulations performs substantially the same function, in substantially the same way, to achieve substantially the same results both relative to each other and relative to the cationic lipid content limitations recited in the Lipid Composition Patents. As noted in the paragraphs above, this opinion is supported by: (a) evidence of Moderna using Plaintiffs' lipid molar ratios for its target PVU Formulation, with 50 mol % cationic lipid, in its Phase 1, 2, and early Phase 3 lots; (b) Moderna's lipid content specification ranges for its drug product, which are sufficiently broad to encompass and/or overlap substantially with the claimed cationic lipid mol % limitations; and (c) Moderna's de-prioritization of studying the intra-batch lipid content heterogeneity of its COVID-19 vaccine drug product.

674. It is further my opinion that specification-conforming lots of Moderna's COVID-19 vaccine drug product produced within the same target formulation (*i.e.*, PVU lots as compared to other PVU lots; v1 lots as compared to other v1 lots; and v2 lots as compared to other v2 lots) are insubstantially different from one another and the cationic lipid content of the mRNA-LNPs in these lots perform substantially the same function, in substantially the same way, to achieve substantially the same results both relative to each other and relative to the cationic lipid content limitations recited in the Lipid Composition Patents. To my knowledge,

Moderna does not contend that lots produced with the same target molar ratio are substantially different from one another. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Further, to my knowledge, Moderna has never asserted to the FDA, public, or otherwise, that lots of Moderna's COVID-19 drug product formulated with the same target lipid molar ratio substantially differ from each other in any respect by virtue of differences in the measured lipid ratio of the lots. To the contrary, as I have explained in detail above, Moderna has consistently maintained that all specification-conforming lots of its COVID-19 vaccine to be of comparable quality, including with respect to their safety, efficacy, and stability. Accordingly, the v1 lots that literally infringe the asserted claims (identified *supra* Section XIII.F.1), including the claimed cationic lipid mol % limitations, are insubstantially different from those that do not infringe literally (if any), and the same is true for Moderna's v2 lots.

675. Additionally, it is my opinion that specification-conforming lots of Moderna's COVID-19 drug product produced within the same mRNA-1273 LNP part number (*e.g.*, lots falling within mRNA-1273 LNP part number 50075 lots as compared to other lots falling within that same part number 50075) are insubstantially different from one another and perform substantially the same function, in substantially the same way, to achieve substantially the same results. To my knowledge, Moderna does not contend that lots produced with the same mRNA-1273 LNP part number are substantially different from one another. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to

Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. In fact, Moderna's treatment of its mRNA-1273 LNP part numbers would indicate that such part numbers are representative of versions of the drug product in which each lot within that version is viewed as equivalent to one another. *Supra* ¶ 355; *see also, e.g.*, MRNA-GEN-02615390 at -422-425 (demonstrating how each of Moderna's part numbers are associated with product specifications); D.I. 225 at ¶ 5 (The parties' Stipulation for samples testing in which Moderna agreed to a provision whereby "Moderna will not make any argument about the applicability of any test data generated by Plaintiffs from produced lots to other lots containing the same mRNA-LNP part number on the basis that such lots containing the same mRNA-LNP part number were not produced pursuant the parties' agreed-upon protocol."). Accordingly, the drug product lots manufactured using mRNA-1273 LNP part number 50075 that literally infringe the asserted claims (identified *supra* Section XIII.F.1), including the claimed cationic lipid mol % limitations, are insubstantially different from the drug product lots manufactured using mRNA-1273 LNP part number 50075 that do not infringe literally (if any), and the same is true for all other drug product lots and corresponding mRNA-1273 LNP part numbers of Moderna's drug product.

676. [redacted]

677. It is my opinion that, just as the mRNA-LNPs of Moderna's specification-conforming drug product lots are insubstantially different from one another and have

insubstantially different content of cationic lipid, it is also the case that each specification-conforming lot of [redacted] *Supra* Section X.D. The target lipid molar ratio of the [redacted] used to manufacture the PVU lots literally infringes the cationic lipid content limitations of the Lipid Composition Patents, and to my knowledge, Moderna does not assert any substantial differences between the [redacted] used to manufacture PVU Formulation lots versus v1 and v2 Formulation lots, and its own documents and representations to the FDA indicate that such LNPs are equivalent. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9; MRNA-GEN-00768481 at -482 ("CQAs are applied to the drug substance, excipients, intermediates (in-process materials), and drug product and are defined by their impact to Safety and Efficacy."); MRNA-GEN-00547580 at -580-582 ("Concentration changes did not impact [redacted] process performance, in-process physical stability, or physiochemical properties against a control batch with the previous lipid concentration targets."); MRNA-GEN-00081323 at -326 [redacted]

[redacted] MRNA-GEN-01352552 at -554.

678. The ultimate function, way of accomplishing the function, and result achieved by the cationic lipid present in [redacted] As noted above, I have not seen any evidence of, nor do I believe that Moderna contends, that the cationic lipid in the particles in Moderna's drug product and [redacted] serve different functions from one another by virtue of variations in its SM-102 lipid mol %, nor do they accomplish their functions in a different way or achieve different results by virtue of variations in its SM-102 lipid mol %. In other words, [redacted] perform substantially the same function, in substantially the same way, and achieve substantially the same results as particles with a target ratio of 50.5:38.9:10.1:0.5 (PVU [redacted]), which fall within the literal scope of the claims. On a more granular level, the SM-102 lipids of each [redacted] achieve the same function of currently (or in the future) electrostatically attracting the mRNA, in the same way through its positive charge in acidic conditions resulting from the structure and structural features of the cationic lipid, as LNPs with 50 mol % cationic lipid. *See supra* ¶¶ 390, 661-667. In addition, I have not seen any evidence to suggest, nor do I believe that Moderna contends, [redacted] achieve different results. To my knowledge, [redacted]

drug product, whether using the v1 Formulation or v2 Formulation, has the same target lipid ratio. *Supra* Section X.B; *see, e.g.*, MRNA-GEN-00039212 at -219; MRNA-GEN-01424228 (showing that, for example, SM-102 LNP part number 40079 was used to manufacture both v1 and v2 Formulation lots); MRNA-GEN-00044166 (PD-REP-102, Moderna's internal report documenting the change from the PVU to the v1 Formulation) at -168 [redacted] should perform substantially the same function, in the same way and yield the same results, and should not differ substantially from one another nor from precursor LNPs with 50 mol % cationic lipid.

679. **Hypothetical Claims.** As I describe above, I have been informed by counsel that an optional way of conducting the doctrine of equivalents analysis is to construct a "hypothetical claim" and assess whether the Accused Product would literally infringe that claim. *Supra* ¶ 45. In my opinion, such a "hypothetical claim" could recite, for example, a lower limit of 45 mol % (rather than 50 mol %) cationic lipid. As I describe at length above in this section, Moderna concluded that there is no difference when the target amount of cationic lipid is decreased [redacted]. As further discussed at length above, mRNA-LNPs with 45-50 mol % cationic lipid are insubstantially different from one another and perform substantially the same function, in substantially the same way, to achieve substantially the same results. Therefore, it is my opinion that a potential "hypothetical claim" would recite a nucleic acid-lipid particle where the lower limit on the amount of cationic lipid is 45 mol %, rather than 50 mol %. For each Asserted

Claim with a cationic lipid mol % limitation, it is possible to assess which lots of Moderna's COVID-19 drug product and SM-102 LNP would fall within the scope of the Asserted Claims having this hypothetical lower limit of 45 mol % cationic lipid, based on their certificates of analysis.

680. Within this hypothetical claim framework, based on information currently available and known to me, I have identified lots of Moderna's COVID-19 drug product and lots of [redacted] (which I use as a proxy for the [redacted], for the reasons explained above, *supra* Section X.D) that would infringe based on a hypothetical claim with a lower limit of 45 mol % cationic lipid, using appropriate rules of rounding and informed by Moderna's COA data. The table below indicates Appendices, on a claim-by-claim basis, which identify the infringing lots. For clarity, I have highlighted the hypothetical claim limitations.

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'069 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 44
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 45
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 20	44.5	≤ SM-102 <	65.5	Appendix 46
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	9.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 21	44.5	≤ SM-102 <	65.5	Appendix 47
	31.5	≤ Cholesterol <	36.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'359 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 48
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 7	44.5	≤ SM-102 <	60.5	Appendix 49
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 9	44.5	≤ SM-102 <	65.5	Appendix 50
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 10	44.5	≤ SM-102 <	65.5	Appendix 51
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 11	44.5	≤ SM-102 <	65.5	Appendix 52
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 12	44.5	≤ SM-102 <	65.5	Appendix 53
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 13	44.5	≤ SM-102 <	65.5	Appendix 54
	29.5	≤ Cholesterol <	35.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 18	44.5	≤ SM-102 <	65.5	Appendix 55
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 56
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	44.5	≤ SM-102 <	60.5	Appendix 57
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'668 Patent, Claim 10	44.5	≤ SM-102 <	65.5	Appendix 58
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	35.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 59
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	44.5	≤ SM-102 <	85.5	Appendix 60
	12.5	≤ Non-Cationic <	49.55	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	44.5	≤ SM-102 <	85.5	Appendix 61
	12.5	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

[redacted]				
Patent Claim	**Lipid Molar Ratio Range (%)**			[redacted]
'069 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 62
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	2.5	
'069 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 63
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 64
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 7	44.5	≤ SM-102 <	60.5	Appendix 65
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

Patent Claim	Lipid Molar Ratio Range (%)			[redacted]
'359 Patent, Claim 9	44.5	≤ SM-102 <	65.5	Appendix 66
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 10	44.5	≤ SM-102 <	65.5	Appendix 67
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 11	44.5	≤ SM-102 <	65.5	Appendix 68
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 12	44.5	≤ SM-102 <	65.5	Appendix 69
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 18	44.5	≤ SM-102 <	65.5	Appendix 70
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 71
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	44.5	≤ SM-102 <	60.5	Appendix 72
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 73
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	44.5	≤ SM-102 <	85.5	Appendix 74
	12.5	≤ Non-Cationic <	49.55	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	

Patent Claim	Lipid Molar Ratio Range (%)			[redacted]
'435 Patent, Claim 8	44.5	≤ SM-102 <	85.5	Appendix 75
	12.5	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

681. The exhibits recited in the above table assume a hypothetical claim limitation of 45 mol % cationic lipid as a lower limit. However, applying the same analysis and calculation rubric, one may identify the batches that infringe with other hypothetical claims with lower limits of cationic lipid that are slightly higher—for example, 46 mol %; 47 mol %; 48 mol %; 48.5 mol %; and 49 mol %—all of which would be equivalent to claims having a lower limit of 50 mol %. One would simply need to take the exhibits listed in the previous paragraph and remove the batches with SM-102 amounts less than the aforementioned hypothetical claims (with appropriate rounding). Those alternative groups of batches are incorporated in my analysis and conclusions, and I reserve the right to rely on them.

b. Non-Cationic Lipid

682. To my knowledge, Moderna does not dispute that its COVID-19 drug product meets the claimed non-cationic lipid mol % limitations of the Lipid Composition patents,[139] nor does Moderna dispute infringement by the Accused Product generally of claim limitations that recite an upper range of non-cationic lipid of 49.5 mol %. *See, e.g.*, Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57, 62-69; Moderna's Fourth Supplemental Objections and Response

[139] In this section of my report, Section XIII.F.2.b, "claimed non-cationic lipid mol % limitations" refers to the non-cationic lipid limitations in the '668 patent claim 1 and the '435 patent claim 1. I recognize that the claims that depend on these claims also incorporate those limitations.

to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. In the Lipid Composition Patents, non-cationic lipid is defined as "any amphipathic lipid as well as any other neutral lipid or anionic lipid." *See, e.g.*, '069 Patent 11:21-26, 11:56-12:50. Claims 7 and 8 of the '435 Patent are dependent on claim 5, which recites that "the non-cationic lipid comprises a mixture of a phospholipid and cholesterol or a derivative thereof." Similarly, claim 1 of the '668 Patent, of which claims 8, 10, and 15 are dependent, recites that the non-cationic lipid "compris[es] a mixture of phospholipid and cholesterol or a derivative thereof." The non-cationic lipid component of Moderna' COVID-19 vaccine corresponds to the cholesterol and DSPC used in the mRNA-LNPs of the Accused Product. *See supra* Sections X.A, XIII.D. Accordingly, the PVU Formulation with 10 mol % DSPC and 38.5 mol % cholesterol (combined 48.5 mol %) and the v2 Formulation with 11 mol % DSPC and 38.5 mol % cholesterol (combined 49.5 mol %) include target lipid content that falls within the claimed non-cationic lipid mol % limitations. *See, e.g.*, Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. To my knowledge, Moderna does not assert any differences between its COVID-19 drug product formulated with the v1 Formulation as compared to the PVU or v2 Formulation on the basis of the combined mol % of phospholipid and cholesterol. *Id*. The v1 Formulation, with a target molar ratio of 11.1 mol % DSPC and 38.9 mol % cholesterol (combined 50 mol %) is insubstantially different from, and performs substantially the same function, in substantially the same way, to achieve substantially the same results, as a target formulation having up to 49.5 mol % non-cationic lipid.

683. As I discuss in detail above, based on Moderna's documents, statements made by Moderna's employees, and representations Moderna has made to the FDA, it is my opinion that the non-cationic lipid mol % of lots of Moderna's COVID-19 vaccine drug product formulated

using the target v1 Formulation (including specifically its 50 mol % target for the combined non-cationic lipid), is insubstantially different from the claimed non-cationic lipid mol % limitations, which undisputedly encompasses the 48.5 and 49.5 mol % non-cationic lipid targets of the PVU and v2 Formulation. *See supra* Sections X.D, XIII.F.2.a. The target non-cationic lipid amount in the v1 Formulation does not introduce any substantial differences in the drug product produced from the v1 Formulation as compared to (a) a product having LNPs with a target composition falling within the claimed non-cationic lipid mol % limitations (e.g., 49.5 mol %), such as in the PVU and v2 Formulation (for which Moderna does not dispute infringement on the basis of non-cationic lipid content) nor (b) lots formulated with the target PVU, v1, and v2 Formulations that contain up to 49.5 mol % non-cationic lipid that literally infringe the Patents-in-Suit. *See, e.g.*, MRNA-GEN-00604539 at -555 [redacted] MRNA-GEN-00508546 at -562 [redacted] It is further my opinion that the non-cationic lipid mol % of Moderna's v1 Formulation lots performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed non-cationic lipid mol % limitations.

684. **Equivalent Function.** The POSA would understand that the function of the non-cationic lipids in the claimed non-cationic lipid mol % limitations is to provide the particle with amphipathicity and hydrophobicity thereby allowing the particle to form a stable complex and

enabling the particles to transfect cells. This function is supported by the disclosure of the Lipid Composition Patents. *See, e.g.*, '435 Patent 12:15-18 ("The term amphipathic lipid refers, in part, to any suitable material wherein the hydrophobic portion of the lipid material orients into a hydrophobic phase, while the hydrophilic portion orients toward the aqueous phase."), 12:42-44 ("The term 'neutral lipid' refers to any of a number of lipid species that exist either in an uncharged or neutral zwitterionic form at a selected pH."), 50:10-13 ("The non-cationic lipids used in the lipid particles of the invention (e.g., SNALP) can be any of a variety of neutral uncharged, zwitterionic, or anionic lipids capable of producing a stable complex."); *supra* Sections VI.B, VIII.B.1. In challenging the validity of the '435 patent in the IPR proceedings before the PTAB, *see supra* Section VIII.C, Moderna relied on the testimony of Dr. Andrew S. Janoff, who explained "it was known that non-cationic 'helper' lipids, e.g., certain phospholipids and/or cholesterols, could be combined with the cationic lipid to influence the ability of the particles to transfect cells." Janoff '435 IPR Declaration at ¶ 63; *see also* '435 IPR Petition at 8, 11. Moderna also relied on the testimony of Dr. Thomas Anchordoquy, who stated that the cholesterol and phospholipid are generally included in particle formulations as "stabilizing component[s] or to provide rigidity to the lipid carrier particle." *Moderna Therapeutics, Inc. v. Arbutus Biopharma Corp.*, IPR2019-00554, Exhibit 1020 ¶ 43 (P.T.A.B. Jan. 2, 2019) ("Anchordoquy '069 IPR Declaration"). Accordingly, I do not understand Moderna to dispute the function of the non-cationic lipid element, including the mol % thereof, recited in the Asserted Claims of the Patents-in-Suit.

685. The function of the cholesterol and phospholipid and their mol % concentration in drug product lots of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, is substantially the same as the mixture of non-cationic lipid and its mol %

in the claimed invention. As discussed earlier in my report, Moderna describes the function of the phospholipid and cholesterol that comprise the non-cationic lipid in its COVID-19 vaccine as promoting "stability," via the structure it provides within the particle, and "fusogenicity" of the LNP. *Supra* ¶ 341; MRNA-GEN-00988589 at -591; MRNA-GEN-02316901 at -922; MRNA-GEN-00018512 at -514; MRNA-GEN-00508546 at -547. I have not seen any evidence, nor does Moderna appear to contend, that the mixture of cholesterol and DSPC lipids within the mRNA-LNPs of any of its specification-conforming drug product lots, including lots formulated with a combined cholesterol and DSPC target of 50 mol % (v1), function substantially differently than the mixture of cholesterol and DSPC lipids in mRNA-LNPs with up to 49.5 mol % non-cationic lipid, including as used in the PVU and v2 Formulations and Moderna's other clinical programs and development programs using up to a 49.5 mol % non-cationic lipid target. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. It is my understanding that across all lots of Moderna's COVID-19 vaccine drug product, the mixture of cholesterol and DSPC lipids and their concentration in the product help promote stability and structure as well as fusogenicity. *See supra* ¶ 341. Furthermore, to my knowledge, Moderna does not contend that the mixture of cholesterol and DSPC and the mixture's mol % concentration in lots formulated with the PVU, v1, and v2 Formulations performs substantially different functions by virtue of differences in the lots' respective target lipid molar ratios or measured lipid content in the formulated product. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs'

Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Indeed, the LNPs of Moderna's COVID-19 vaccine drug product, whether formulated with the PVU, v1, or v2 Formulations, including their respective mol % targets for the mixture of cholesterol and DSPC, perform the same function of [redacted] and enablement of "cellular uptake of the nanoparticle, endosomal escape, and ultimately productive cytosolic display of the mRNA such that protein translation may occur." MRNA-GEN-00988461 at -468; *see also* MRNA-GEN-00306589 at -597-600. Moderna's description of the role served by the mRNA-LNPs of the Accused Product—encapsulation of the mRNA, delivery of the mRNA, and eventual facilitation of protein translation—has remained constant throughout Moderna's regulatory submissions, notwithstanding the change in the target mol % of the mixture of cholesterol and DSPC in the v1 and v2 Formulations. *See, e.g.*, MRNA-GEN-00999602; MRNA-GEN-00988461 at -467-468; MRNA-GEN-00305704; MRNA-GEN-00302728 at -733; MRNA-GEN-01806150; MRNA-GEN-00177578; MRNA-GEN-00047244 at -248; MRNA-GEN-00046242 at -246; MRNA-GEN-01799476 at -478-479; MRNA-GEN-01799027.

686. I am aware of statements—by Moderna and in the literature—suggesting that the non-cationic lipids may be serving additional functions in the LNP. *See, e.g.*, '435 IPR Petition at 11 (stating that "variations in the proportions of non-cationic lipids in certain formulations were reported to impact their ability to deliver nucleic acid payloads"). However, I have not seen any evidence—and I am not aware of Moderna contending—that any such function would differ substantially between lots formulated with a target non-cationic lipid amount of 50 mol % (v1), as compared to mRNA-LNPs with up to 49.5 mol % cationic lipid, including as used in the PVU and v2 Formulations. To the contrary, as I discuss in more detail below, Moderna found

that such changes in the amount of non-cationic lipid in its mRNA-LNPs did *not* affect efficacy. *See infra* ¶¶ 691-692. That is consistent with my opinion that the function of the amount of non-cationic lipid is the same across Moderna's different target formulations and as compared to the claimed amounts.

687. **Function in an equivalent way.** The POSA would further understand the mixture of cholesterol and phospholipid and the mixture's mol % concentration in drug product lots of the of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, to perform substantially the same function of the mixture of non-cationic lipid of the Asserted Claims, including the recited non-cationic mol %, in substantially the same way. The way in which the mixture of cholesterol and DSPC of the drug product achieve their function is through their structure, chemical composition, and concentration, which enables the lipids to provide amphipacicity and hydrophobicity to help provide structure and stability as well as to promote fusogenicity. *See supra* ¶ 341. The same chemical mechanism is disclosed in the Lipid Composition Patents. *See, e.g.*, '435 Patent 12:15-18, 12:42-44, 50:10-13.

688. It is my understanding that cholesterol and DSPC in all lots of Moderna's COVID-19 vaccine drug product, regardless of the target or measured mol % of the non-cationic lipids in that lot, do not change in their structure or structural features across the lots. *See supra* ¶ 341. Moderna does not appear to contend that the cholesterol and DSPC within the mRNA-LNPs of any of its specification-conforming lots, including lots formulated with a target non-cationic lipid of 50 mol % (v1) function in a substantially different way than cholesterol and DSPC lipids in mRNA-LNPs with up to 49.5 mol % non-cationic lipid, including as used in the PVU and v2 Formulations and Moderna's other clinical programs and development programs using an up to 49.5 mol % non-cationic lipid target. *See* Moderna's Corrected Sixteenth

Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 22-23; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Indeed, the mRNA-LNPs of Moderna's COVID-19 vaccine drug product, including within lots formulated with the PVU, v1, and v2 Formulations, function in substantially the same way. As noted above, the mRNA-LNPs of the Accused Product encapsulate the mRNA to "protect[] the mRNA from nucleolytic degradation in biological fluids" and enable "cellular uptake of the nanoparticle, endosomal escape, and ultimately productive cytosolic display of the mRNA such that protein translation may occur." *Supra* ¶ 685. I have not seen any evidence, nor does Moderna appear to contend, that the mRNA-LNPs of any of its lots of the COVID-19 vaccine drug product, including lots formulated with a target non-cationic lipid content of 50 mol % (v1) function in a substantially different way from mRNA-LNPs with up to 49.5 mol % non-cationic lipid, including as used in the PVU and v2 Formulations and Moderna's other clinical programs and development programs using a non-cationic lipid target of up to 49.5 mol %. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. The underlying mechanism of action for the LNPs in all lots of Moderna's COVID-19 vaccine drug product, across all of Moderna's target PVU, v1, and v2 Formulations, has consistently been represented by Moderna to the FDA as being the same, and I am aware of no reason why the mechanism of action of these LNPs should differ.

689. **Equivalent results.** It is further my opinion that the non-cationic lipid mixture (of cholesterol and DSPC) and its mol % concentration in drug product lots of the Accused

Product, including within lots formulated with the PVU, v1, and v2 Formulations, achieve substantially the same result as the non-cationic lipid mixture and its mol % in the claimed invention. As explained in the Lipid Composition Patents, the result of the non-cationic lipid limitation, including its recited mol % in the claims, in the context of the invention as a whole, is the effective and efficient intracellular delivery of nucleic acid. *See, e.g.*, '435 patent, 2:66-3:1 (observing the "strong need in the art for novel and more efficient methods and compositions for introducing nucleic acids such as siRNA into cells"), 5:62-6:5 (disclosing that the inventive nucleic acid-lipid particles, including the claimed non-cationic lipid mol % limitations, "advantageously impart increased activity of the encapsulated nucleic acid," "improved tolerability of the formulations in vivo" and "are substantially non-toxic to mammals such as humans."), 6:24-30 ("For instance, the '1:57 SNALP' and '1:62 SNALP' formulations described herein are exemplary formulations of the present invention that are particularly advantageous because they provide improved efficacy and tolerability in vivo, are serum-stable, are substantially non-toxic, are capable of accessing extravascular sites, and are capable of reaching target cell populations."); 6:31-38 (noting that the particles of the invention encapsulate the active or therapeutic agent (i.e., nucleic acid)). As I explain below, Moderna's COVID-19 vaccine drug product, whether formulated with the PVU, v1, or v2 Formulations, including drug product formulations with reported non-cationic lipid content values of 49.5 to 53 mol % non-cationic lipid, achieve substantially the same result, including with respect to efficacy (immunogenicity), safety, and stability compared to formulations using up to 49.5 mol % non-cationic lipid, including the PVU and v2 Formulations, which Moderna does not dispute meet the claimed non-cationic lipid mol % limitations. *See supra* Sections X.D, IX.C; *see also, e.g.*, Parsons 6/7/2024 Tr. 191:2-9 ("We believed that additional safety data would not be required.

That's the reason that we made the change in the way that we did. Clearly we did not believe that there was an impact to immunogenicity, and so the change could be affirmatively made without an impact to the clinical study."), 202:17-203:4 (Q. "Do you know if there are significant differences in safety and efficacy across batches with different lipid compositions?" A. "So we obviously studied many batches of the vaccine as part of clinical development of the product. I am not aware of any variations that were clinically meaningful.").

690. Consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, each specification-conforming lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, exhibit substantially equivalent immunogenicity and efficacy, including as compared to formulations with up to 49.5 mol % non-cationic lipid that fall within the claimed non-cationic lipid mol % limitations. *See supra* Sections X.D, XIII.F.2.a; MRNA-GEN-00601091 at -092-3 (July 29, 2020 email from Jack Kramarczyk brainstorming a justification for the switch to the v1 Formulation, "[w]e have data to support the 'no impact' statement"). In fact, Moderna's own expert whom the company relied on for the '435 IPR, Dr. Anchordoquy, asserted that minor variations in the amount of non-cationic lipid would not impact a product's performance. In particular, Dr. Anchordoquy described how a POSA would not expect a particle with a 1 mol % difference in non-cationic lipid "to behave differently in any impactful way." Anchordoquy '069 IPR Declaration at ¶ 43.

691. In particular, Moderna has repeatedly concluded and represented that the changes in non-cationic lipid mol % accompanying the switch from the PVU to the v1 Formulation and then to the v2 Formulation had no substantial impact on the immunogenicity of the Accused Product. *See supra* Section X.D, *supra* ¶ 663; MRNA-GEN-00508546 at -554 (DPAD-00823,

stating that "[i]t should be noted that slight variations in the percentage of SM-102, DSPC or PEG lipid can be made without a detectable difference in immunogenicity (Figure 4). Decreasing the molar percentage of SM-102 from 50 to 48% did not change the immunogenicity. [redacted] present in the formulation."); MRNA-GEN-00601091 at -093 (Email from Jack Kramarczyk, July 29, 2020, stating that "[t]he overarching fact is that the expression and antibody response were unaffected by these small changes").

692. Numerous of Moderna's own formulation studies, including studies used to justify its changes to the COVID-19 drug product target formulation, demonstrate no substantial differences in immunogenicity between mRNA-LNP lots with target lipid content falling within the claimed non-cationic lipid mol % limitations and mRNA-LNP lots with target lipid content [redacted] MRNA-GEN-00734102 at -108 [redacted]

[redacted] Parsons 6/7/2024 Tr. 203:18-208:15. In addition to comparable immunogenicity, Moderna also concluded from these two studies that there was "[n]o meaningful impact on SM-102 LNP CQAs [critical quality attributes] from [the] lipid composition change." MRNA-GEN-00734102 at -108. [redacted] *See, e.g.*, MRNA-GEN-00192423 (DS-IND-0110, approved December 1, 2021); MRNA-GEN-00199673 at -200030 (showing that report DS-IND-0110 was submitted to the FDA). I do not believe that Moderna contends that any of its lots of the Accused Product differ substantially with respect to immunogenicity by virtue of its non-cationic lipid content compared to LNPs having up to 49.5 mol % non-cationic lipid. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. On the contrary, Moderna sold the lots without any indication, to the FDA or the public, that they differed substantially in immunogenicity or any other respect.

693. In addition, consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, each specification-conforming lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, exhibit substantially equivalent safety, including as compared to formulations with up to 49.5 mol % non-cationic lipid that fall within the claimed non-cationic lipid mol % limitations. *See supra* Section X.D, ¶ 665; *see also, e.g.,* Parsons 6/7/2024 Tr. 191:2-9 ("We

believed that additional safety data would not be required. That's the reason that we made the change in the way that we did.), 226:9-227:8 (Q. "Did you ever tell the FDA that there could be tolerability differences between these two formulations?" A. "We submitted the toxicology reports that documented the safety of the product." Q. "And did those submissions show that the V1 [F]ormulation was more tolerable than –" A. "We did not submit separate toxicology reports for that V1 [F]ormulation" . . . Q. "So you didn't submit any data to the FDA showing that the 48.5 percent composition [redacted] the 50 percent composition?" A. "No, we did not."), 300:12-302:19 (testifying, when asked whether variations in the SM-102 values measured across PVU and v1 lots of Moderna's COVID-19 drug product as listed in the Justification of Specifications section of the BLA yielded any differences in product quality, "[o]ur view was that they did not have a significant impact on quality or efficacy of the product . . . or safety"); Kramarczyk 4/30/2024 Tr. 195:4-8 ("Safety and tolerability and reactogenicity of a vaccine are critical biological attributes of the vaccine. And it was not a goal expressly stated to improve safety, tolerability, or reactogenicity."). I have not seen any evidence, nor do I believe Moderna to have ever contended or otherwise represented, that the variation in the combined mol % of DSPC and cholesterol in its COVID-19 drug product has any substantial impact on the product's safety. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9; *supra* Section X.D; ¶ 665.

694. Finally, consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, lots formulated with the PVU, v1, and v2 Formulations exhibit substantially equivalent stability, including as compared to formulations

with a measured non-cationic lipid content of up to 49.5 mol %. *See supra* Section X.D, ¶ 666; *see also* MRNA-GEN-01802160 (BLA 125752 Manufacturing Process Development {SM-102 LNP})at -165 (concluding that "[t]hese concentration changes did not impact SM-102 LNP process performance, in-process physical stability, or physicochemical properties" as it pertains to the switch to the v1 Formulation); MRNA-GEN-00192423 at -423 (DS-IND-0110 mRNA-1273 LNP 2.5% PEG2000-DMG Comparability Report stating that "[a]nalytical comparability of the process change was assessed by 1) release, 2) stability when available, and 3) extended characterization testing, against pre-defined acceptance criteria" as it pertains to the switch to the v2 Formulation); MRNA-GEN-00089073 at -073 (Moderna correspondence to the FDA advocating for identical v1 and v2 Formulation shelf-life treatment). In particular, Moderna has concluded and represented that variations in the mol % of non-cationic lipid caused by the switch to the v1 and v2 Formulations has no substantial impact on the stability of the Accused Product. *See supra* Section X.D, ¶ 666; *see also, e.g.*, Parsons 6/7/2024 Tr. 188:1-189:8 [redacted] 190:1-19 [redacted]

[redacted] When the FDA asked Moderna about the impact on freeze-thaw of switching from the [redacted] which Moderna presumably would have done had it thought that the difference in mol % of these lipid components was relevant to freeze-thaw stability. MRNA-GEN-00089027 at -027. I do not understand Moderna to contend that the different non-cationic lipid mol % values measured across the lots of its drug product cause the mRNA-LNPs within its formulations to differ substantially with respect to stability, including as compared to mRNA-LNPs with up to 49.5 mol % non-cationic lipid. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) 5-9; *supra* Section X.D, ¶ 666.

695. **Insubstantial Differences.** It is my further opinion that, in view of the current and historical understandings in the field, the non-cationic lipid content of each lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, are insubstantially different both from one another and insubstantially different from the claimed non-cationic lipid mol % limitations. *See supra* Section X.D; *see also* MRNA-GEN-01264023 at -023; *see also* MRNA-GEN-01156478 at -527 [redacted] (emphasis added)). Indeed, Moderna was sufficiently confident that its drug product formulated with the v1 Formulation would be equivalent to its drug product formulated with the PVU Formulation (using 48.5 mol % non-

cationic lipid undisputedly within the claimed non-cationic lipid mol % limitations) [redacted] Parsons 6/7/2024 Tr. 130:3-12. The variations in the mol % of non-cationic lipid across the lots of Moderna's COVID-19 drug product are insubstantial, and even Moderna itself has described the changes to its target formulation of the Accused Product as "minor,"[140] "subtle,"[141] "slight,"[142] a "small change,"[143] and a "rounding error[]."[144] As I describe at length above in this Section, there is no evidence that Moderna's modifications of its target lipid ratios of non-cationic lipid from 48.5 mol % to 50 mol % to 49.5 mol % produced any substantial change in any product quality attribute. Indeed, given the heterogeneity of lipid compositions within Moderna's LNP batches, *see supra* Sections IX.E, X.E.2, it is likely that the distribution of non-cationic lipid amounts across particles is highly overlapping between the PVU, v1, and v2 Formulations (in other words, batches made with the PVU, v1, and v2 formulations are likely to have many particles with overlapping amounts of non-cationic lipid). Moderna has repeatedly represented that the variations in non-cationic lipid content in its COVID-19 drug product do not yield any difference in the performance of the function of the lipid particles, including with regard to safety, efficacy, and stability of its product.

[140] *See, e.g.*, MRNA-GEN-00508546 at -562.

[141] *See, e.g.*, MRNA-GEN-00601091 at -094.

[142] *See, e.g.*, MRNA-GEN-00604539 at -555; MRNA-GEN-00657578 at -578 ("[T]he lipid content of this product is being adjusted slightly to reduce the mole% of SM-102 to below 50% for IP purposes.").

[143] *See, e.g.*, MRNA-GEN-00604539 at -549.

[144] *See, e.g.*, MRNA-GEN-00656142.

696. That the target lipid molar ratio originally used for numerous of Moderna's vaccine programs as well as the first lots of the COVID-19 vaccine formulated with the PVU Formulation (*i.e.*, 50:10:38.5:1.5) was taken from Plaintiffs' work and changed due to intellectual-property considerations provides further support that Moderna's COVID-19 drug product is insubstantially different from mRNA-LNPs with 48.5 mol % non-cationic lipid that fall within the literal scope of the non-cationic lipid claims. *See supra* ¶ 668; *see also supra* Sections IX.A, X.D. As noted earlier, I do not understand Moderna to contend that its lots formulated with the 50:38.5:10:1.5 target PVU Formulation and lots formulated with the 48:38.5:11:2.5 target v2 Formulation do not meet the claimed non-cationic lipid mol % limitations. *Supra* ¶ 682.

697. In fact, Moderna's express goal when changing its formulation of various vaccine programs in the 2018-2019 timeframe and again in 2020 for the COVID-19 vaccine drug product was to create a product that was insubstantially different from its formulations with 48.5 mol % non-cationic lipid in order to avoid the need to conduct additional clinical trials. *See supra* ¶ 669.

698. Further evidence that each formulation of Moderna's COVID-19 drug product is insubstantially different from drug products with up to 49.5 mol % non-cationic lipid can be found in the fact that [redacted] The lipid content specifications for lots formulated with the PVU, v1, and v2 Formulations are sufficiently broad to encompass and/or overlap substantially with the molar ratio limitations of the claims of the'668 Patent and '435 Patent, as I demonstrated with calculations I made earlier in this report. *See supra* Section X.B. Further, as

discussed above, I understand that Moderna previously adopted the same analysis to explain that the [redacted] *See supra* Section X.B; *see also, e.g.*, Hoge 5/22/2024 Tr. 197:8-13; Ryan Declaration ¶ 5 (discussing Moderna's mRNA-1777 RSV vaccine product candidate). Moderna specifically highlighted the fact that the [redacted] *see* MRNA-GEN-01352552 at -554 (BLA Section 3.2.S.2.6) [redacted]

699. Moderna made minor changes to the lipid content specification ranges of the Accused Product when switching from the PVU to v1 to v2 Formulations. *Supra* Section X.D; *see also, e.g.*, MRNA-GEN-00547580 at -583-584; MRNA-GEN-02634802 at -811, -816-819; MRNA-GEN-00556478 at -478-479. The very purpose of specification ranges and acceptance criteria is to ensure product consistency or comparability as it pertains to quality, safety, and efficacy. *See, e.g.*, FDA Guidance Document Q6A, "Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances" at Section 1.2 ("Specifications are one part of a total control strategy for the drug substance and drug product designed to ensure product quality and consistency."), Section 2.5 ("The basis for the acceptance criteria at the time of filing should necessarily focus on safety and efficacy."). Dr. Parsons, a member of Moderna's COVID-19 Specification Committee, testified that Moderna's "assertion as part of the proposed specification limits was that if those differences

were present, they would be present at an acceptable level," and explained that "[o]ur view was that they did not have a significant impact on quality or efficacy of the product . . . [o]r safety." Parsons 6/7/2024 Tr. 301:7-19. Dr. Parsons further testified that Moderna "set specifications based on our clinical experience and the process performance that is relevant to different critical quality attributes." *Id*. at 313:15-18. When setting its specifications, Moderna specifically intended to yield drug product comparable to the drug product used in the clinical trials (with the PVU target lipid molar ratio using 48.5 mol % non-cationic lipid), and Moderna did so by [redacted] across its various lots. *See, e.g.*, MRNA-GEN-00998152 (BLA Section 3.2.P.5.6 Justification of Specifications {0.10 mg/mL}) at -206-209 (Figures 27-32 describing distribution of cholesterol and DSPC lipid content); MRNA-GEN-02634802 at -811. Lots within Moderna's specification could be—and were—sold as Moderna's COVID-19 vaccine and used to vaccinate the U.S. population, without any indication that the lots differed from each other in any substantial or meaningful way. The reason is simple—they did not differ in any substantial or meaningful way. This opinion is consistent with the opinions offered by Dr. Kimberly Benton. *See* Opening Expert Report of Kimberly A. Benton, Ph.D. Sec. V.

700. As discussed above, additional evidence of the lack of substantial differences between the formulations of Moderna's specification-conforming COVID-19 drug product lots, including lots that that fall within the claimed non-cationic lipid mol % limitations, can be found in its lack of testing of within-batch compositional heterogeneity, despite strong reason to suspect that the lipid content of the mRNA-LNPs within its COVID-19 drug product batches varies, [redacted] *Supra* ¶ 672; *see also supra* Sections X.E.2, IX.E. [redacted]

[redacted]

[redacted] Parsons 6/7/2024 Tr. 257:4-14; *supra* ¶¶ 463, 672. [redacted]

[redacted]

[redacted]

[redacted]

[redacted]

701. As discussed earlier, based on Moderna's own evidence, representations it has made in its own internal reports, to others (including the FDA), in the circumstances of this case, and in view of the technology and state of the art, specification-conforming PVU Formulation lots are insubstantially different from specification-conforming v1 Formulation lots and are further insubstantially different from specification-conforming v2 Formulation lots, and the relative proportion of non-cationic lipid within the three formulations performs substantially the same function, in substantially the same way, to achieve substantially the same results both relative to each other and relative to the claimed non-cationic lipid mol % limitations. As noted in the paragraphs above, this opinion is supported by: (a) evidence of Moderna using Plaintiffs' lipid molar ratios for its target PVU Formulation, with 48.5 mol % non-cationic lipid, in its Phase 1, 2, and early Phase 3 lots and its use of 49.5 mol % non-cationic lipid in its v2 Formulation; (b) Moderna's lipid content specification ranges for its drug product, which are sufficiently broad to encompass and/or overlap substantially with the claimed non-cationic lipid mol % limitations; and (c) Moderna's de-prioritization of studying the intra-batch lipid content heterogeneity of its COVID-19 vaccine drug product.

702. It is further my opinion that specification-conforming lots of Moderna's COVID-19 vaccine drug product produced within the same target formulation (*i.e.*, PVU lots as

compared to other PVU lots; v1 lots as compared to other v1 lots; and v2 lots as compared to other v2 lots) are insubstantially different from one another and that the non-cationic lipid content of the mRNA-LNPs in these lots perform substantially the same function, in substantially the same way, to achieve substantially the same results both relative to each other and relative to the claimed non-cationic lipid mol % limitations. To my knowledge, Moderna does not contend that lots produced with the same target molar ratio are substantially different from one another. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Further to my knowledge, Moderna has never asserted to the FDA, public, or otherwise, that lots of Moderna's COVID-19 drug product formulated with the same target lipid molar ratio substantially differ from each other in any respect by virtue of differences in the measured lipid ratio of the lots. To the contrary, as I have explained in detail above, Moderna has consistently maintained that all specification-conforming lots of its COVID-19 vaccine to be of comparable quality, including with respect to their safety, efficacy, and stability. Accordingly, the v1 lots that literally infringe the asserted claims (identified *supra* Section XIII.F.1), including the claimed non-cationic lipid mol % limitations, are insubstantially different from those that do not infringe literally (if any), and the same is true for Moderna's v2 lots.

703. Additionally, it is my opinion that specification-conforming lots of Moderna's COVID-19 drug product produced within the same mRNA-1273 LNP part number (*e.g.*, lots falling within mRNA-1273 LNP part number 50075 lots as compared to other lots falling within that same part number 50075) are insubstantially different from one another and perform substantially the same function, in substantially the same way, to achieve substantially the same

results. To my knowledge, Moderna does not contend that lots produced with the same mRNA-1273 LNP part number are substantially different from one another. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. In fact, Moderna's treatment of its mRNA-1273 LNP part numbers would indicate that such part numbers are representative of versions of the drug product in which each lot within that version is viewed as equivalent to one another. *Supra* ¶ 355; *see also, e.g.*, MRNA-GEN-02615390 at -422-425 (demonstrating how each of Moderna's part numbers are associated with product specifications); D.I. 225 (The parties' Stipulation for samples testing in which Moderna agreed to a provision whereby "Moderna will not make any argument about the applicability of any test data generated by Plaintiffs from produced lots to other lots containing the same mRNA-LNP part number on the basis that such lots containing the same mRNA-LNP part number were not produced pursuant the parties' agreed-upon protocol."). Accordingly, the drug product lots manufactured using mRNA-1273 LNP part number 50075 that literally infringe the asserted claims (identified *supra* Section XIII.F.1), including the claimed non-cationic lipid mol % limitations, are insubstantially different from the drug product lots manufactured using mRNA-1273 LNP part number 50075 that do not infringe literally (if any), and the same is true for all other drug product lots and corresponding mRNA-1273 LNP part numbers of Moderna's drug product.

704. [redacted]

[redacted]

705. It is my opinion that, just as the mRNA-LNPs of Moderna's specification-conforming drug product lots are insubstantially different from one another and have insubstantially different content of non-cationic lipid, it is also the case that each specification-conforming lot of [redacted] used to manufacture the Accused Product, including lots of [redacted] *Supra* Section X.D. The target lipid molar ratio of the [redacted] used to manufacture the PVU lots literally infringes the non-cationic lipid content limitations of the Lipid Composition Patents, and to my knowledge, Moderna does not assert any substantial differences between the [redacted] used to manufacture PVU Formulation lots versus v1 and v2 Formulation lots, and its own documents and representations to the FDA indicate that such LNPs are equivalent. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) 5-9; MRNA-GEN-00768481 at -482 ("CQAs are applied to the drug substance, excipients, intermediates (in-

process materials), and drug product and are defined by their impact to Safety and Efficacy."); MRNA-GEN-00547580 at -580-582 ("Concentration changes did not impact SM102 LNP process performance, in-process physical stability, or physicochemical properties against a control batch with the previous lipid concentration targets."); MRNA-GEN-00081323 at -326 [redacted] MRNA-GEN-01352552 at -554.

706. The ultimate function, way of accomplishing the function, and result achieved by the non-cationic lipid present in [redacted]—as well as the [redacted]—are the same as in the drug product, as these LNPs are a [redacted] to those same particles. As noted above, I have not seen any evidence of, nor do I believe that Moderna contends, that the non-cationic lipid in the particles in Moderna's drug product and its precursor particles serve different functions from one another by virtue of variations in its cholesterol and DSPC lipid mol %, nor do they accomplish their functions in a different way or achieve different results by virtue of variations in its cholesterol and DSPC lipid mol %. In other words, [redacted] perform substantially the same function, in substantially the same way, and achieve substantially the same results as particles with a target ratio of 50.5:38.9:10.1:0.5 (PVU [redacted]), which fall within the literal scope of the claims. On a more granular level, the combination of cholesterol and DSPC of each [redacted]

[redacted] achieve the same function of providing the particle with amphipathicity and hydrophobicity thereby allowing the particle to form a stable complex and (in the future) enabling the particles to transfect cells, in the same way through the structure, structural features, and concentration of the non-cationic lipids, as LNPs with up to 49.5 mol % non-cationic lipid. *See supra* ¶¶ 390, 684-688. In addition, I have not seen any evidence to suggest, nor do I believe that Moderna contends, that [redacted] achieve different results. To my knowledge, [redacted] *Supra* Section X.B; *see, e.g.*, MRNA-GEN-00039212 at -219; MRNA-GEN-01424228 [redacted] MRNA-GEN-00044166 [redacted] at -168 [redacted] (emphasis added)). [redacted] should perform substantially the same function, in the same way and yield the same results, and should not differ substantially from one another nor from [redacted] with up to 49.5 mol % non-cationic lipid.

707. **Hypothetical Claims.** As I describe above, I have been informed by counsel that an optional way of conducting the doctrine of equivalents analysis is to construct a "hypothetical claim" and assess whether the Accused Product would literally infringe that claim. *Supra* ¶ 45. In my opinion, such a "hypothetical claim" could recite, for example, an upper limit of 53 mol % (rather than 49.5 mol %) non-cationic lipid. As I describe at length above in this section,

Moderna concluded that there is no difference when the target amount of non-cationic lipid is increased to 53 mol%. *See e.g.*, MRNA-GEN-00734102 at -108 (describing comparable immunogenicity and critical quality attributes (CQAs) between [redacted]). As further discussed at length above, mRNA-LNPs with 49.5-53 mol % non-cationic lipid are insubstantially different from one another and perform substantially the same function, in substantially the same way, to achieve substantially the same results. Therefore, it is my opinion that a potential "hypothetical claim" would recite a nucleic acid-lipid particle where the upper limit on the amount of non-cationic lipid is 53 mol %, rather than 49.5 mol %. For each Asserted Claim with a non-cationic lipid mol % limitation, it is possible to assess which lots of Moderna's COVID-19 drug product and SM-102 LNP would fall within the scope of the Asserted Claims having this hypothetical upper limit of 53 mol % non-cationic lipid, based on their certificates of analysis.

708. Within this hypothetical claim framework, based on information currently available and known to me, I have identified lots of Moderna's COVID-19 drug product and lots of [redacted] (which I use as a proxy for the [redacted] for the reasons explained above, *supra* Section X.D) that would infringe based on a hypothetical claim with an upper limit of 53 mol % non-cationic lipid, using appropriate rules of rounding and informed by Moderna's COA data. The table below indicates Appendices, on a claim-by-claim basis, which identify the infringing lots. For clarity, I have highlighted the hypothetical claim limitations.

Drug Product				
Patent Claim	**Lipid Molar Ratio Range (%)**			**LDP Lot #**
'668 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 76
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	49.5	≤ SM-102 <	60.5	Appendix 77
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 78
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	35.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 79
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	49.5	≤ SM-102 <	85.5	Appendix 80
	12.5	≤ Non-Cationic <	53.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	49.5	≤ SM-102 <	85.5	Appendix 81
	12.5	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

[redacted]				
Patent Claim	**Lipid Molar Ratio Range (%)**			[redacted]
'668 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 82
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

Patent Claim	Lipid Molar Ratio Range (%)			[redacted]
'668 Patent, Claim 8	49.5	≤ SM-102 <	60.5	Appendix 83
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 84
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	49.5	≤ SM-102 <	85.5	Appendix 85
	12.5	≤ Non-Cationic <	53.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	49.5	≤ SM-102 <	85.5	Appendix 86
	12.5	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

709. The exhibits recited in the above table assume a hypothetical claim limitation of 53 mol % non-cationic lipid as an upper limit. However, it would be equally possible to generate lists of batches that infringe with other hypothetical claims with upper limits of non-cationic lipid that are slightly lower—for example, 52 mol %; 51 mol %; and 50 mol %—all of which would be equivalent to claims having an upper limit of 49.5 mol %. One would simply need to take the exhibits listed in the previous paragraph and remove the batches with non-cationic lipid (DSPC + cholesterol) amounts more than the aforementioned hypothetical claims (with appropriate rounding). Those alternate lists of batches are incorporated into and included in my analysis and conclusions and opinions, here, and I reserve the right to set forth such an analysis explicitly in the future.

c. Conjugated Lipid / PEG

710. Whereas Moderna disputes infringement of the v2 Formulation on the basis of their target conjugated lipid mol %, to my knowledge, Moderna does not dispute that the PVU and v1 Formulations meets the conjugated lipid mol % limitations of the Lipid Composition Patents. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57, 65, 122-123; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9; *see also*, *e.g.*, MRNA-GEN-01374118.

711. Based on Moderna's documents, statements made by Moderna's employees, and representations Moderna has made to the FDA, it is my opinion that the conjugated lipid mol % of lots of Moderna's COVID-19 vaccine drug product formulated using the target v2 Formulation (including specifically its 2.5 mol % target for the PEG2000-DMG conjugated lipid), is insubstantially different from the claimed conjugated lipid mol % limitations, which undisputedly encompasses the 1.5 mol % conjugated lipid target of the PVU and v1 Formulations that Moderna used to formulate lots of the Accused Product in its clinical trials as well as commercial lots of the vaccine. Furthermore, it is my opinion that the conjugated lipid mol % of Moderna's v2 Formulation lots performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claimed conjugated lipid mol % limitations.[145] As I will explain below, the increase in the target conjugated lipid from 1.5 mol % in the PVU and v1 Formulations to 2.5 mol % in the v2 Formulation, and the

[145] In this section of my report, Section XIII.F.2.c, "claimed conjugated lipid mol % limitations" refers to the conjugated lipid limitations or the PEG lipid conjugate limitations in the '069 patent claims 1 and 15; the '359 patent claims 1 and 18; the '668 patent claims 1 and 15; the '435 patent claim 1; and the '378 patent claims 1 and 25. I recognize that the claims that depend on these claims also incorporate those limitations.

subsequent formulation of various lots with measured lipid content values of greater than 2 mol % conjugated lipid do not render the COVID-19 drug product substantially different from: (a) a product having LNPs with a target composition of 1.5 mol % conjugated lipid, such as in the PVU and v1 Formulations (for which Moderna does not dispute infringement on the basis of conjugated lipid content) nor (b) lots formulated with the target PVU, v1, and v2 Formulations that contain 2 mol % (or less) conjugated lipid that literally infringe the claimed conjugated lipid mol % limitations. As discussed earlier in my report, in light of the Court's claim construction ruling and conventional rules of rounding, Plaintiffs' claims cover up to but do not include precisely 2.5 mol % PEG2000-DMG, *e.g.*, 2.49, 2.499, or 2.499 mol% (with an infinitely repeating number of nines), meaning that numerically, there is an infinitely small difference between the target PEG2000-DMG mol % of Moderna's v2 Formulation and Plaintiffs' claimed conjugated lipid mol % limitations. *Supra* Section V.A.

712. **Equivalent Function.** The POSA would understand that the function of the conjugated lipid in the claimed conjugated lipid mol % limitations is to promote particle stability (e.g., via decreasing the aggregation of particles), which can impact fusogenicity and circulation time. This function is supported by the disclosure of the Lipid Composition Patents as well the contemporaneous scientific literature. *See, e.g.*, '069 patent, 11:56-12:4 (noting the conjugated lipid's role in preventing particle aggregation), 57:27-32 ("By controlling the composition and concentration of the lipid conjugate, one can control the rate at which the lipid conjugate exchanges out of the nucleic acid-lipid particle and, in turn, the rate at which the nucleic acid-lipid particle becomes fusogenic."), 86:9-13 (noting extended blood circulation times in relation to PEG); *see also, e.g.*, Semple 2001 at 156 ("In order to minimize aggregation and fusion between particles during the formulation process, PEG-CerC14, a steric barrier lipid, was

included in the formulation."); *supra* Sections VI.B, VIII.B.1. In challenging the validity of the '069 and '435 patents in the IPR proceedings before the PTAB, *see supra* Section VIII.C, Moderna relied on the testimony of Dr. Andrew S. Janoff, who explained to the Board that a "'conjugated lipid' (*e.g.*, a PEG-lipid) can be added to increase *in vivo* circulation time by providing a neutral, hydrophilic coating to the particle's exterior," and cited to Heyes 2005 for the proposition that the presence of PEG-lipids stabilize the particles during the formulation process. Janoff '069 IPR Declaration at ¶ 64. Dr. Janoff additionally described the role that the concentration of PEG plays in fusogenicity. *Id*. at ¶ 121. Accordingly, I do not understand Moderna to dispute the function of the conjugated lipid element, including the mol % thereof, recited in the Asserted Claims of the Patents-in-Suit.

713. The function of the PEG2000-DMG conjugated lipid and its mol % concentration in drug product lots of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, is substantially the same as the conjugated lipid and its mol % in the claimed invention. As discussed earlier in my report, Moderna describes the function of the PEG lipid in its COVID-19 vaccine as "enhanc[ing] colloidal stability of the LNP dispersion" and impacting "cell uptake" of the LNP MRNA-GEN-00988589 at -592; *supra* ¶ 341; *see also* MRNA-GEN-02316901 at -922. I have not seen any evidence, nor does Moderna appear to contend, that the PEG lipids within the mRNA-LNPs of any of its specification-conforming drug product lots, including lots formulated with a target PEG lipid content of 2.5 mol % (v2), function substantially differently than PEG lipids in mRNA-LNPs with 2 mol % PEG lipid or less, including as used in the PVU and v1 Formulations and Moderna's other clinical programs and development programs using a 1.5 mol % PEG lipid target. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos.

1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. It is my understanding that across all lots of Moderna's COVID-19 vaccine drug product, the PEG lipids and their concentration in the product help coat the particle's exterior to enhance stability of the LNPs and impact fusogenicity and circulation time. *See supra* ¶ 341; MRNA-GEN-00988589 at -592; MRNA-GEN-00018512 at -514; *see also* MRNA-GEN-02316901 at -922. Furthermore, to my knowledge, Moderna does not contend that the PEG lipid and its mol % concentration in lots formulated with the PVU, v1, and v2 Formulations performs substantially different functions by virtue of differences in the lots' respective target lipid molar ratios or measured lipid content in the formulated product. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Indeed, the LNPs of Moderna's COVID-19 vaccine drug product, whether formulated with the PVU, v1, or v2 Formulations, including their respective mol % targets for the PEG lipid, perform the same function of "encapsulation of the CX-038839 mRNA in the SM-102 LNP [to] protect[] the mRNA from nucleolytic degradation in biological fluids" and enablement of "cellular uptake of the nanoparticle, endosomal escape, and ultimately productive cytosolic display of the mRNA such that protein translation may occur." MRNA-GEN-00988461 at -468; *see also* MRNA-GEN-00306589 -597-600. Moderna's description of the role served by the mRNA-LNPs of the Accused Product—encapsulation of the mRNA, delivery of the mRNA, and eventual facilitation of protein translation—has remained constant throughout Moderna's regulatory submissions, notwithstanding the change in the target PEG lipid mol % in the v2 Formulation. *See, e.g.*, MRNA-GEN-00999602; MRNA-GEN-

00988461 at -467-468; MRNA-GEN-00305704; MRNA-GEN-00302728 at -733; MRNA-GEN-01806150; MRNA-GEN-00177578; MRNA-GEN-00047244 at -248; MRNA-GEN-00046242 at -246; MRNA-GEN-01799476 at -478-479; MRNA-GEN-01799027; *see also* MRNA-GEN-01256981 (Email from Don Parsons, May 21, 2021) at -982 [redacted]

714. I am aware of statements—by Moderna and in the literature—suggesting that the PEG lipid may be serving additional functions in the LNP. *See, e.g.*, Janoff '069 IPR Declaration ¶ 64 (citing Gao, Ex. 1009, to note PEG's potential role in minimizing nonspecific interactions with blood components); Semple 2001 at 162 (noting role in reducing opsonization). However, I have not seen any evidence—and I am not aware of Moderna contending—that any such function would differ substantially between lots formulated with a target PEG lipid amount of 2.5 mol % (v2), as compared to mRNA-LNPs with 1.5% PEG lipid, including as used in the PVU and v1 Formulations, or as compared to mRNA-LNPs failing within the claimed conjugated lipid mol % limitations, such as with 2.499 mol % PEG lipid. To the contrary, as I discuss in more detail below, Moderna found that such changes in the amount of PEG lipid in its mRNA-LNPs did *not* affect efficacy. *See infra* ¶ 719. That is consistent with my opinion that the function of the amount of conjugated lipid is the same across Moderna's different target formulations and as compared to the claimed amounts.

715. **Function in an Equivalent Way.** The POSA would further understand the PEG lipid and its mol % concentration in drug product lots of the of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, to perform substantially the same function of the conjugated lipid of the Asserted Claims, including its recited mol %, in

substantially the same way. The way in which the PEG lipids of the drug product achieve their function is through their structure, chemical composition, and concentration. *See supra* ¶ 341. As Moderna has described, the [redacted] MRNA-GEN-00988589 at -592. The same chemical mechanism is disclosed in the Lipid Composition Patents. *See, e.g.*, '069 patent, 57:28-39 (describing how the PEG composition and concentration impact "the rate at which the lipid conjugate exchanges out of the nucleic acid-lipid particle and, in turn, the rate at which the nucleic acid-lipid particle becomes fusogenic"); 86:9-13 (discussing blood clearance).

716. It is my understanding that the PEG lipids in all lots of Moderna's COVID-19 vaccine drug product, regardless of the target or measured mol % of PEG in that lot, embody essentially the same structure[146] and possess the same structural features. *See supra* ¶ 341. Moderna does not appear to contend that the PEG lipids within the mRNA-LNPs of any of its specification-conforming lots, including lots formulated with a target PEG lipid of 2.5 mol % (v2) function in a substantially different way than PEG lipids in mRNA-LNPs with 1.5 mol %

[146] As discussed earlier, *supra* ¶ 346, the molecular weight of PEG2000-DMG is variable due to it being a polydisperse polymer; the number of PEG repeat units present in any particular molecule can vary from polymer chain to polymer chain in a given preparation. However, I do not understand Moderna to contend, nor had Moderna ever represented to the FDA or otherwise, that the function, way of achieving its function, or results of the PEG lipid differ by virtue of these minor variations in the number of PEG repeat units. *See, e.g.,* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9.

(and up to 2.499 mol %) PEG lipid, including as used in the PVU and v1 Formulations and Moderna's other clinical programs and development programs. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 22-23; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Indeed, the mRNA-LNPs of Moderna's COVID-19 vaccine drug product, including within lots formulated with the PVU, v1, and v2 Formulations, function in substantially the same way. Furthermore, I have not seen any evidence, nor does Moderna appear to contend, that the mRNA-LNPs of any of its lots of the COVID-19 vaccine drug product, including lots formulated with a target PEG lipid of 2.5 mol% (v2) function in a substantially different way from mRNA-LNPs with 1.5 mol % (and up to 2.499 mol %) PEG lipid, including as used in the PVU and v1 Formulations and Moderna's other clinical programs and development programs. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) 5-9. The underlying mechanism of action for the LNPs in all lots of Moderna's COVID-19 vaccine drug product, across all of Moderna's target PVU, v1, and v2 Formulations, has consistently been represented by Moderna to the FDA as being the same, and I am aware of no reason why the mechanism of action of these LNPs should differ.

717. **Equivalent Results.** It is further my opinion that the PEG lipid and its mol % concentration in drug product lots of the Accused Product, including within lots formulated with the PVU, v1, and v2 Formulations, achieve substantially the same result as the conjugated lipid and its mol % in the claimed invention. As explained in the Lipid Composition Patents, the

result of the PEG lipid limitation, including its recited mol % in the claims, in the context of the invention as a whole, is the effective and efficient intracellular delivery nucleic acid. *See, e.g.*, '069 patent, 2:55-57 (observing the "strong need in the art for novel and more efficient methods and compositions for introducing nucleic acids such as siRNA into cells"), 5:51-61 (disclosing that the inventive nucleic acid-lipid particles, including the claimed conjugated lipid mol %, "advantageously impart increased activity of the encapsulated nucleic acid," "improved tolerability of the formulations in vivo" and "are substantially non-toxic to mammals such as humans."), 6:13-19 ("For instance, the '1:57 SNALP' and '1:62 SNALP' formulations described herein are exemplary formulations of the present invention that are particularly advantageous because they provide improved efficacy and tolerability in vivo, are serum-stable, are substantially non-toxic, are capable of accessing extravascular sites, and are capable of reaching target cell populations."); 57:50-55 (noting that the particles of the invention encapsulate and protect from degradation the active or therapeutic agent (i.e., nucleic acid)). As I explain below, Moderna's COVID-19 vaccine drug product, whether formulated with the PVU, v1, or v2 Formulations, including drug product formulations with reported lipid content values of [redacted] *See supra* Sections X.D, IX.C; *see also, e.g.*, Parsons 6/7/2024 Tr. 202:17-203:4 (Q. "Do you know if there are significant differences in safety and efficacy across batches with different lipid compositions?" A. "So we obviously studied many batches of the vaccine as part of clinical development of the product. I am not aware of any variations that were clinically meaningful.").

718. Consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, each specification-conforming lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, exhibit substantially equivalent immunogenicity and efficacy, including as compared to formulations with up to 2.499 mol % conjugated lipid that fall within the claimed conjugated lipid mol % limitations. *See supra* Section X.D; MRNA-GEN-00192423 (DS-IND-0110 2.5% PEG 2000 DMG Comparability Report)[147] at -423 [redacted]

719. In particular, Moderna has repeatedly concluded and represented that the increased target PEG lipid mol % accompanying the switch from the v1 to the v2 Formulation had no substantial impact on the immunogenicity of the Accused Product. *See supra* Section X.D; MRNA-GEN-00604539 at -555 (PD-REP-0101, noting that [redacted] MRNA-GEN-00601091 at -093 (July 29, 2020 email from Jack Kramarczyk, [redacted] MRNA-GEN-00192423 [redacted]

[147] As I noted earlier, this report was provided to the FDA. MRNA-GEN-00199673 at -200030.

[redacted] at -423 [redacted] Hoge 5/22/2024 Tr. 258:2-11 [redacted] MRNA-GEN-00539393 at -409 [redacted] -413 [redacted] In fact, I understand that [redacted] it was Moderna's explicit goal to not change immunogenicity. Kramarczyk 4/30/2024 Tr. 61:17-62:18 (Q. "The next two bullets on this slide say, 'We are not setting out to create a more immunogenic product.' And then the next one is, 'We are not setting out to increase tolerability.' Do you see that?" A. "Yes, I do." Q. "What do those goals mean?" A. ". . . A key element always of making product and process changes is to not disrupt the historic clinical data that was in place, in this case from Phase 1. And comparable to Phase 1 from immunogenicity perspective and comparable to Phase 1 from a tolerability perspective are, generally speaking, two critical elements of making process

and product changes and maintaining comparability such that we don't have to interfere with clinical development progress.").

720. Moderna's own formulation study that was used to justify its changes to the COVID-19 drug product target formulation, *see supra* ¶ 439, demonstrated no substantial differences in immunogenicity between mRNA-LNP lots [redacted] MRNA-GEN-00734102 at -108 (displaying the results from study #2891 (right)). Dr. Parsons re-affirmed the findings of the study, as he testified that Moderna "saw comparable immunogenicity across those changes" reflected in study #2891. Parsons 6/7/2024 Tr. at 212:1-7. Study #2891 features CMV data, but as noted earlier, "what [Moderna] expected was that the same general observation that the activity of the vaccine -- the COVID vaccine would be comparable across this lipid composition range." Parsons 6/7/2024 Tr. 203:18-208:15. In addition to comparable immunogenicity, Moderna also concluded from these two studies that there was "[n]o meaningful impact on SM-102 LNP CQAs [critical quality attributes] from [the] lipid composition change." *Id*.

721. I do not believe that Moderna contends that any of its lots of the Accused Product differ substantially with respect to immunogenicity by virtue of its PEG lipid content compared to LNPs having 1.5 mol % (and up to 2.499 mol %) conjugated lipid. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to

Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. On the contrary, Moderna sold the lots without any indication, to the FDA or the public, that they differed substantially in immunogenicity or any other respect.

722. In addition, consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, each specification-conforming lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, exhibit substantially equivalent safety, including as compared to formulations with 1.5 mol % (and up to 2.499 mol %) PEG lipid that fall within the claimed conjugated lipid mol % limitations. *See supra* Section X.D. I do not believe that Moderna contends that any of its lots of the Accused Product have different tolerability or safety by virtue of its PEG lipid content. In particular, Moderna has concluded and represented that variations in the mol % of PEG lipid in the Accused Product, including increased target PEG lipid concentration caused by the switch to the v2 Formulations, have no substantial impact on the safety of its COVID-19 vaccine drug product. *See supra* Section X.D; *see also, e.g.,* Kramarczyk 4/30/2024 Tr. 195:4-8 ("Safety and tolerability and reactogenicity of a vaccine are critical biological attributes of the vaccine. And it was not a goal expressly stated to improve safety, tolerability, or reactogenicity."); Hoge 5/22/2024 Tr. 258:2-11 [redacted] MRNA-GEN-00192423 [redacted] at -423 [redacted]

[redacted]

[redacted] Nor have I seen data from Moderna demonstrating differences in safety when the PEG lipid in its products is increased, including to 3 mol %.

723. As I will describe in greater detail below, consistent with what Moderna has repeatedly represented to the FDA and stated in its own documents and correspondence, lots formulated with the PVU, v1, and v2 Formulations exhibit substantially equivalent stability, including as compared to formulations with a measured lipid content of 1.5 mol % (and up to 2.499 mol %) conjugated lipid. *See supra* Section X.D. In particular, Moderna has concluded and represented that variations in the mol % of PEG lipid in the Accused Product have no substantial impact on the stability of the Accused Product. *See supra* Section X.D. For example, Moderna's corporate designee Don Parsons offered the following testimony, when asked about Moderna's Justification of Specification document for its [redacted] Parsons 6/7/2024 Tr. 308:6-310:12 (emphasis added); MRNA-GEN-00998152 at -209-212. As discussed earlier in the report and will be discussed in greater detail below, Moderna's justification for switching to the v2 Formulation appears to be [redacted]

[redacted] however, the correspondence, data, and representations cited throughout this report and this section show otherwise. *See supra* X.D. Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9; MRNA-GEN-02635779 at -784 (3.2.P.2.2.1.1 LNP Composition Justification).

724. There are numerous examples of Moderna representing to the FDA that v1 Formulation lots with a target PEG lipid content of 1.5 mol % exhibit equivalent stability to v2 Formulation lots with a target PEG lipid content of 2.5 mol %, and asserting that differences in PEG lipid mol % will not affect stability. For example, Moderna proposed to the FDA to maintain "identical" shelf-life claims for v1 and v2 Formulation lots that showed "consistency [in] stability profiles," and the main justification cited for this assertion was that [redacted] on "mRNA purity, mean particle size or encapsulation." MRNA-GEN-00089073 at -073. In response to an FDA Request for Further Information regarding the potential impact of the freeze-thaw step of Moderna's new drug product part number (v2 Formulation with a target of 2.5 mol % PEG2000-DMG), Moderna asserted that there would be "[n]o impact," and justified this assertion using data from its v1 Formulation lots (with a target of 1.5 mol % PEG2000-DMG). MRNA-GEN-00089027 (Response to FDA on Request for Further Information – EUA 27073.311 Received on February 17, 2022) at -027 [redacted]

[redacted] (emphasis added)). [redacted] MRNA-GEN-00192423 at -423. [redacted] I take them at their word and assume Moderna was honest with the FDA.

725. In addition to assertions to the FDA, numerous studies and reports by Moderna indicate comparable stability across its COVID-19 Drug Product, including as compared to drug product lots with lipid content values measured to have 2 mol % PEG2000-DMG. *See supra* Section X.D; *see also, e.g.*, MRNA-GEN-02615528 (PD-REP-0716) at -529 [redacted] -531 [redacted] Parsons 6/7/2024 Tr. 353:20-354:15 [redacted]

[redacted] MRNA-GEN-00736354 (PD-REP-0436) at -357 [redacted]

726. [redacted] *See supra* Section X.D; MRNA-GEN-00530699 at -712 [redacted] Parsons 6/7/2024 Tr 457:3-11 [redacted] MRNA-GEN-00539393 (PD-REP-0294) at -409; US 2024/0009131, FIG. 5B [redacted] FIG. 27A [redacted]

727. [redacted] *see, e.g.*, Smith 5/14/2024 Tr. 267:6-270:4; Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 40-41 (citing PD-REP-0443, MRNA-GEN-00967986), however, as I discussed earlier, this study provides little to no support for this conclusion. *See supra* ¶ 442. [redacted]

[redacted]

MRNA-GEN-00967986 at -8009. [redacted]

Supra Section X.G. [redacted]

Supra ¶ 442; *see also, e.g.*, Parsons 6/7/2024 Tr. 178:6-20 [redacted] 340:19-342:2 [redacted] 342:19-343:8 [redacted]; MRNA-GEN-00967986 at -997. [redacted]

[148] Don Parsons was designated to provide testimony on (a) "stability studies for the Accused Product that analyzed impact on lipid molar ratio, including studies at approved storage conditions for the mRNA-LNP and drug product described in regulatory filings for the Accused Product," and (b) technical reasons underlying "the rationale for the lipid molar ratios used in the Accused Product." Plaintiffs' 30(b)(6) Topic Nos. 11 and 24.

[redacted] *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9.

728. **Insubstantial Differences.** It is my further opinion that, in view of the current and historical understandings in the field, the conjugated lipid content of each lot of Moderna's COVID-19 drug product, including lots formulated with the PVU, v1, and v2 Formulations, are insubstantially different both from one another and insubstantially different from the claimed conjugated lipid mol % limitations. *See supra* Section X.D; *see also* MRNA-GEN-01156478 at -527 [redacted] (emphasis added)). The variations in the mol % of PEG lipid across the lots of Moderna's COVID-19 drug product are insubstantial, and even Moderna itself has described the changes to its target formulation of the Accused Product as "minor,"[149] "subtle,"[150] "slight,"[151] a "small change,"[152] and a "rounding error[]."[153] As I describe at length above in this Section, there is no evidence that Moderna's modifications of its target lipid ratios of PEG lipid from 1.5

[149] *See, e.g.*, MRNA-GEN-00508546 at -562.

[150] *See, e.g.*, MRNA-GEN-00601091 at -094.

[151] *See, e.g.*, MRNA-GEN-00604539 at -555; MRNA-GEN-00657578 at -578 ("[T]he lipid content of this product is being adjusted slightly to reduce the mole% of SM-102 to below 50% for IP purposes.").

[152] *See, e.g.*, MRNA-GEN-00604539 at -549.

[153] *See, e.g.*, MRNA-GEN-00656142.

mol % to 2.5 mol % produced any substantial change in any product quality attribute. Moderna has repeatedly represented that the variations in PEG lipid content in its COVID-19 drug product do not yield any difference in the performance of the function of the lipid particles, including with regard to safety, efficacy, and stability of its product.

729. That the target lipid molar ratio originally used for numerous of Moderna's vaccine programs as well as the first lots of the COVID-19 vaccine formulated with the PVU Formulation (*i.e.*, 50:10:38.5:1.5) was taken from Plaintiffs' work and changed related to intellectual-property considerations provides further support that Moderna's COVID-19 drug product lots with 2.5 mol % and greater PEG are insubstantially different from mRNA-LNPs with up to 2.499 mol % conjugated lipid that fall within the literal scope of the conjugated lipid claims. *See supra* Sections IX.A, X.D; MRNA-GEN-02619870 (Dr. Hoge, asserting in an email chain, that there are "incredibly strong business reasons" to pursue a formulation with lower amino lipid, and Dr. Parsons responding that they were looking into both decreasing the amino lipid and increasing PEG); Parsons 6/7/2024 Tr. 106:1-6 [redacted]

730. In fact, Moderna's express goal when changing its formulation of various vaccine programs in the 2018-2019 timeframe and again for the COVID-19 vaccine drug product was to create a product that was insubstantially different from its formulations with 1.5 mol % conjugated lipid in order to avoid the need to conduct additional clinical trials. *See e.g.*, MRNA-GEN-01747429 at -431 ("We are not setting out to create a more immunogenic product" and

"[w]e are not setting out to increase tolerability."); Kramarczyk 4/30/2024 Tr. 173:16-20 ("One of our express goals was that CMV changes should match prior experience for biological endpoints. And I think we achieved that range -- we achieved that goal in the ranges of lipid compositions we explored or identified."); MRNA-GEN-02634802 at -811 (Moderna's BLA Justification of Specifications, noting in the context of the switch to the v2 Formulation, that "[t]he lipid content specifications are adjusted to reflect the formulation modifications of mRNA-1273 DP," stating that the specification limits they selected are "intended to ensure consistency of commercial lots with lots used in clinical trials," and further noting that this selection "incorporate[d] clinical knowledge"); Parsons 6/7/2024 Tr. 191:2-9 ("We believed that additional safety data would not be required. That's the reason that we made the change in the way that we did. Clearly we did not believe that there was an impact to immunogenicity, and so the change could be affirmatively made without an impact to the clinical study."). Moderna's goal of creating a sufficiently equivalent product so as to avoid re-conducting Phase I and II testing was particularly critical during the pandemic, for which there was an urgent need to develop the vaccine as quickly as possible and a strong desire to not fall behind other vaccines being developed at that time. *See, e.g.*, MRNA-GEN-02645641 at -644 (May 15, 2020 PowerPoint presentation titled "Board Discussion," stating that "[a]ny further delays in investing risks losing a share of the most valuable early [COVID-19 vaccine] deliveries"); *infra* Section XVI. As noted earlier, I do not understand Moderna to contend that its lots formulated with the target PVU and v1 Formulations do not meet the conjugated lipid mol % claim limitations of the Lipid Composition Patents. *Supra* ¶ 710.

731. Further evidence that each formulation of Moderna's COVID-19 drug product is insubstantially different from drug products with up to 2 mol % conjugated lipid can be found in

the fact that Moderna's lipid content specification ranges and the resulting intended lipid molar ratios for its drug product [redacted] as I demonstrated with calculations I made earlier in this report. *See supra* Section X.B. Further, as discussed above, [redacted] *See supra* Section X.B; *see also, e.g.*, Hoge 5/22/2024 Tr. 197:8-13; Ryan Declaration ¶ 5 (discussing Moderna's mRNA-1777 RSV vaccine product candidate).

732. Moderna made minor changes to the lipid content specification ranges of the Accused Product when switching from the PVU to v1 to v2 Formulations. *Supra* Section X.D; *see also, e.g.*, MRNA-GEN-00547580 at -583-584; MRNA-GEN-02634802 at -811, -816-819; MRNA-GEN-00556478 at -478. The very purpose of specification ranges and acceptance criteria is to ensure product consistency or comparability as it pertains to quality, safety, and efficacy. *See, e.g.*, FDA Guidance Document Q6A, "Specifications: Test Procedures and Acceptance Criteria for New Drug Substances and New Drug Products: Chemical Substances" at Section 1.2 ("Specifications are one part of a total control strategy for the drug substance and drug product designed to ensure product quality and consistency."), Section 2.5 ("The basis for the acceptance criteria at the time of filing should necessarily focus on safety and efficacy."). Dr. Parsons, a member of Moderna's COVID-19 Specification Committee, testified that Moderna's "assertion as part of the proposed specification limits was that if those differences

were present, they would be present at an acceptable level," and explained that "[o]ur view was that they did not have a significant impact on quality or efficacy of the product . . . [o]r safety." Parsons 6/7/2024 Tr. 301:7-19. Dr. Parsons further testified that Moderna "set specifications based on our clinical experience and the process performance that is relevant to different critical quality attributes." *Id*. at 313:15-18. When setting its specifications, Moderna specifically intended to yield drug product comparable to the drug product used in the clinical trials (with the PVU target lipid molar ratio using 1.5 mol % conjugated lipid), and Moderna did so by examining the PEG lipid content across its various lots. *See, e.g.*, MRNA-GEN-00998152 (BLA Section 3.2.P.5.6 Justification of Specifications {0.10 mg/mL}) at -210-211 (Figures 34-35 describing distribution of PEG lipid content); MRNA-GEN-02634802 at -811. Lots within Moderna's specification could be—and were—sold as Moderna's COVID-19 vaccine and used to vaccinate the U.S. population, without any indication that the lots differed from each other in any substantial or meaningful way. The reason is simple—they did not differ in any substantial or meaningful way. This opinion is consistent with the opinions offered by Dr. Kimberly Benton. *See* Opening Expert Report of Kimberly A. Benton, Ph.D. Sec. V.

733. Additional evidence of the lack of substantial differences between the formulations of Moderna's specification-conforming COVID-19 drug product lots, including lots that that fall within the claimed conjugated lipid mol % ranges, can be found in its lack of testing of within-batch compositional heterogeneity. Moderna had strong reason to suspect that the lipid content of the mRNA-LNPs within its COVID-19 drug product batches varies, yet Moderna made the decision to avoid testing the intra-batch compositional heterogeneity because Moderna did "not believe that it was important to safety or efficacy." *Supra* ¶¶ 463, 672; MRNA-GEN-01274243 at -243. In my opinion, this evidence suggests that Moderna does not view mRNA-

LNPs [redacted] to be substantially different from mRNA-LNPs with 1.5 mol % (and up to 2.499 mol %) PEG lipid, or Moderna would have made it a higher priority to study this attribute.

734. Based on Moderna's own evidence, representations it has made in its own internal reports, to others (including the FDA), and in the circumstances of this case, and in view of the technology and state of the art, specification-conforming PVU Formulation lots are insubstantially different from specification-conforming v1 Formulation lots and are further insubstantially different from specification-conforming v2 Formulation lots, and the relative proportion of conjugated lipid within the three formulations performs substantially the same function, in substantially the same way, to achieve substantially the same results both relative to each other and relative to the conjugated lipid content limitations recited in the Lipid Composition Patents. As noted in the paragraphs above, this opinion is supported by: (a) evidence of Moderna's use of a target of 1.5 mol % conjugated lipid in its clinical and v1 commercial lots; (b) Moderna's lipid content specification ranges for its drug product, which are sufficiently broad to encompass and/or overlap substantially with the claimed conjugated lipid mol % limitations; and (c) Moderna's de-prioritization of studying the intra-batch lipid content heterogeneity of its COVID-19 vaccine drug product.

735. It is further my opinion that specification-conforming lots of Moderna's COVID-19 vaccine drug product produced within the same target formulation (*i.e.*, PVU lots as compared to other PVU lots; v1 lots as compared to other v1 lots; and v2 lots as compared to other v2 lots) are insubstantially different from one another and the conjugated lipid content of the mRNA-LNPs in these lots perform substantially the same function, in substantially the same way, to achieve substantially the same results both relative to each other and relative to the

conjugated lipid content limitations recited in the Lipid Composition Patents. To my knowledge, Moderna does not contend that lots produced with the same target molar ratio are substantially different from one another. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 11-57; Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. Further to my knowledge, Moderna has never asserted to the FDA, public, or otherwise, that lots of Moderna's COVID-19 drug product formulated with the same target lipid molar ratio substantially differ from each other in any respect by virtue of differences in the measured lipid ratio of the lots. To the contrary, as I have explained in detail above, Moderna has consistently maintained that all specification-conforming lots of its COVID-19 vaccine to be of comparable quality, including with respect to their safety, efficacy, and stability. Accordingly, the v1 lots that literally infringe the asserted claims (identified *supra* Section XIII.F.1), including the claimed conjugated lipid mol % limitations, are insubstantially different from those that do not infringe literally (if any), and the same is true for Moderna's v2 lots.

736. Additionally, it is my opinion that specification-conforming lots of Moderna's COVID-19 drug product produced within the same mRNA-1273 LNP part number (*e.g.*, lots falling within mRNA-1273 LNP part number 50075 lots as compared to other lots falling within that same part number 50075) are insubstantially different from one another and perform substantially the same function, in substantially the same way, to achieve substantially the same results. To my knowledge, Moderna does not contend that lots produced with the same mRNA-1273 LNP part number are substantially different from one another. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos.

1-10) (July 15, 2024) at 11-57 (July 15, 2024); Moderna's Fourth Supplemental Objections and Response to Plaintiffs' Third Set of Interrogatories (Nos. 12-17) (June 7, 2024) at 5-9. In fact, Moderna's treatment of its mRNA-1273 LNP part numbers would indicate that such part numbers are representative of versions of the drug product in which each lot within that version is viewed as equivalent to one another. *Supra* ¶ 355; *see also, e.g.*, MRNA-GEN-02615390 at -422-425 (demonstrating how each of Moderna's part numbers are associated with product specifications); D.I. 225 (The parties' Stipulation for samples testing in which Moderna agreed to a provision whereby "Moderna will not make any argument about the applicability of any test data generated by Plaintiffs from produced lots to other lots containing the same mRNA-LNP part number on the basis that such lots containing the same mRNA-LNP part number were not produced pursuant the parties' agreed-upon protocol"). Accordingly, the drug product lots manufactured using mRNA-1273 LNP part number 50075 that literally infringe the asserted claims (identified *supra* Section XIII.F.1), including the claimed conjugated lipid mol % limitations, are insubstantially different from the drug product lots manufactured using mRNA-1273 LNP part number 50075 that do not infringe literally (if any), and the same is true for all other drug product lots and corresponding mRNA-1273 LNP part numbers of Moderna's drug product.

737. **Hypothetical Claims.** As I describe above, I have been informed by counsel that an optional way of conducting the doctrine of equivalents analysis is to construct a "hypothetical claim" and assess whether the Accused Product would literally infringe that claim. *Supra* ¶ 45. In my opinion, such a "hypothetical claim" could recite, for example, an upper limit of 3 mol % (rather than 2 mol %) conjugated lipid. As I describe at length above in this section, Moderna concluded that there is no difference when the target amount of [redacted]

mol %. As further discussed at length above, mRNA-LNPs with 2-3 mol % conjugated lipid are insubstantially different from one another and perform substantially the same function, in substantially the same way, to achieve substantially the same results. Therefore, it is my opinion that a potential "hypothetical claim" would recite a nucleic acid-lipid particle where the upper limit on the amount of conjugated lipid is 3 mol %, rather than 2 mol %. For each Asserted Claim with a conjugated lipid mol % limitation, it is possible to assess which lots of Moderna's COVID-19 drug product would fall within the scope of the Asserted Claims having this hypothetical upper limited of 3 mol % conjugated lipid, based on their certificates of analysis.

738. Within this hypothetical claim framework, based on information currently available and known to me, I have identified lots of Moderna's COVID-19 drug product that would infringe based on a hypothetical claim with an upper limit of 3 mol % conjugated lipid, using appropriate rules of rounding and informed by Moderna's COA data. The table below indicates Appendices, on a claim-by-claim basis, which identify the infringing lots. For clarity, I have highlighted the hypothetical claim limitations.

Drug Product				
Patent Claim	**Lipid Molar Ratio Range**			**LDP Lot #**
'069 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 87
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	3.5	
'069 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 88
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	3.5	
'069 Patent, Claim 20	49.5	≤ SM-102 <	65.5	Appendix 89
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	9.5	
	0.45	≤ PEG2K-DMG <	3.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range**			**LDP Lot #**
'069 Patent, Claim 21	49.5	≤ SM-102 <	65.5	Appendix 90
	31.5	≤ Cholesterol <	36.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 91
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 7	49.5	≤ SM-102 <	60.5	Appendix 92
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 9	49.5	≤ SM-102 <	65.5	Appendix 93
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 94
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 11	49.5	≤ SM-102 <	65.5	Appendix 95
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 12	49.5	≤ SM-102 <	65.5	Appendix 96
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 13	49.5	≤ SM-102 <	65.5	Appendix 97
	29.5	≤ Cholesterol <	35.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 18	49.5	≤ SM-102 <	65.5	Appendix 98
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 1	49.5	≤ SM-102 <	65.5	Appendix 99
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range**			**LDP Lot #**
'668 Patent, Claim 8	49.5	≤ SM-102 <	60.5	Appendix 100
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 10	49.5	≤ SM-102 <	65.5	Appendix 101
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	35.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 15	49.5	≤ SM-102 <	65.5	Appendix 102
	N/A	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	3.5	
'435 Patent, Claim 7	49.5	≤ SM-102 <	85.5	Appendix 103
	12.5	≤ Non-Cationic <	49.55	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'435 Patent, Claim 8	49.5	≤ SM-102 <	85.5	Appendix 104
	12.5	≤ Non-Cationic <	49.55	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	
'378 Patent, Claim 1	N/A	≤ SM-102 <	N/A	Appendix 105
	29.5	≤ Non-Cationic <	55.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	3.5	
'378 Patent, Claims 2 and 13	N/A	≤ SM-102 <	N/A	Appendix 106
	29.5	≤ Non-Cationic <	55.5	
	24.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	3.5	
'378 Patent, Claims 7, 18, and 24	N/A	≤ SM-102 <	N/A	Appendix 107
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.05	≤ PEG2K-DMG <	3.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range**			**LDP Lot #**
'378 Patent, Claim 25	N/A	≤ SM-102 <	N/A	Appendix 108
	29.5	≤ Non-Cationic <	55.5	
	34.5	≤ Cholesterol <	45.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	

739. The exhibits recited in the above table assume a hypothetical claim limitation of 3 mol % conjugated lipid as an upper limit. However, applying the same analysis and calculation rubric, one may identify the batches that infringe with other hypothetical claims with upper limits of conjugated lipid that are slightly lower—for example, 2.5 mol %—which would be equivalent to claims having an upper limit of 2 mol %. One would simply need to take the exhibits listed in the previous paragraph and remove the batches with conjugated lipid amounts more than the aforementioned 2.5 mol% hypothetical claim (with appropriate rounding). Those alternative lists of batches are incorporated in my analysis and conclusions and I reserve the right to set forth such an analysis explicitly in the future.

* * *

740. In previous sections, I have set forth hypothetical claims related to cationic and non-cationic lipid. *Supra* ¶¶ 679, 707. Those hypothetical claims can also be applied together—for example, a hypothetical claim could include a lower limit on cationic lipid of 45 mol %, an upper limit of non-cationic lipid of 53 mol %, and an upper limit on conjugated lipid of 3 mol %. Below I have set forth a table that includes those three hypothetical claim limitations (which I have highlighted). Hypothetical claims using the other exemplary hypothetical claim limitations set forth in this report with respect to the cationic lipid, the non-cationic lipid, and the conjugated lipid would be infringed under the same analysis, and I reserve the right to testify about those

hypothetical claims and the resulting infringement, even though I do not set forth each such permutation in a separate table and associated appendices.

Drug Product				
Patent Claim	**Lipid Molar Ratio Range [%]**			**LDP Lot #**
'069 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 109
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	3.5	
'069 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 110
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	10.5	
	0.5	≤ PEG2K-DMG <	3.5	
'069 Patent, Claim 20	44.5	≤ SM-102 <	65.5	Appendix 111
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	9.5	
	0.45	≤ PEG2K-DMG <	3.5	
'069 Patent, Claim 21	44.5	≤ SM-102 <	65.5	Appendix 112
	31.5	≤ Cholesterol <	36.5	
	3.5	≤ DSPC <	10.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 113
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 7	44.5	≤ SM-102 <	60.5	Appendix 114
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 9	44.5	≤ SM-102 <	65.5	Appendix 115
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'359 Patent, Claim 10	44.5	≤ SM-102 <	65.5	Appendix 116
	29.5	≤ Cholesterol <	40.5	
	3.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 11	44.5	≤ SM-102 <	65.5	Appendix 117
	29.5	≤ Cholesterol <	40.5	
	4.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	3.5	

Drug Product				
Patent Claim	**Lipid Molar Ratio Range [%]**			**LDP Lot #**
'359 Patent, Claim 12	44.5	≤ SM-102 <	65.5	Appendix 118
	29.5	≤ Cholesterol <	40.5	
	5.5	≤ DSPC <	12.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 13	44.5	≤ SM-102 <	65.5	Appendix 119
	29.5	≤ Cholesterol <	35.5	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'359 Patent, Claim 18	44.5	≤ SM-102 <	65.5	Appendix 120
	29.5	≤ Cholesterol <	40.5	
	2.5	≤ DSPC <	15.5	
	0.5	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 121
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 8	44.5	≤ SM-102 <	60.5	Appendix 122
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 10	44.5	≤ SM-102 <	65.5	Appendix 123
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	35.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	
'668 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 124
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	3.5	
'435 Patent, Claim 7	44.5	≤ SM-102 <	85.5	Appendix 125
	12.5	≤ Non-Cationic <	53.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	3.5	
'435 Patent, Claim 8	44.5	≤ SM-102 <	85.5	Appendix 126
	12.5	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	3.5	

Patent Claim	Lipid Molar Ratio Range			[redacted]
'668 Patent, Claim 1	44.5	≤ SM-102 <	65.5	Appendix 127
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 8	44.5	≤ SM-102 <	60.5	Appendix 128
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	
'668 Patent, Claim 15	44.5	≤ SM-102 <	65.5	Appendix 129
	N/A	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.5	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 7	44.5	≤ SM-102 <	85.5	Appendix 130
	12.5	≤ Non-Cationic <	53.5	
	N/A	≤ Cholesterol <	N/A	
	2.5	≤ DSPC <	15.5	
	0.45	≤ PEG2K-DMG <	2.5	
'435 Patent, Claim 8	44.5	≤ SM-102 <	85.5	Appendix 131
	12.5	≤ Non-Cationic <	53.5	
	29.5	≤ Cholesterol <	40.5	
	N/A	≤ DSPC <	N/A	
	0.45	≤ PEG2K-DMG <	2.5	

741. Additionally, I have been asked by counsel to prepare a table listing on a claim-by-claim basis the lots that would infringe based on Moderna COA data under both a literal infringement analysis, *supra* Section XIII.F.1, or the doctrine-of-equivalents above, *supra* Sections XIII.F.2.a ("Cationic"), XIII.F.2.b ("Non-Cationic"), XIII.F.2.c ("Conjugated Lipid"), ¶ 740 (combined), and including my literal infringement analysis for the '651 patent, *supra* Section XII.F. I have supplied this table in **Appendix 132**. For the purpose of Appendix 132, I have applied each of my analyses under the doctrine of equivalents to all of the lipid molar ratios in all of the asserted claims of the Lipid Composition Patents, even if under my analysis the

above ranges would be the same as under a literal analysis. For example, my analysis under the doctrine of equivalents for the cationic lipid for claim 1 of the '378 patent would be the same as for literal infringement because claim 1 of the '378 does not contain a cationic lipid molar ratio range. Likewise, Appendix 132 also applies the combined doctrine-of-infringement analysis to claims that do not contain more than one limitation at issue and for which the combined doctrine-of-equivalents analysis would be same as the analysis for single limitation, such as for claim 1 of the '378 patent, for which I have only applied the doctrine of equivalents for the conjugated lipid.

G. Serum Stability ('069 patent, claim 16)

742. Claim 16 of the '069 patent recites, "wherein the nucleic acid in the nucleic acid-lipid particle is not substantially degraded after incubation of the particle in serum at 37° C. for 30 minutes."

743. As I explain above, Moderna's documents make clear that the LNPs of the Accused Product protect the mRNA payload from degradation. *Supra* Section X.F; MRNA-GEN-00177803 at -805 ("Encapsulated mRNA is protected from nucleolytic degradation in biological fluids . . . ."). For example, Moderna's pharmacokinetic study using "an LNP of the same composition" indicated that the T_{max} of the mRNA construct was 2 hours. MRNA-GEN-00089706 at -708 ("After a single IM dose in male rats, the time after dosing at which the maximum concentration was observed in plasma (T_{max}) was 2 hours for all constructs and was followed by a rapid elimination phase, with a half-life ($T_{1/2}$) estimated to range from 2.7 to 3.8 hours."). As such, it is my opinion that the mRNA in Moderna's Accused Product is not substantially degraded after incubation of the particle in serum at 37° C for 30 minutes.

744. In its interrogatory response regarding infringement of the Lipid Composition Patents, Moderna does not dispute that the Accused Product would infringe this limitation. *See*

Additionally, encapsulation of the mRNA in a lipid particle of appropriate composition is critical to cellular uptake of the nanoparticle, endosomal escape, and ultimately productive cytosolic display of the mRNA such that protein translation may occur."). Therefore, the use of Moderna's COVID-19 vaccine is a method for introducing a nucleic acid into a cell, comprising contacting the cell with a nucleic acid-lipid particle. It is also a method for the in vivo delivery of a nucleic acid, comprising administering to a mammalian subject a nucleic acid-lipid particle.

758. In its interrogatory response regarding infringement of the Lipid Composition Patents, Moderna does not dispute that the Accused Product would infringe these limitations. *See* Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 15-57.

XIV. INDIRECT INFRINGEMENT

759. As discussed above, *supra* Section III.B.2, I have been informed by counsel that indirect infringement requires someone to have directly infringed the Patents-in-Suit. I understand that a party is liable for indirect infringement if it actively induced, encouraged, or materially contributed to the infringing activity. I understand that indirect infringement occurs through induced or contributory infringement.

760. I understand that Moderna's only contention concerning Moderna's indirect infringement of the Patents-in-Suit is that "Liability under each of §§ 271(b) and (c) requires a finding of direct infringement," and because Moderna contends that "the Accused Products do not, and will not, directly infringe the Asserted Patents," there is no indirect infringement. Moderna's Corrected Sixteenth Supplemental Objections and Responses to Plaintiffs' First Set of Interrogatories (Nos. 1-10) (July 15, 2024) at 34. As noted above with respect to each of the Asserted Claims, I disagree with Moderna's position that it does not directly infringe the Asserted Claims.

A. Induced Infringement (35 U.S.C. § 271(b))

761. I understand that the accused infringer is liable for induced infringement if the accused infringer actively induced a third party to directly infringe the asserted patent claim literally or under the doctrine of equivalents, pursuant to 35 U.S.C. § 271(b). As with direct infringement, I have been informed that induced infringement is determined on a claim-by-claim basis.

762. I further have been informed by counsel that the alleged infringer is liable for active inducement of a claim if the patentee proves by a preponderance of the evidence that (1) the induced acts carried out by a third party infringe the asserted claim, (2) the alleged infringer took action during the time the patent was in force that was intended to cause and led to the infringing acts by the third party, and (3) the alleged infringer was aware of the asserted patent and knew that the acts of the third party, if taken, would constitute infringement of the patent.

763. Moderna's actions were intended to, and did, cause and result in the direct infringement of the patent by third parties, including patient-users and healthcare providers. As discussed below, doses of Moderna's COVID-19 vaccine were provided for the specific purpose of administration to individuals. *See infra* ¶ 777. As noted above with respect to each of the Asserted Claims, *supra* Sections XII, XIII, the use of Moderna's Accused Product—whether by administering, distributing, or taking other actions—infringes each limitation of the Asserted Claims.

764. Moderna intentionally acted and encouraged other third parties to use and/or make the Accused Product in such a manner that it directly infringed the Patents-in-Suit.

765. For example, Moderna intentionally encouraged doctors and other healthcare professionals to administer the COVID-19 vaccine through the use of labeling on packages of Moderna's COVID-19 vaccine, through package inserts and through prescribing information.

For example, Moderna's Prescribing Information, revised as of April 2024 and included as a package insert with Moderna's COVID-19 vaccine provides instructions for the administration of the COVID-19 vaccine:

> **2.2 Administration**
>
> Administer SPIKEVAX intramuscularly.
>
> **2.3 Dosing and Schedule**
>
> SPIKEVAX is administered as a single 0.5 mL dose.
>
> For individuals previously vaccinated with any COVID-19 vaccine, administer the dose of SPIKEVAX at least 2 months after the last dose of COVID-19 vaccine.

MRNA-GEN-02659606 at -608; *see also* MRNA-GEN-00048298 (SPIKEVAX® 7.5 mL label); MRNA-GEN-00050284 (SPIKEVAX® package insert revised January 2022), at -295 ("The nucleoside-modified mRNA in SPIKEVAX is encapsulated in lipid particles, which enable delivery of the nucleoside-modified mRNA into host cells to allow expression of the SARS-CoV-2 S antigen. The vaccine elicits an immune response to the S antigen, which protects against COVID-19."); MRNA-GEN-00050284 at -284 ("Highlights of Prescribing Information" stating that "SPIKEVAX is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age and older" and it is "[f]or intramuscular injection only. SPIKEVAX is administered intramuscularly as a series of two doses (0.5 mL each) one month apart. (2.3)").

766. Similarly, Moderna's insert for "Information for Recipients and Caregivers" includes the following language:

What is SPIKEVAX?
SPIKEVAX is a vaccine to help protect you against COVID-19. SPIKEVAX is for people 18 years of age and older. Vaccination with SPIKEVAX may not protect all people who receive the vaccine.

MRNA-GEN-00050318; *see also* MRNA-GEN-00050284 at -285 ("SPIKEVAX is a vaccine indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 18 years of age or older.").

767. Moderna has also intentionally and actively engaged in marketing campaigns and promoted its vaccine to the public, in order to encourage individuals to use and administer Moderna's COVID-19 vaccine. For example, Moderna has engaged in national marketing campaigns with the objective to "increase vaccine consideration and get audience to vaccinate by promoting vaccine confidence." MRNA-GEN-01355377 at -379. Separately, Moderna has engaged in marketing campaigns targeting health care providers to promote Moderna's COVID-19 vaccine. *E.g.*, MRNA-GEN-01355857.

768. Further, the distribution data that Moderna has produced in this case sets forth that Moderna shipped, or caused its contractors to ship, Moderna's COVID-19 vaccine to third parties who were the intended vaccination partners. *E.g.,* MRNA-GEN-00939821 (worksheet titled "Distribution"). Indeed, Moderna's corporate witness regarding this distribution data testified that portions of the distribution data were received from Moderna's "third-party logistics provider McKesson RXC," and that "McKesson RXC is actually the entity who is shipping the vaccine ***on behalf of Moderna***." Thomas 5/23/2024 Tr. 25:8-26:2 (emphasis added).

769. As these documents and testimony show, Moderna actively encouraged third parties to administer and or use the COVID-19 Vaccine.

770. Moderna knew that the acts that the third parties engaged in would infringe the Patents-in-Suit. As described elsewhere in my report, *supra* Section VIII.C, *infra* Section XVIII, Moderna was aware that the Accused Product infringed the Patents-in-Suit.

771. Moderna was aware of the Patents-in-Suit. Moderna first learned about Plaintiffs' LNP technology from Tony de Fougerolles, "an early, early employee" at Moderna, who "was quite familiar with the patents-in-suit" from his prior work at Alnylam. Francis 5/22/2024 Tr. 40:3-41:9, 63:18-64:6 ("As I mentioned, our chief scientific officer, Tony [de Fougerolles], came from Alnylam, which had an active collaboration with Tekmira. So he is aware – he should have – he must have been aware at that time of Tekmira's [LNP] portfolios."). Moreover, as noted above, I understand that Moderna challenged two of the Patents-in-Suit—the '069 and '435 patents—via *inter partes* review proceedings. *Supra* Section VIII.C. Moderna repeatedly referenced wanting to avoid intellectual property, which appears to be a reference to Plaintiffs' Lipid Composition Patents. *See infra* Section XVIII.A.

B. Contributory Infringement (35 U.S.C. § 271(c))

772. I have been informed by counsel that contributory infringement constitutes offering to sell or selling an item that is a material component of the patented invention, so that the buyer directly infringes the patent. I understand that to be a contributory infringer, the alleged infringer must know that the part being offered or sold is designed specifically for infringing the patented invention and is not a component suitable for non-infringing uses. I understand that to establish contributory infringement, the patentee must show that the alleged infringer (1) sold or offered to sell a component of the Accused Product; (2) the component is a material part of the invention; (3) the component is not a staple article of commerce capable of substantial non-infringing use; and (4) the alleged infringer had knowledge of the asserted patent and knowledge that the component was especially made or adapted for use in an infringing

manner. 35 U.S.C. § 271(c). I have been informed that a "staple article of commerce capable of substantial non-infringing use" is a component that has uses other than as a component of the patented product, and that such uses are not unusual, farfetched, illusory, impractical, or experimental.. I understand that, as with direct infringement, contributory infringement is determined on a claim-by-claim basis.

773. Moderna supplied or caused to be supplied the components that are an important component part of the invention of the Patents-in-Suit. For example, Moderna supplied the [redacted], to its contracted manufacturing organizations for further manufacture into the Accused Product. *Supra* Section X.B. Moderna further supplied the mRNA-1273 RNA to its contracted manufacturing organizations for further manufacture into the Accused Product. *Supra* Section X.B.

774. Moreover, Moderna's witness has testified that "[t]he lipid nanoparticle is an important part of . . . the vaccine mechanism of action." Parsons 6/7/2024 Tr. 389:4-6.

775. Further, Moderna's [redacted] is a product component that is especially made or especially adapted for use in Moderna's COVID-19 vaccine, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. For example, I understand that Moderna does not commercially sell its [redacted]. Moreover, as described above, there is no substantial use for Moderna's [redacted], outside of its use in Moderna's COVID-19 vaccine.[154]

[154] I understand that Moderna recently launched its second commercial product, mRESVIA, an RSV vaccine. The launch of mRESVIA does not affect my analysis, since the acts of infringement accused here pre-date that launch. Moreover, Moderna has not argued mRESVIA affects the analysis of substantial non-infringing uses, and I have not had the benefit of necessary discovery to evaluate the makeup of mRESVIA.

776. Moderna's mRNA-1273 RNA is also a component supplied by Moderna that is especially made or especially adapted for use in the Moderna's COVID-19 vaccine, and is not a staple article or commodity of commerce suitable for substantial noninfringing use. There is no substantial use for Moderna's mRNA-1273 RNA, outside of its use in Moderna's COVID-19 vaccine, which infringes each of the Asserted Claims of the Patents-in-Suit, since the mRNA payload in Moderna's COVID-19 vaccine is a unique mRNA sequence that "encodes for the pre-fusion stabilized Spike glycoprotein of the 2019-novel Coronavirus (SARS-CoV-2)." MRNA-GEN-02636425 at -425.

777. Moderna knew that the [redacted] and mRNA-1273 RNA components that it supplied were especially made or adapted for uses that would infringe the Patents-in-Suit. For example, Moderna manufactured those components with the knowledge that they would be combined in a manner that infringed the Patents-in-Suit, and indeed, it intended that result. Moderna also manufactured and distributed its COVID-19 vaccine with the intent that it be used by and administered to the public. Moderna's witnesses repeatedly stated that they understood and intended that Moderna's COVID-19 vaccine would be administered to individuals. For example, Moderna's designated corporate witness regarding the benefits of the Accused Product testified that "[t]hese vaccines are intended to be broadly available to the public . . . ." Bennett 5/20/2024 Tr. 353:1-10. Mr. Al Thomas further testified that as part of his role at Moderna, he was brought on in 2020 "to help Moderna prepare for a large-scale national deployment of the vaccine." Thomas 5/23/2024 Tr. 32:2-5. He further testified that "Moderna would provide vaccine to the U.S. government distribution hubs. The U.S. government would then distribute to the vaccination sites. My communication [sic] were to the potential vaccination site so that they would begin to be prepared." Thomas 5/23/2024 Tr. 32:19-33:2. In other words, Moderna's

witnesses have made clear that Moderna both intended for its product to be administered and distributed by these other parties, and Moderna provided assistance to these parties in doing so. As described above, the administration of Moderna's COVID-19 vaccine to third parties is an act that infringes the Patents-in-Suit. *Supra* Sections XIII.J, XIV.

778. Moderna's contracted manufacturers also—at Moderna's direction and with Moderna's knowledge— infringed the Patents-in-Suit by using these components. As I have already described, *see supra* Section X.A, Moderna manufactures its COVID-19 vaccine using both mRNA-1273 RNA and [redacted]. Moderna's Process Validation Master Plan ("PVMP") for mRNA-1273, lays out four processes during Moderna's manufacture of mRNA-1273. MRNA-GEN-02615390 at -398-399. [redacted] *See* MRNA-GEN-02615390 at -398-399. Each of these steps are completed at Moderna's own facilities, or at CMOs, which I understand are either in the United States or abroad. MRNA-GEN-02615390 at -399. For example, Moderna's PVMP identifies the following CMOs at which batches of mRNA-1273 or its components were made for commercial manufacturing capabilities:

- Lonza Biologics, Inc (Lonza Portsmouth, NH);
- Lonza AG (Lonza Visp, Switzerland);
- Catalent Indiana LLC (Catalent Bloomington, IN);
- Rovi San Sebastian de Los Reyes (Rovi SSRR) (Madrid, Spain);
- Baxter (Bloomington, IN);
- Recipharm (Monts, France);

- Samsung (Incheon South Korea);
- Patheon Manufacturing Services LLC (Greenville, NC);
- Thermo Fisher Monza (IT); and
- Thermo Fisher Ferentino (IT).

MRNA-GEN-02615390 at -400. Moderna knew that these steps taken at its direction would infringe the Patents-in-Suit. *See infra* Section XVIII.

779. Further, I understand from the spreadsheets and distribution data that Moderna has produced in this case that Moderna, or its contractors, shipped Moderna's COVID-19 vaccine to third parties who were the intended vaccination partners. *E.g.,* MRNA-GEN-00939821 (worksheet titled "Distribution"). Moderna's corporate witness regarding this distribution data testified that portions of the distribution data were received from Moderna's "third-party logistics provider McKesson RXC," and that "McKesson RXC is actually the entity who is shipping the vaccine on behalf of Moderna." Thomas 5/23/2024 Tr. 25:8-26:2.

780. Moderna's COVID-19 vaccine, and the components that Moderna supplied in the U.S. are not staple articles, and do not have a substantial non-infringing use.

781. As stated above, Moderna was aware of the Patents-in-Suit. Moderna first learned about Plaintiffs' LNP technology from Tony de Fougerolles, "an early, early employee" at Moderna, who "was quite familiar with the patents-in-suit" from his prior work at Alnylam. Francis 5/22/2024 Tr. 40:3-41:9; Francis 5/22/2024 Tr. 63:18-64:6 ("As I mentioned, our chief scientific officer, Tony [de Fougerolles], came from Alnylam, which had an active collaboration with Tekmira. So he is aware – he should have – he must have been aware at that time of Tekmira's [LNP] portfolio."). Moreover, as noted above, I understand that Moderna challenged two of the Patents-in-Suit—the '069 and '435 patents—via *inter partes* review proceedings.

Supra Section VIII.C. In addition, as discussed above, Moderna noted Plaintiffs and their IP regularly throughout Moderna's early development work and reformulation efforts. *Supra* Sections IX.A, IX.B, IX.C.

818. With respect to Section 271(f)(2), as I describe above, some batches of the Accused Product contain mRNA-1273 RNA and/or [redacted] that was supplied from the United States. As described above, [redacted] and mRNA-1273 RNA are components that were especially made or adapted for use in the Accused Product and are not capable of substantial non-infringing uses. At Moderna's direction, one or more of these components of the Accused Product were supplied outside the United States and then combined in a manner that, if it had occurred in the United States, would have infringed the Patents-in-Suit as described in Sections XII and XIII, *supra.* As described in Section XVIII, *infra*, Moderna knew that this combination it directed was covered by the Patents-in-Suit and knew that the combination it directed would be infringing if it occurred in the United States.

XVIII. WILLFULNESS

819. I have been asked to provide opinions related to the willfulness of Moderna's infringement of the Patents-in-Suit. I set forth my understanding of the legal standard for willful infringement above. *Supra* Section III.B.5. In view of the below evidence, it is my opinion that Moderna willfully infringed the Asserted Claims of the Patents-in-Suit.

A. Moderna was aware of the Patents-in-Suit.

820. Moderna first learned about Plaintiffs' LNP technology from Tony de Fougerolles, "an early, early employee" at Moderna, who "was quite familiar with the patents-in-suit" from his prior work at Alnylam. Francis 5/22/2024 Tr. 40:3-41:9, 63:18-64:6 ("As I mentioned, our chief scientific officer, Tony [de Fougerolles], came from Alnylam, which had an active collaboration with Tekmira. So he is aware – he should have – he must have been aware at that time of Tekmira's [LNP] portfolio."). De Fougerolles started Moderna's LNP program. *See* MRNA-GEN-01737721 at -722. Starting from this early time period, Moderna was aware of Plaintiffs' work. *See* MRNA-GEN-01759821 (February 2013 email from Dr. Whorinskey

stating that she "blinded[] delivery vehicle[] slide 15[] as it will just make them mad/turned off to us otherwise" and that "[t]his way we can . . . leave them wondering if it is ***theirs*** . . ." (emphasis added)); MRNA-GEN-01674430 (October 2014 email from Stéphane Bancel commenting on Moderna's "monkey data with his [] LNP," referencing Tekmira's Paul Brennan.). Beginning in or about the 2013, 2014 timeframe, Moderna's Chief Business Office, Said Francis, testified that he had at least 5 discussions with Moderna's lawyers "about Tekmira's LNP patents." Francis 5/22/2024 Tr. 145:4-146:9. Moreover, I understand that, in April 2014, Moderna discussed and was advised that Tekmira was "the inventor of the original formulation with MC3 . . . they call it SNALP [stable-nucleic acid lipid particle] technology[]." MRNA-GEN-01754010 at -011; Francis 5/22/2024 Tr. 138:18-140:1 ("Q. So you were satisfied that you could get a license to that LNP technology of Tekmira's that you needed here through Alnylam as opposed [to] through Tekmira itself? A. I disagree with that statement. I did not say that."). Moderna referred to Tekmira's LNP as a "[v]alidated LNP formulation," and Tekmira "as the RNA industry gold standard" including for mRNA. MRNA-GEN-01240180 at -190-191; Francis 5/22/2024 Tr. 195:4-9. Moreover, the first contact between Moderna and Tekmira was "2012, early 2013." Francis 5/22/2024 Tr. 46:7-16. Since then, Moderna and Genevant (and its predecessors) "explor[ed] collaborations, and that includes licensing." Francis 5/22/2024 Tr. 46:17-47:22. Moderna spent about ten years discussing a license with Genevant (and its predecessors) for the Patents-in-Suit. Bancel 6/28/2024 Tr. 141:12-143:10. Moreover, one of Moderna's "2017 Platform objectives" was: "Fix backward risk balance . . . LNP/Abus." MRNA-GEN-01503761; Hoge 5/22/2024 Tr. 320:19-322:18.

821. Moderna's documents and testimony make clear that it was aware of the Lipid Composition Patents. *See, e.g.*, Parsons 6/7/2024 Tr. 26:16-20 ("We were aware that there were

some – there was intellectual property around lipid molar ratios, and we wanted to avoid infringing that if that was possible to do."), 28:13-19 ("Q. How did the objective of trying to avoid intellectual property inform the development efforts with respect to the CMV product? A. Only to the extent that if we could satisfy all of our other technical objectives, we would not infringe."), 106:1-6 [redacted] MRNA-GEN-01747429 at -431 ("Avoid licensing (intellectual property regarding 50 mole percent cationic lipid)"); MRNA-GEN-00587058 at -068-069; MRNA-GEN-00657578 at -578 ("the lipid content of this product is being adjusted slightly to reduce the mole% of SM-102 to below 50% for IP purposes."); MRNA-GEN-01264023 at -023 (2018 Email correspondence noting that the lipid composition used by Moderna was "virtually identical" to Patisiran); Kramarczyk 4/30/2024 Tr. 60:4-8 ("At the time I understood that 50 mole percent cationic lipid was covered under a granted patent, not by Moderna. And I think the goal of avoiding licensing a patented formulation is clear."). Additionally, Moderna challenged two of the Lipid Composition Patents in IPR proceedings. *Supra* Section VIII.C. During those challenges, Moderna submitted a declaration explaining that the "stated lipid ratios" based on the "batch specifications" for another program would "overlap with the claimed molar ratio ranges in [the] '435 patent." Ryan Declaration ¶ 5; *supra* ¶ 361.

822. Moreover, Moderna was aware of the Lipid Composition Patents and the subject matter they cover, as evidenced by, for example, references to the '069 Patent and related applications during examination of Moderna's own patents. For example, Moderna's patent, U.S. Patent No. 9,271,996, filed on May 18, 2013, as U.S. application number 13/897,371 and

issued on March 1, 2016, cited to the '069 patent. *See, e.g.*, U.S. Patent No. 9,271,996, at [56] (filed May 18, 2013) (citing *e.g.*, '069 Patent; U.S. Patent Application Serial No. 14/0065228).

B. Moderna tried and failed to design around the Lipid Composition Patents.

823. Moderna failed to design around the Lipid Composition Patents. As I describe above, Moderna's President, Stephen Hoge, directed his technical team to explore compositions having only 40 mol % cationic lipid in view of "incredibly strong business reasons" for why such a composition would be preferable, reflecting what Moderna understood was needed to design around the Lipid Composition Patents. *Supra* ¶ 302. [redacted] and ultimately used the target v1 and v2 Formulations, having target cationic lipid ratios of 48.5 mol % and 48 mol %, respectively. *Supra* Section X.D.

C. Moderna copied the Lipid Composition Patents.

824. As I explain above, I understand that evidence that an infringer intentionally copied the patentee's patented technology in developing the accused product is relevant to willfulness. *Supra* ¶ 48. Moderna's entire "platform" was built on its copying of the 50:38.5:10:1.5 (ionizable lipid:cholesterol:phospholipid:PEG-lipid) formulation, which it used in numerous successful clinical programs over the years, *supra* Section IX.A, including the COVID-19 PVU Formulation, *supra* Section X.D.1. Moderna's documents make clear that Moderna did not develop that formulation itself, but rather copied it from Plaintiffs' work. *See, e.g.*, *supra* Section IX.A; *supra* ¶¶ 223-225, 238-245. Moderna's subsequent v1 and v2 Formulations are only minor modifications that still infringe the Lipid Compositions and were intentionally designed to produce the same results as Plaintiffs' 50:38.5:10:1.5 formulation. *See*

supra Sections X.D.2, X.D.3, XIII.F.2; *see also* MRNA-GEN-01156478 at -527 (Moderna stating that its "Phase 2 study" of CMV mRNA-1647, which I understand to use the same target ratio as the v2 Formulation, "contains the ***same lipid nanoparticle ("LNP")*** used in the Phase 1 study," which I understand to use the same target ratios as the PVU Formulation (emphasis added)). An October 2018 Moderna development presentation for the CMV vaccine reflects that Moderna used a 50 mol % ionizable lipid formulation—which fell within the range claimed by Plaintiffs' patented LNP technology—for its Phase 1 study, and that Moderna was planning to change the molar ratio that it used in Phase 2. *See* MRNA-GEN-00646562 at -563, -574. In that presentation, Moderna identified the "[b]enefit" of using a 48 mol % cationic lipid as "IP and Stability." *See* MRNA-GEN-00646562 at -574. When asked at his deposition about the "IP benefits" referenced in the presentation, Dr. Parsons testified that "we were generally aware that there were – there was intellectual property out there which claimed 50 percent mol ratio of the ionizable lipid," and that Moderna was [redacted] Parsons 6/7/2024 Tr. 90:18-91:9, 93:8-12. However, as I state above, such a minor modification in a formulation would still infringe the Lipid Composition Patents.

D. Moderna's own lipid content testing of the Accused Product demonstrated infringement of the Lipid Composition Patents.

825. Moderna's own testing demonstrated the fact that its [redacted] *Supra* ¶ 600;

MRNA-GEN-00530699 at -701. [redacted] *Supra* Section IX.E; MRNA-GEN-00896095 (2019 Q4 Process and Product Consistency Whitepaper) at -095 ("Heterogeneity can be easily categorized into two general bins of "Bulk Heterogeneity" and "Particle Heterogeneity" (Figure 1)."). [redacted] *Supra* Section X.E.2. I note that one of Moderna's analytical scientists proposed to conduct more extensive heterogeneity testing on the COVID-19 vaccine, but Dr. Parsons appears to have refused to let those experiments occur, due to the "uncomfortable questions" they could have posed. *Supra* ¶ 463. Finally, Moderna's own data (*e.g.*, its certificates of analysis) indicate that it infringes the Patents-in-Suit. *Supra* Section XIII.F. Moderna's corporate witness testified that Moderna had calculated the mol % of "a few lots" of its COVID-19 vaccine, which did show lipid content variability. Parsons 6/7/2024 Tr. 103:1-104:20. To the extent Moderna would have done that calculation on all of its COVID-19 lots—which it plainly knew how to do—Moderna would have understood that it was, in fact, infringing the Lipid Composition Patents. Likewise, Moderna knew or should have known that it would infringe the '651 patent, in view of its encapsulation specification and data. *Supra* Section XII.

E. Moderna attempted to avoid public disclosure of the lipid ratios and components used in its formulations, reflecting Moderna's understanding

that it infringed the Lipid Composition Patents and its desire to hide that fact.

826. Moderna appears to have attempted to conceal its infringement of the Lipid Composition Patents. For example, Dr. Hassett was instructed to remove the target lipid molar ratio of the LNPs used in one of her papers for Moderna. MRNA-GEN-01602947 at -948 (email from Edward Miracco stating, "We don't want to publish the ratio"). Along similar lines, Dr. Benenato—seemingly at the direction of Dr. Hoge—modified scientific presentations to obscure the role that MC3 played in Moderna's development of its ionizable lipids. MRNA-GEN-01430937 ("I know it is hard as a chemist but we have to fib a bit and not tell the whole structure story. The slides look great, . . . but I think you need to take out the mc3 part of the story."); Benenato 5/17/2024 Tr. 20:19-31:3; *compare* MRNA-GEN-01430930 (original slides), *with* MRNA-GEN-01430946 (edited slides); MRNA-GEN-01746643 (June 2019 Email chain including Email from Stephen Hoge) at -645 ("I'd prefer if we didn't have MC3 explicitly labeled in any of our data slides.").

827. Similarly, Moderna's Director of Vaccine Access and Partnerships, Hamilton Bennett, edited documents so as to remove reference to the lipid molar ratio of Moderna's Accused Product. For example, she edited documents that were provided to the U.S. Government so as ensure that the composition of Moderna's LNP was not posted publicly. *See* MRNA-GEN-01084500 at -528; Bennett 5/20/2024 Tr. 293:13-297:8. Similarly, she informed colleagues at the NIH that "we need to redact the formulation" before distributing them publicly. MRNA-GEN-01115170 at-170. Similarly, in a draft report for the European Medicines Agency, Don Parsons commented on the portion of text with the molar ratio 48.5:38.9:11.1:1.5, stating "Remove if not publicly disclosed." MRNA-GEN-02407201 at -251. It appears that the molar ratio as well as the statement that their ratio is "very similar to optimal ratios reported in the

literature" were removed from the final report. *Compare* MRNA-GEN-02407201 at -251, *with* MRNA-GEN-00680127 at -152.

828. In contrast to Moderna's redactions and decisions not to disclose the molar ratio of its COVID-19 vaccine, I understand that Pfizer has publicly disclosed the molar ratio of its COMIRNATY vaccine. For example, Pfizer's Fact Sheet for Healthcare Providers for its COVID-19 vaccine specifies the quantity of each of the four lipid components of its vaccine, as follows:

> Each 0.3 mL dose of COMIRNATY also includes the following ingredients:
> lipids (0.43 mg ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate),
> 0.05 mg 2-(polyethylene glycol 2000)-N,N-ditetradecylacetamide,
> 0.09 mg 1,2-distearoyl-sn-glycero-3-phosphocholine, and 0.19 mg cholesterol), 0.06 mg tromethamine,
> 0.4 mg tromethamine hydrochloride, and 31 mg sucrose.

https://www.fda.gov/media/151707/download?attachment at p. 20-21 (Section 11 – Description).

829. Moderna's Fact Sheet for Healthcare Providers for its COVID-19 vaccine does not specify the same information. Instead, Moderna's Fact Sheet simply provides the combined lipid content for all four lipids in the COVID-19 vaccine, as follows:

> Each dose of the Moderna COVID-19 Vaccine contains the following ingredients: a total lipid content of 1.93 mg (SM-102, polyethylene glycol [PEG] 2000 dimyristoyl glycerol [DMG], cholesterol, and 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC]), 0.31 mg tromethamine, 1.18 mg tromethamine hydrochloride, 0.043 mg acetic acid, 0.20 mg sodium acetate trihydrate, and 43.5 mg sucrose.

MRNA-GEN-01206800 at -819.

830. The contrast between Moderna's and Pfizer's conduct shows that Moderna's explanation that it did not want to disclose the relevant details of its product for confidentiality reasons was nothing more than pretext.

831. In addition, I understand that in or around March 2021, in response to Moderna's contention that its COVID-19 vaccine did not infringe the Patents-in-Suit, Plaintiffs asked

Moderna to provide "any mRNA-1273 samples that cannot be used in humans" to assess Moderna's claim. GENV-00247327 at -329. Moderna did not agree to provide samples at that time. *Id.* at -328; *see also* D.I. 1 (Plaintiffs' Original Complaint for Patent Infringement) ¶ 61.

XIX. MODERNA'S MRNA-LNP COLLABORATION AGREEMENTS

832. [redacted]

833. [redacted]