IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACUITAS THERAPEUTICS INC., Plaintiff, v. GLAXOSMITHKLINE BIOLOGICALS SA AND GLAXOSMITHKLINE LLC, Defendants.	)	C.A. No.: _____ **JURY TRIAL DEMANDED** [redacted] **REDACTED - PUBLIC VERSION FILED JANUARY 3, 2025**

COMPLAINT FOR DECLARATORY JUDGMENT OF NON-INFRINGEMENT AND INVALIDITY

Plaintiff Acuitas Therapeutics Inc. ("Acuitas"), for its Complaint against Defendants GlaxoSmithKline Biologicals SA ("GSK Biologicals") and GlaxoSmithKline LLC ("GSK LLC") (collectively, "GSK" or "Defendants"), alleges as follows:

NATURE OF THE ACTION

1. Through this action, Acuitas seeks a declaratory judgment that the leading COVID-19 vaccine, sold under the name Comirnaty®, does not infringe U.S. Patent Nos. 11,638,693 (the "'693 Patent"), 11,638,694 (the "'694 Patent"), 11,666,534 (the "'534 Patent"), 11,766,401 (the "'401 Patent"), and 11,786,467 (the "'467 Patent") (collectively, the "Patents-in-Suit"), which are attached to this Complaint as **Exhibits A–E**, respectively. Acuitas also seeks a declaratory judgment finding each of the Patents-in-Suit is invalid.

2. This declaratory judgment action arises as a result of threats that Acuitas faces from GSK's patent infringement lawsuit against its customers and partners BioNTech and Pfizer for their sales of the COVID-19 vaccine Comirnaty®. *See GlaxoSmithKline Biologicals SA v. Pfizer, Inc.*, C.A. No. 24-512, D.I. 26, ¶ 8 (First Amended Complaint) (D. Del. August 14, 2024) ("GSK Amended Complaint").

3. Comirnaty® is an mRNA COVID-19 vaccine, which is the result of a joint development effort between BioNTech, its partner Pfizer, and Plaintiff Acuitas. Comirnaty® contains messenger RNA ("mRNA"), developed by BioNTech, that can prompt the body to develop immunity to SARS-CoV-2. Such mRNA, however, needs to be formulated in a way that ensures that (i) the mRNA is not rapidly broken down after injection and before entering the cells, and (ii) the mRNA can enter the cells, where it needs to be in order to work. Acuitas invented the technology in Comirnaty® that protects and delivers mRNA: a lipid nanoparticle ("LNP") that encapsulates BioNTech's mRNA payload. Acuitas invented several of the LNP components, which are fats called lipids, including a PEG-conjugated lipid, ALC-159, and an ionizable lipid, ALC-0315. Acuitas also invented the recipe using those lipids to make the mRNA-LNPs and the manufacturing process to make the mRNA-LNP vaccine.

4. Acuitas's development of the lipids and co-development of the mRNA-LNP in Comirnaty® is a result of a decade of research and development efforts by Acuitas scientists. The considerable time, effort, and ingenuity that Acuitas spent developing and perfecting the lipids and LNP delivery technology that effectively delivers mRNA into the cell contributed to Comirnaty®'s success. GSK had no part in that work.

5. Acuitas's business model is to develop LNP delivery technology and license it in collaborations with partners who use the technology to develop mRNA-based products. One such collaboration is with BioNTech, in its development of Comirnaty®. It is vital to Acuitas's business that its partners, such as BioNTech, can use Acuitas's LNP delivery technology free and clear of third-party patent-infringement claims, and the threat of such claims in the future.

6. Now, partners of Acuitas, like BioNTech, must contend with the risk of opportunistic litigation by GSK, which did not invent and had nothing to do with the success of Acuitas's lipids, Acuitas's LNPs, or the vaccines that include them.

7. GSK's claims of infringement against BioNTech and Pfizer are baseless, and its patents are invalid. Without a declaratory judgment so holding, (i) Acuitas faces the possibility and threat of indemnity obligations to BioNTech, and (ii) Acuitas faces uncertainty and potential monetary and reputational damage with respect to its partners' and potential partners' ability to use its technology free from the threat of patent infringement accusations from GSK. Specifically, GSK has pointed to Acuitas's proprietary lipids and LNP technology used in Comirnaty® in its infringement allegations against BioNTech and Pfizer. Because of GSK's allegations, [redacted] between Acuitas Therapeutics Inc. and BioNTech RNA Pharmaceuticals GmbH, which, on information and belief, is now part of BioNTech SE. *See* **Exhibits F–G.**

8. To protect itself against the potential damage Acuitas faces with respect to Comirnaty® as a result of GSK's lawsuit against BioNTech and Pfizer, Acuitas brings this action seeking declaratory judgment that Comirnaty® does not infringe any valid and enforceable claim of the Patents-in-Suit, and that the claims of the Patents-in-Suit are invalid.

THE PARTIES

9. Plaintiff Acuitas is a Canadian corporation organized and existing in British Columbia, Canada, with a principal place of business at 6190 Agronomy Road, Suite 405, Vancouver, British Columbia, V6T 1Z3, Canada. Acuitas is a leading biotechnology company that specializes in developing lipids and LNP technology for use in mRNA therapeutics. Acuitas collaborates with various partners, including companies, NGOs, and academic institutions, to

develop mRNA-LNP therapeutics. As applicable to this case, Acuitas has partnered with non-parties BioNTech and Pfizer on the mRNA-LNP used for Comirnaty®.

10. On information and belief, GSK Biologicals is a corporation organized and existing under the laws of Belgium, with its principal place of business at Avenue Fleming 20, 1300 Wavre, Belgium.

11. On information and belief, GSK LLC is a limited liability corporation organized and existing under the laws of Delaware, with its principal place of business at 2929 Walnut Street, Suite 1700, Philadelphia, PA 19104. GSK LLC produces and distributes pharmaceutical products.

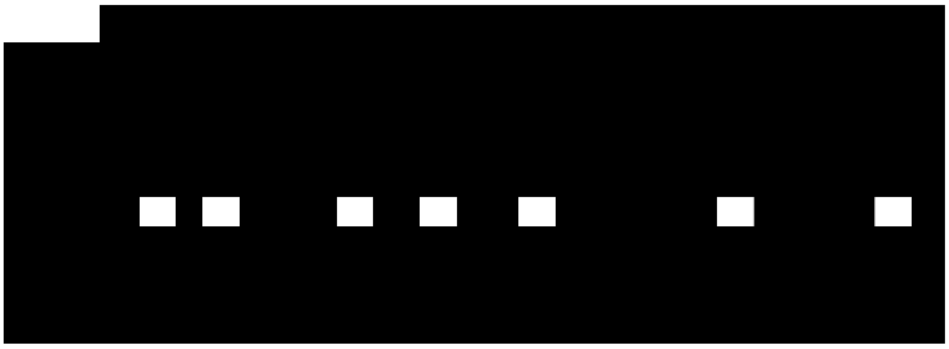
JURISDICTION AND VENUE

12. Acuitas hereby incorporates by reference all of the allegations of Paragraph 1–11.

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

14. Subject matter jurisdiction exists at least because Acuitas faces the possibility and threat of indemnity obligations to BioNTech and because Acuitas faces uncertainty and potential monetary and reputational damage with respect to its partners' and potential partners' ability to use its technology free from the threat of patent infringement accusations from GSK.

15. This Court has subject matter jurisdiction based on BioNTech's indemnification demands with respect to GSK's litigation against BioNTech and Pfizer. [redacted]



[redacted]

Exhibit G [redacted]

16. [redacted] That provision, in part, states:

[redacted]

Exhibit H (Non-Exclusive License Agreement by and between Acuitas Therapeutics, Inc. and BioNTech RNA Pharmaceuticals GmbH dated April 7, 2020) at 21.

17. Although Acuitas denies that it is obligated to indemnify BioNTech, that does not change the fact that Acuitas faces a substantial threat given the damages claims in GSK's lawsuit against BioNTech and Pfizer. For example, in its complaint against BioNTech and Pfizer, GSK accuses several different versions of Comirnaty®, including the original monovalent COVID-19 vaccine that was approved in 2021 and the more recently approved bivalent COVID-19 vaccine, of infringing its patents. GSK alleges it is entitled to all damages related to the manufacture, use, sale, marketing, offer for sale, and/or importation of all versions of the vaccine. GSK claims that Pfizer and BioNTech have "reaped billions of dollars in revenue" from their alleged infringement of GSK's patents. GSK Amended Complaint ¶ 6. GSK further alleges that, for example, Pfizer reported "over $8 billion in U.S. revenue (and over $37 billion globally) in 2022 and over $2 billion in U.S. revenue (and over $11 billion globally) in 2023." *Id.* ¶ 97. Acuitas is a small company, with fewer than 100 employees, compared with GSK, BioNTech, and Pfizer, and the possibility of indemnification, or even a dispute with BioNTech over indemnification, would cause significant harm to Acuitas. GSK's complaint against Pfizer and BioNTech focuses heavily on Acuitas's lipids, including the ionizable lipid ALC-0315, and Acuitas's LNP technology. GSK Amended Complaint ¶¶ 110, 117.

18. Subject matter jurisdiction, therefore, exists based on the possibility and threat of indemnity obligations to BioNTech that Acuitas faces as a result of GSK's lawsuit against BioNTech and Pfizer.

19. Subject matter jurisdiction for this declaratory judgment action also exists based on the uncertainty and potential monetary and reputational damage with respect to Acuitas's business that it faces as a result of GSK's lawsuit against BioNTech and Pfizer. As explained above, Acuitas's business model relies on its ability to license its technologies to its partners for use in

commercial products and development projects free from the threat of patent litigation by third parties, such as GSK. Acuitas's patented technology has never belonged to GSK, and Acuitas has both a reputational and financial interest in protecting its business model as well as its innovations, which GSK now claims to have invented via its patent infringement action against BioNTech and Pfizer. Companies like Pfizer and BioNTech may choose not to partner with or license technology from Acuitas in the future if such technology forms part of the basis of third-party infringement allegations.

20. In addition, Acuitas does not have an adequate remedy other than this declaratory judgment action, particularly with respect to its potential indemnity obligations to BioNTech.

21. For at least these reasons, or a combination thereof, this Court has subject matter jurisdiction over this declaratory judgment action.

22. This Court has personal jurisdiction over GSK Biologicals and GSK LLC because they have purposefully availed themselves of the jurisdiction of, and therefore consented to be sued by Acuitas in, this Court by filing suit in this District against Pfizer and BioNTech in a lawsuit that asserted the Patents-in-Suit and that is about Comirnaty®, which contains Acuitas's lipids and LNP technology. The Patents-in-Suit and Comirnaty® are also the subject of this action. Thus, this action relates to the same patents that GSK Biologicals and GSK LLC have asserted in this District and the same product that GSK Biologicals and GSK LLC have accused of infringing those patents in this District. Accordingly, GSK Biologicals and GSK LLC have therefore purposefully availed themselves of the jurisdiction of this District with respect to the subject matter of this action.

23. Moreover, this Court has personal jurisdiction over GSK LLC because GSK LLC is incorporated and organized under the laws of Delaware.

24. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

FACTUAL BACKGROUND

25. While the mRNA-LNP vaccines (Comirnaty® manufactured by Pfizer and BioNTech and SpikeVax® manufactured by Moderna, Inc. ("Moderna")) gained expedited regulatory approval and were widely distributed across the world in a global effort to combat the COVID-19 pandemic, GSK's recombinant-protein COVID-19 vaccine VidPrevtyn Beta, manufactured in partnership with Sanofi SA ("Sanofi") was a failure. VidPrevtyn Beta relied on older recombinant-protein vaccine technology, as opposed to mRNA-LNP technology. The GSK-Sanofi vaccine was never approved by the Food and Drug Administration ("FDA"). Although the GSK-Sanofi vaccine received marketing authorization in the European Union on November 10, 2022, the vaccine was withdrawn from the market for "commercial reasons." *See* European Medicines Agency, Public Statement, dated March 11, 2024, available at https://www.ema.europa.eu/en/documents/public-statement/public-statement-vidprevtyn-beta-withdrawal-marketing-authorisation-european-union_en.pdf.

26. In contrast, Comirnaty® has been on the market for more than three years and is the primary reason that the COVID-19 pandemic has ended. As GSK knows, Acuitas, Pfizer, and BioNTech began collaborating when the global threat from COVID-19 was first recognized and with the goal of rapidly bringing a vaccine against the deadly virus to market as quickly as possible. At that time, BioNTech had access to Acuitas's LNP technology, and had been collaborating with Acuitas on the use of that technology for other clinical applications for several years. Clinical trials of the COVID-19 vaccine began in late April of 2020, with preliminary Phase 3 clinical trial results demonstrating the vaccine's safety and efficacy published in just over six months. By November 9, 2020, it had been publicly reported that Acuitas was partnered with BioNTech, and

that Acuitas's lipids and LNP technology were used in Pfizer and BioNTech's Comirnaty® vaccine. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted its clinical trial data as part of its Emergency Use Authorization ("EUA") request to the FDA for administering its mRNA vaccine to people 16 years of age and older. On December 10, 2020, the FDA granted the first EUA for a COVID-19 vaccine to Comirnaty®. The FDA fully approved Comirnaty® on August 23, 2021.

27. After seeing the overwhelming success of mRNA vaccines in fighting the COVID-19 pandemic and having failed to develop a COVID-19 mRNA vaccine of its own, GSK saw an opportunity to claim credit for other people's hard work and make money through litigation. GSK dusted off a decade-old patent portfolio that it had acquired from Novartis Vaccines and Diagnostics, Inc. ("Novartis") in 2015, and started filing new continuation applications and crafting claims in pending applications in an attempt to ensnare Comirnaty® and claim credit for mRNA-LNP innovation in which it had no part. *See, e.g.*, *See GlaxoSmithKline Biologicals SA v. Pfizer, Inc.*, C.A. No. 24-512, D.I. 32, ¶¶ 55–99 (Answer to First Amended Complaint) (D. Del. Aug. 30, 2024) ("Pfizer/BioNTech Answer").

28. On December 22, 2021, about four months after the FDA approved Comirnaty®, GSK filed three patent applications: U.S. Patent Application No. 17/560,138, which issued on June 6, 2023, as the '534 Patent, U.S. Patent Application No. 17/560,059, which issued on September 26, 2023, as the '401 Patent, and U.S. Patent Application No. 17/560,019, which issued on October 17, 2023, as the '467 Patent.

29. On June 23, 2022, GSK filed two more patent applications, U.S. Patent Application No. 17/808,519, which issued on May 2, 2023, as the '693 Patent, and U.S. Patent Application No. 17/848,299, which issued on May 2, 2023, as the '694 Patent.

30. All of the Patents-in-Suit claim priority to fourteen-year-old applications filed in 2010.

31. At the time that GSK filed or amended claims in each of the applications that led to the Patents-in-Suit, there was already a vast amount of information in the public domain about the mRNA-LNP that was used in Comirnaty®.

32. GSK then asserted these patents against BioNTech and Pfizer for patent infringement based on the sales of their mRNA-LNP vaccine, Comirnaty®. Although GSK alleges in its complaint that BioNTech and Pfizer's "technical and financial success with COVID-19 vaccines is [due to] the technology of GSK's patented inventions" (*see* GSK Amended Complaint ¶5), in fact, none of the claims in the Patents-in-Suit existed until after Comirnaty® received full FDA approval on August 23, 2021.

THE PATENTS-IN-SUIT

U.S. Patent No. 11,638,693

33. On information and belief, GSK Biologicals is the owner of all rights, title, and interest in the '693 Patent, entitled "Vaccine for Eliciting Immune Response Comprising RNA Encoding an Immunogen and Lipid Formulations Comprising Mole Percentage of Lipids." The '693 Patent issued on May 2, 2023. The '693 Patent names Andrew Geall as its inventor. Dr. Geall assigned the '693 Patent to Novartis Vaccines and Diagnostics, Inc., which assigned the '693 Patent to Novartis AG (collectively, "Novartis"), which assigned the '693 Patent to GSK Biologicals.

34. The '693 Patent has one independent claim, Claim 1. Claim 1 claims:

> 1. A formulation comprising:
> ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen; and

lipids comprising: (a) from 20 mole % to 70 mole % cationic lipid, (b) an anionic or a zwitterionic lipid, (c) a polyethylene glycol-conjugated (PEG-conjugated) lipid, and (d) from 5 mole % to 80 mole % cholesterol; wherein:

the lipids encapsulate at least half of the RNA molecules;

the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo; and

the cationic lipid comprises a tertiary amine and has a pK_a from 6.07 to 7.6; and

whereby the pKa is determined at standard temperature and pressure by the following:

(1) admixing 400 μL of 2 mM cationic lipid that is in ethanol and 800 μL of 0.3 mM fluorescent probe 6-(p-toluidino)-2-naphthalenesulfonic acid (TNS), which is in 90 volume % ethanol and 10 volume % methanol, thereby obtaining a lipid/TNS mixture;

(2) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a first buffer consisting essentially of a sodium salt buffer comprising 20 mM sodium phosphate, 25 mM sodium citrate, 20 mM sodium acetate, and 150 mM sodium chloride, wherein the first buffer has a pH from 4.44 to 4.52, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a first mixture, and dispensing 100 μL of the first mixture in a first well of a 96-well plate, which has a clear bottom;

(3) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a second buffer consisting essentially of the sodium salt buffer, wherein the second buffer has a pH of 5.27, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a second mixture, and dispensing 100 μL of the second mixture in a second well of the 96-well plate;

(4) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a third buffer consisting essentially of the sodium salt buffer, wherein the third buffer has a pH from 6.15 to 6.21, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a third mixture, and dispensing 100 μL of the third mixture in a third well of the 96-well plate;

(5) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a fourth buffer consisting essentially of the sodium salt buffer, wherein the fourth buffer has a pH of 6.57, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fourth mixture, and dispensing 100 μL of the fourth mixture in a fourth well of the 96-well plate;

(6) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a fifth buffer consisting essentially of the sodium salt buffer, wherein the fifth buffer has a pH from 7.10 to 7.20, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fifth mixture, and dispensing 100 μL of the fifth mixture in a fifth well of the 96-well plate;

(7) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a sixth buffer consisting essentially of the sodium salt buffer, wherein the sixth buffer has a pH from 7.72 to 7.80, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a sixth mixture, and dispensing 100 μL of the sixth mixture in a sixth well of the 96-well plate;

(8) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a seventh buffer consisting essentially of the sodium salt buffer, wherein the seventh buffer has a pH from 8.27 to 8.33, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a seventh mixture, and dispensing 100 μL of the seventh mixture in a seventh well of the 96-well plate;

(9) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of an eighth buffer consisting essentially of the sodium salt buffer, wherein the eighth buffer has a pH from 10.47 to 11.12, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining an eighth mixture, and dispensing 100 μL of the eighth mixture in an eighth well of the 96-well plate;

(10) measuring the fluorescence at a wavelength of 431 nm with an excitation wavelength of 322 nm and a cut-off below a wavelength of 420 nm of each of the first through eighth wells and an empty well of the 96-well plate, thereby obtaining a measured fluorescence for each of the p empty well and the first through eighth wells;

(11) subtracting the measured fluorescence of the empty well from each of the measured fluorescences of the first through eighth wells, thereby obtaining a blank-subtracted fluorescence for each of the first through eighth mixtures;

(12) normalizing each of the blank-subtracted fluorescences of the first through eighth mixtures to the blank-subtracted fluorescence of the first mixture thereby obtaining a relative fluorescence for each of the first through eighth mixtures, the relative fluorescence being 1 for the first mixture;

(13) obtaining a line of best fit of the pHs of the first through eighth buffers versus the respective relative fluorescences of the first through eighth mixtures; and

(14) defining the pKa as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained.

U.S. Patent No. 11,638,694

35. On information and belief, GSK Biologicals is the owner of all rights, title, and interest in the ’694 Patent, entitled “Vaccine for Eliciting Immune Response Comprising Lipid Formulations and RNA encoding multiple immunogens.” The ’694 Patent issued on May 2, 2023.

The ’694 Patent names Andrew Geall as its inventor. Dr. Geall assigned the ’694 Patent to Novartis, which assigned the ’694 Patent to GSK Biologicals.

36. The ’694 Patent has one independent claim, claim 1. Claim 1 claims:

> 1. A formulation comprising:
>
> a first species of ribonucleic acid (RNA) molecules comprising a sequence that encodes a first immunogen;
>
> a second species of RNA molecules comprising a sequence that encodes a second immunogen; and
>
> lipids comprising: (a) a cationic lipid, (b) an anionic lipid or a zwitterionic lipid, (c) a polyethylene glycol-conjugated (PEG-conjugated) lipid, and (d) a cholesterol, wherein:
>
> the lipids encapsulate at least half of the first species of RNA molecules and at least half of the second species of RNA molecules;
>
> the cationic lipid comprises a tertiary amine and has a pKa from 6.07 to 7.6; and
>
> the formulation is immunogenic in vivo by eliciting an antibody response against the first immunogen and the second immunogen in vivo; and
>
> whereby the pKa is determined at standard temperature and pressure by the following:
>
> (1) admixing 400 μL of 2 mM of the cationic lipid that is in ethanol and 800 μL of 0.3 mM of fluorescent probe 6-(p-toluidino)-2-naphthalenesulfonic acid (TNS), which is in 90 volume % ethanol and 10 volume % methanol, thereby obtaining a lipid/TNS mixture;
>
> (2) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a first buffer consisting essentially of a sodium salt buffer consisting of 20 mM sodium phosphate, 25 mM sodium citrate, 20 mM sodium acetate, and 150 mM sodium chloride, wherein the first buffer has a pH from 4.44 to 4.52, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a first mixture, and dispensing 100 μL of the first mixture in a first well of a 96-well plate, which has a clear bottom;
>
> (3) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a second buffer consisting essentially of the sodium salt buffer, wherein the second buffer has a pH of 5.27, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a second mixture, and dispensing 100 μL of the second mixture in a second well of the 96-well plate;
>
> (4) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a third buffer consisting essentially of the sodium salt buffer, wherein the third buffer has a pH from 6.15 to 6.21, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a third mixture, and dispensing 100 μL of the third mixture in a third well of the 96-well plate;

(5) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a fourth buffer consisting essentially of the sodium salt buffer, wherein the fourth buffer has a pH of 6.57, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fourth mixture, and dispensing 100 μL of the fourth mixture in a fourth well of the 96-well plate;

(6) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a fifth buffer consisting essentially of the sodium salt buffer, wherein the fifth buffer has a pH from 7.10 to 7.20, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a fifth mixture, and dispensing 100 μL of the fifth mixture in a fifth well of the 96-well plate;

(7) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a sixth buffer consisting essentially of the sodium salt buffer, wherein the sixth buffer has a pH from 7.72 to 7.80, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a sixth mixture, and dispensing 100 μL of the sixth mixture in a sixth well of the 96-well plate;

(8) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of a seventh buffer consisting essentially of the sodium salt buffer, wherein the seventh buffer has a pH from 8.27 to 8.33, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining a seventh mixture, and dispensing 100 μL of the seventh mixture in a seventh well of the 96-well plate;

(9) admixing 7.5 μL of the lipid/TNS mixture and 242.5 μL of an eighth buffer consisting essentially of the sodium salt buffer, wherein the eighth buffer has a pH from 10.47 to 11.12, which has been adjusted with 12N hydrochloric acid or 6N sodium hydroxide, thereby obtaining an eighth mixture, and dispensing 100 μL of the eighth mixture in an eighth well of the 96-well plate;

(10) measuring the fluorescence at a wavelength of 431 nm with an excitation wavelength of 322 nm and a cut-off below a wavelength of 420 nm of each of the first through eighth wells and an empty well of the 96-well plate, thereby obtaining a measured fluorescence for each of the empty well and the first through eighth wells;

(11) subtracting the fluorescence of the empty well from each of the measured fluorescences of the first through eighth wells, thereby obtaining a blank-subtracted fluorescence for each of the first through eighth mixtures;

(12) normalizing each of the blank-subtracted fluorescences of the first through eighth mixtures to the blank-subtracted fluorescence of the first mixture, thereby obtaining a relative fluorescence for each of the first through eighth mixtures, the relative fluorescence being 1 for the first mixture;

(13) obtaining a line of best fit of the pHs of the first through eighth buffers versus the respective relative fluorescences of the first through eighth mixtures; and

(14) determining the pKa as the pH on the line of best fit at which a relative fluorescence of 0.5 is obtained.

U.S. Patent No. 11,666,534

37. On information and belief, GSK Biologicals is the owner of all rights, title, and interest in the '534 Patent, entitled "Methods of Administering Lipid Formulations with Viral Immunogens." The '534 Patent issued on June 6, 2023. The '534 Patent names Andrew Geall as its inventor. Dr. Geall assigned the '534 Patent to Novartis, which assigned the '534 Patent to GSK Biologicals.

38. The '534 Patent has two independent claims, claims 1 and 37. Claim 1 claims:

1. A method of eliciting an immune response against an immunogen in a subject, the method comprising:

administering to the subject an immunologically effective unit dose of a formulation comprising:

ribonucleic acid (RNA) molecules comprising a sequence that encodes the immunogen, wherein the immunogen comprises a respiratory syncytial virus immunogen, an Epstein-Barr virus immunogen, a cytomegalovirus immunogen, a coronavirus spike polypeptide immunogen, an influenza virus A immunogen, a *Varicella zoster* virus immunogen, or a flavivirus immunogen; and

lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol;

wherein the lipids encapsulate at least half of the RNA molecules; and

wherein the immune response against the immunogen comprises an antibody response against the immunogen.

Claim 37 claims:

37. A method of eliciting an immune response against an immunogen in a subject, the method comprising:

administering to the subject an immunologically effective unit dose of a formulation comprising:

ribonucleic acid molecules comprising a sequence that encodes the immunogen, wherein the immunogen comprises a respiratory syncytial virus immunogen, an Epstein-Barr virus immunogen, a cytomegalovirus immunogen, a coronavirus spike polypeptide immunogen, an influenza

virus A immunogen, a *Varicella zoster* virus immunogen, or a flavivirus immunogen; and

lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated lipid, and cholesterol;

wherein the tertiary amine cationic lipid is not 1,2-dilinoleyloxy-N,N-dimethyl-3-aminopropane;

wherein the lipids encapsulate at least half of the RNA molecules; and

wherein the immune response against the immunogen comprises an antibody response against the immunogen.

U.S. Patent No. 11,766,401

39. On information and belief, GSK Biologicals is the owner of all rights, title, and interest in the '401 Patent, entitled "Methods of Administering Lipid Formulations with Immunogens." The '401 Patent issued on September 26, 2023. The '401 Patent names Andrew Geall as its inventor. Dr. Geall assigned the '401 Patent to Novartis, which assigned the '401 Patent to GSK Biologicals.

40. The '401 Patent has one independent claim, claim 1. Claim 1 claims:

1. A method of eliciting an immune response against an immunogen in a human or a cow, the method comprising:

administering to the human or the cow an immunologically effective unit dose of a formulation comprising:

RNA molecules comprising a sequence that encodes the immunogen; and

lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol; and

wherein the lipids encapsulate at least half of the RNA molecules and the immune response against the immunogen comprises an antibody response against the immunogen.

U.S. Patent No. 11,786,467

41. On information and belief, GSK Biologicals is the owner of all rights, title, and interest in the '467 Patent, entitled "Lipid Formulations with Immunogens." The '467 Patent issued on October 17, 2023. The '467 Patent names Andrew Geall as its inventor. Dr. Geall assigned the '467 Patent to Novartis, which assigned the '467 Patent to GSK Biologicals.

42. The ’467 Patent has one independent claim, claim 1. Claim 1 claims:

> 1. A formulation comprising:
> ribonucleic acid (RNA) molecules comprising a sequence that encodes an immunogen; and
> lipids comprising a tertiary amine cationic lipid, a polyethylene glycol-conjugated (PEG-conjugated) lipid, and cholesterol;
> wherein the formulation is immunogenic in vivo by eliciting an antibody response against the immunogen in vivo;
> wherein the lipids encapsulate at least half of the RNA molecules.

COUNT I
(NON-INFRINGEMENT OF THE ’693 PATENT)

43. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–42.

44. For the reasons stated herein and above, there is an actual controversy between Acuitas and GSK as to whether the mRNA-LNP formulation in Comirnaty® meets all of the limitations of any valid claim of the ’693 Patent and whether the manufacture, use, offer to sell, or sale of Comirnaty ® in the United States, or the importation of Comirnaty® into the United States, infringes any valid claim of the ’693 Patent.

45. GSK has alleged that Comirnaty® infringes at least claim 1 of the ’693 Patent. GSK Amended Complaint ¶ 105.

46. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

47. The manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, does not infringe any valid claim of the ’693 Patent.

48. For example, the mRNA-LNP formulation in Comirnaty® does not comprise a “cationic lipid” as described in the specification and set forth by the claims of the ’693 Patent.

49. As explained above, without a declaratory judgment of non-infringement, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

50. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in Comirnaty® does not meet all of the limitations of any valid and enforceable claim of the '693 Patent and that the manufacture, use, offer to sell, and sale of Comirnaty® in the United States, and the importation of Comirnaty® into the United States, does not infringe any valid and enforceable claim of the '693 Patent.

COUNT II
(INVALIDITY OF THE '693 PATENT)

51. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–50.

52. For the reasons stated herein and above, there is an actual case or controversy between Acuitas and GSK as to the validity of the claims of the '693 Patent.

53. GSK has alleged that Comirnaty® infringes at least claim 1 of the '693 Patent. GSK Amended Complaint ¶ 105.

54. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

55. Each of the claims of the '693 Patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, *et seq*.

56. For example, the claims of the '693 Patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following references, all of which are prior art to the '693 Patent under 35 U.S.C. § 102: Chen, U.S. Patent Application Publication No. 2010/0324120 (published Dec. 23, 2010); Maclachlan, WO 2005/120152

(published Dec. 22, 2005); Hope, WO 2010/042877 (published Apr. 15, 2010); Hope, WO 2011/075656 (published June 23, 2011); Thalhamer, WO 2009/040443 (published Apr. 2, 2009); O'Hagan, WO 2002/026209 (published April 4, 2002); Semple, WO 1998/51278 (published Nov. 19, 1998); Holland, U.S. Patent No. 5,885,613; Von Der Mulbe, U.S. Pub. No. 2005/0032730 (published Feb. 10, 2005); Chen, U.S. Pub. No. 2006/0240554 (published Oct. 26, 2006); Hope, U.S. App. No. 61/287,995 (filed Dec. 18, 2009); Guild, U.S. App. No. 61/265653 (filed Dec. 1, 2009), later filed as U.S. Pub. No. 2011/0244026 (published Oct. 6, 2011); Frédéric Martinon et al., *Induction of virus-specific cytotoxic T lymphocytes* in vivo *by liposome-entrapped mRNA*, 23 EUR. J. IMMUNOLOGY 1719-22 (1993); Austin Bailey & Pieter Cullis, *Modulation of Membrane Fusion by Asymmetric Transbilayer Distributions of Amino Lipids*, 33 BIOCHEMISTRY 12573-80 (1994); Ronald Soong & Peter Macdonald, *PEG molecular weight and lateral diffusion of PEG-ylated lipids in magnetically aligned bicelles*, 1768 BIOCHIMICA ET BIOPHYSICA ACTA 1805-14 (2007); E. Jane Manning & G.C. Millson, *Infectivity of Liposomally Encapsulated Nucleic Acids Isolated from EMC Virus and Scrapie-Infected Mouse Brain*, 20 INTERVIROLOGY 164-68 (1983); Tazewell Wilson et al., *The Introduction of Poliovirus RNA into Cells via Lipid Vesicles (Liposomes)*, 17 CELL 77-84 (May 1979); Sean Semple et al., *Rational design of cationic lipids for siRNA delivery*, 28 Nature Biotech. 172-76 (2010); Escriou, WO 2002/095023 (published Nov. 28, 2002); and José Mario Barichello et al., *Complexation of siRNA and pDNA with Cationic Liposomes: The Important Aspects in Lipoplex Preparation*, METHODS IN MOLECULAR BIOLOGY, 605, 461-72 (2010).

57. The claims of the '693 Patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112, including because the specification does not describe or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's

mRNA-LNP formulations, including the mRNA-LNP formulation in Comirnaty®. For example, to the extent GSK reads its claims to cover lipids like those in Comirnaty®, the disclosure in the specification does not describe or enable such lipids.

58. The claims of the ’693 Patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention.

59. As explained above, without a declaratory judgment of invalidity, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK’s infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

60. Acuitas hereby seeks a declaration that the claims of the ’693 Patent are invalid.

COUNT III
(NON-INFRINGEMENT OF THE ’694 PATENT)

61. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–60.

62. For the reasons stated herein and above, there is an actual controversy between Acuitas and GSK as to whether the mRNA-LNP formulation in Comirnaty® meets all of the limitations of any valid claim of the ’694 Patent and whether the manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, infringes any valid claim of the ’694 Patent.

63. GSK has alleged that Comirnaty® infringes at least claim 1 of the ’694 Patent. GSK Amended Complaint ¶ 135.

64. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

65. The manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, does not infringe any valid claim of the '694 Patent.

66. For example, the mRNA-LNP formulation in Comirnaty® does not comprise a "cationic lipid" as described in the specification and set forth by the claims of the '694 Patent.

67. As explained above, without a declaratory judgment of non-infringement, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

68. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in Comirnaty® does not meet all of the limitations of any valid and enforceable claim of the '694 Patent and that the manufacture, use, offer to sell, and sale of Comirnaty® in the United States, and the importation of Comirnaty® into the United States, does not infringe any valid and enforceable claim of the '694 Patent.

COUNT IV
(INVALIDITY OF THE '694 PATENT)

69. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–68.

70. For the reasons stated herein and above, there is an actual case or controversy between Acuitas and GSK as to the validity of the claims of the '694 Patent.

71. GSK has alleged that Comirnaty® infringes at least claim 1 of the '694 Patent. GSK Amended Complaint ¶ 135.

72. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

73. Each of the claims of the ’694 Patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, *et seq*.

74. For example, the claims of the ’694 Patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by the following references, all of which are prior art to the ’694 Patent under 35 U.S.C. § 102: Chen, U.S. Patent Application Publication No. 2010/0324120 (published Dec. 23, 2010); Maclachlan, WO 2005/120152 (published Dec. 22, 2005); Hope, WO 2010/042877 (published Apr. 15, 2010); Hope, WO 2011/075656 (published June 23, 2011); Thalhamer, WO 2009/040443 (published Apr. 2, 2009); O’Hagan, WO 2002/026209 (published April 4, 2002); Semple, WO 1998/51278 (published Nov. 19, 1998); Holland, U.S. Patent No. 5,885,613; Von Der Mulbe, U.S. Pub. No. 2005/0032730 (published Feb. 10, 2005); Chen, U.S. Pub. No. 2006/0240554 (published Oct. 26, 2006); Hope, U.S. App. No. 61/287,995 (filed Dec. 18, 2009); Guild, U.S. App. No. 61/265653 (filed Dec. 1, 2009), later filed as U.S. Pub. No. 2011/0244026 (published Oct. 6, 2011); Frédéric Martinon et al., *Induction of virus-specific cytotoxic T lymphocytes* in vivo *by liposome-entrapped mRNA*, 23 EUR. J. IMMUNOLOGY 1719-22 (1993); Austin Bailey & Pieter Cullis, *Modulation of Membrane Fusion by Asymmetric Transbilayer Distributions of Amino Lipids*, 33 BIOCHEMISTRY 12573-80 (1994); Ronald Soong & Peter Macdonald, *PEG molecular weight and lateral diffusion of PEG-ylated lipids in magnetically aligned bicelles*, 1768 BIOCHIMICA ET BIOPHYSICA ACTA 1805-14 (2007); E. Jane Manning & G.C. Millson, *Infectivity of Liposomally Encapsulated Nucleic Acids Isolated from EMC Virus and Scrapie-Infected Mouse Brain*, 20 INTERVIROLOGY 164-68 (1983); Tazewell Wilson et al., *The Introduction of Poliovirus RNA into Cells via Lipid Vesicles (Liposomes)*, 17 CELL 77-84 (May 1979); Sean Semple *et al*., *Rational design of cationic lipids for siRNA delivery*,

28 NATURE BIOTECH. 172-76 (2010); Escriou, WO 2002/095023 (published Nov. 28, 2002); and José Mario Barichello et al., *Complexation of siRNA and pDNA with Cationic Liposomes: The Important Aspects in Lipoplex Preparation*, METHODS IN MOLECULAR BIOLOGY, 605, 461-72 (2010).

75. The claims of the '694 Patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112, including because the specification does not describe, or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in Comirnaty®. For example, to the extent GSK reads its claims to cover lipids like those in Comirnaty®, the disclosure in the specification does not describe or enable such lipids.

76. The claims of the '694 Patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention.

77. As explained above, without a declaratory judgment of invalidity, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

78. Acuitas hereby seeks a declaration that the claims of the '694 Patent are invalid.

COUNT V
(NON-INFRINGEMENT OF THE '534 PATENT)

79. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–78.

80. For the reasons stated herein and above, there is an actual controversy between Acuitas and GSK as to whether the mRNA-LNP formulation in Comirnaty® meets all of the limitations of any valid claim of the '534 Patent and whether the manufacture, use, offer to sell, or

sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, infringes any valid claim of the '534 Patent.

81. GSK has alleged that Comirnaty® infringes at least claim 1 of the '534 Patent. GSK Amended Complaint ¶ 163.

82. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

83. The manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, does not infringe any valid claim of the '534 Patent.

84. For example, the mRNA-LNP formulation in Comirnaty® does not comprise a "cationic lipid" as described in the specification and set forth by the claims of the '534 Patent.

85. As explained above, without a declaratory judgment of non-infringement, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

86. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in Comirnaty® does not meet all of the limitations of any valid and enforceable claim of the '534 Patent and that the manufacture, use, offer to sell, and sale of Comirnaty® in the United States, and the importation of Comirnaty® into the United States, does not infringe any valid and enforceable claim of the '534 Patent.

COUNT VI
(INVALIDITY OF THE '534 PATENT)

87. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–86.

88. For the reasons stated herein and above, there is an actual case or controversy between Acuitas and GSK as to the validity of the claims of the '534 Patent.

89. GSK has alleged that Comirnaty® infringes at least claim 1 of the '534 Patent. GSK First Amended Complaint ¶ 163.

90. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

91. Each of the claims of the '534 Patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, *et seq*.

92. For example, the claims of the '534 Patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following references, all of which are prior art to the '534 Patent under 35 U.S.C. § 102: Chen, U.S. Patent Application Publication No. 2010/0324120 (published Dec. 23, 2010); Maclachlan, WO 2005/120152 (published Dec. 22, 2005); Hope, WO 2010/042877 (published Apr. 15, 2010); Hope, WO 2011/075656 (published June 23, 2011); Thalhamer, WO 2009/040443 (published Apr. 2, 2009); O'Hagan, WO 2002/026209 (published April 4, 2002); Semple, WO 1998/51278 (published Nov. 19, 1998); Holland, U.S. Patent No. 5,885,613; Von Der Mulbe, U.S. Pub. No. 2005/0032730 (published Feb. 10, 2005); Chen, U.S. Pub. No. 2006/0240554 (published Oct. 26, 2006); Hope, U.S. App. No. 61/287,995 (filed Dec. 18, 2009); Guild, U.S. App. No. 61/265653 (filed Dec. 1, 2009), later filed as U.S. Pub. No. 2011/0244026 (published Oct. 6, 2011); Frédéric Martinon et al., *Induction of virus-specific cytotoxic T lymphocytes* in vivo *by liposome-entrapped mRNA*, 23 EUR. J. IMMUNOLOGY 1719-22 (1993); Austin Bailey & Pieter Cullis, *Modulation of Membrane Fusion by Asymmetric Transbilayer Distributions of Amino Lipids*, 33 BIOCHEMISTRY 12573-80 (1994); Ronald Soong & Peter Macdonald, *PEG molecular weight and lateral diffusion of PEG-ylated lipids in magnetically aligned bicelles*, 1768 BIOCHIMICA ET BIOPHYSICA ACTA 1805-14

(2007); E. Jane Manning & G.C. Millson, *Infectivity of Liposomally Encapsulated Nucleic Acids Isolated from EMC Virus and Scrapie-Infected Mouse Brain*, 20 INTERVIROLOGY 164-68 (1983); Tazewell Wilson et al., *The Introduction of Poliovirus RNA into Cells via Lipid Vesicles (Liposomes)*, 17 CELL 77-84 (May 1979); Sean Semple *et al*., *Rational design of cationic lipids for siRNA delivery*, 28 NATURE BIOTECH. 172-76 (2010); Escriou, WO 2002/095023 (published Nov. 28, 2002); and José Mario Barichello et al., *Complexation of siRNA and pDNA with Cationic Liposomes: The Important Aspects in Lipoplex Preparation*, METHODS IN MOLECULAR BIOLOGY, 605 461-72 (2010).

93. The claims of the '534 Patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112, including because the specification does not describe, or enable a person of ordinary skill in the art to make and use a formulation like Acuitas's mRNA-LNP formulations, including the mRNA-LNP formulation in Comirnaty®. For example, to the extent GSK reads its claims to cover lipids like those in Comirnaty®, the disclosure in the specification does not describe or enable such lipids.

94. The claims of the '534 Patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention.

95. As explained above, without a declaratory judgment of invalidity, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

96. Acuitas hereby seeks a declaration that the claims of the '534 Patent are invalid.

COUNT VII
(NON-INFRINGEMENT OF THE '401 PATENT)

97. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–96.

98. For the reasons stated herein and above, there is an actual controversy between Acuitas and GSK as to whether the mRNA-LNP formulation in Comirnaty® meets all of the limitations of any valid claim of the '401 Patent and whether the manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, infringes any valid claim of the '401 Patent.

99. GSK has alleged that Comirnaty® infringes at least claim 1 of the '401 Patent. GSK Amended Complaint ¶ 188.

100. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

101. The manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, does not infringe any valid claim of the '401 Patent.

102. For example, the mRNA-LNP formulation in Comirnaty® does not comprise a "cationic lipid" as described in the specification and set forth by the claims of the '401 Patent.

103. As explained above, without a declaratory judgment of non-infringement, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

104. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in Comirnaty® does not meet all of the limitations of any valid and enforceable claim of the '401 Patent and that the manufacture, use, offer to sell, and sale of Comirnaty® in the United States, and the importation of Comirnaty® into the United States, does not infringe any valid and enforceable claim of the '401 Patent.

COUNT VIII
(INVALIDITY OF THE '401 PATENT)

105. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–104.

106. For the reasons stated herein and above, there is an actual case or controversy between Acuitas and GSK as to the validity of the claims of the '401 Patent.

107. GSK has alleged that Comirnaty® infringes at least claim 1 of the '401 Patent. GSK Amended Complaint, ¶ 188.

108. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

109. Each of the claims of the '401 Patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, *et seq*.

110. For example, the claims of the '401 Patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following references, all of which are prior art to the '401 Patent under 35 U.S.C. § 102: Chen, U.S. Patent Application Publication No. 2010/0324120(published Dec. 23, 2010); Maclachlan, WO 2005/120152 (published Dec. 22, 2005); Hope, WO 2010/042877 (published Apr. 15, 2010); Hope, WO 2011/075656 (published June 23, 2011); Thalhamer, WO 2009/040443 (published Apr. 2, 2009); O'Hagan, WO 2002/026209 (published April 4, 2002); Semple, WO 1998/51278 (published Nov. 19, 1998); Holland, U.S. Patent No. 5,885,613; Von Der Mulbe, U.S. Pub. No. 2005/0032730 (published Feb. 10, 2005); Chen, U.S. Pub. No. 2006/0240554 (published Oct. 26, 2006); Hope, U.S. App. No. 61/287,995 (filed Dec. 18, 2009); Guild, U.S. App. No. 61/265653 (filed Dec. 1, 2009), later filed as U.S. Pub. No. 2011/0244026 (published Oct. 6, 2011); Frédéric Martinon et al., *Induction of virus-specific cytotoxic T lymphocytes* in vivo *by liposome-entrapped mRNA*, 23

EUR. J. IMMUNOLOGY 1719-22 (1993); Austin Bailey & Pieter Cullis, *Modulation of Membrane Fusion by Asymmetric Transbilayer Distributions of Amino Lipids*, 33 BIOCHEMISTRY 12573-80 (1994); Ronald Soong & Peter Macdonald, *PEG molecular weight and lateral diffusion of PEG-ylated lipids in magnetically aligned bicelles*, 1768 BIOCHIMICA ET BIOPHYSICA ACTA 1805-14 (2007); E. Jane Manning & G.C. Millson, *Infectivity of Liposomally Encapsulated Nucleic Acids Isolated from EMC Virus and Scrapie-Infected Mouse Brain*, 20 INTERVIROLOGY 164-68 (1983); Tazewell Wilson et al., *The Introduction of Poliovirus RNA into Cells via Lipid Vesicles (Liposomes)*, 17 CELL 77-84 (May 1979); Sean Semple et al., *Rational design of cationic lipids for siRNA delivery*, 28 NATURE BIOTECH. 172-76 (2010); Escriou, WO 2002/095023 (published Nov. 28, 2002); and José Mario Barichello et al., *Complexation of siRNA and pDNA with Cationic Liposomes: The Important Aspects in Lipoplex Preparation*, METHODS IN MOLECULAR BIOLOGY, 605, 461-72 (2010).

111. The claims of the ’401 Patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112, including because the specification does not describe, or enable a person of ordinary skill in the art to make and use a formulation like Acuitas’s mRNA-LNP formulations, including the mRNA-LNP formulation in Comirnaty®. For example, to the extent GSK reads its claims to cover lipids like those in Comirnaty®, the disclosure in the specification does not describe or enable such lipids.

112. The claims of the ’401 Patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention.

113. As explained above, without a declaratory judgment of invalidity, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

114. Acuitas hereby seeks a declaration that the claims of the '401 Patent are invalid.

COUNT IX
(NON-INFRINGEMENT OF THE '467 PATENT)

115. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–114.

116. For the reasons stated herein and above, there is an actual controversy between Acuitas and GSK as to whether the mRNA-LNP formulation in Comirnaty® meets all of the limitations of any valid claim of the '467 Patent and whether the manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, infringes any valid claim of the '467 Patent.

117. GSK has alleged that Comirnaty® infringes at least claim 1 of the '467 Patent. GSK Amended Complaint ¶ 214.

118. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

119. The manufacture, use, offer to sell, or sale of Comirnaty® in the United States, or the importation of Comirnaty® into the United States, does not infringe any valid claim of the '467 Patent.

120. For example, the mRNA-LNP formulation in Comirnaty® does not comprise a "cationic lipid" as described in the specification and set forth by the claims of the '467 Patent.

121. As explained above, without a declaratory judgment of non-infringement, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK's infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

122. Acuitas hereby seeks a declaration that the mRNA-LNP formulation in Comirnaty® does not meet all of the limitations of any valid and enforceable claim of the '467 Patent and that the manufacture, use, offer to sell, and sale of Comirnaty® in the United States and the importation of Comirnaty® into the United States, does not infringe any valid and enforceable claim of the '467 Patent.

COUNT X
(INVALIDITY OF THE '467 PATENT)

123. Acuitas incorporates by reference herein all of the allegations of Paragraphs 1–122.

124. For the reasons stated herein and above, there is an actual case or controversy between Acuitas and GSK as to the validity of the claims of the '467 Patent.

125. GSK has alleged that Comirnaty® infringes at least claim 1 of the '467 Patent. GSK First Amended Complaint ¶ 214.

126. The lipids and LNP technology used in Comirnaty® come from Acuitas. The mRNA used in Comirnaty® comes from BioNTech.

127. Each of the claims of the '467 Patent fails to meet one or more of the statutory requirements and/or conditions for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, *et seq*.

128. For example, the claims of the '467 Patent are invalid as anticipated under 35 U.S.C. § 102 or rendered obvious under 35 U.S.C. § 103 by at least the following references, all of which are prior art to the '467 Patent under 35 U.S.C. § 102: Chen, U.S. Patent Application Publication No. 2010/0324120 (published Dec. 23, 2010); Maclachlan, WO 2005/120152 (published Dec. 22, 2005); Hope, WO 2010/042877 (published Apr. 15, 2010); Hope, WO 2011/075656 (published June 23, 2011); Thalhamer, WO 2009/040443 (published Apr. 2, 2009); O'Hagan, WO 2002/026209 (published April 4, 2002); Semple, WO 1998/51278 (published Nov.

19, 1998); Holland, U.S. Patent No. 5,885,613; Von Der Mulbe, U.S. Pub. No. 2005/0032730 (published Feb. 10, 2005); Chen, U.S. Pub. No. 2006/0240554 (published Oct. 26, 2006); Hope, U.S. App. No. 61/287,995 (filed Dec. 18, 2009); Guild, U.S. App. No. 61/265653 (filed Dec. 1, 2009), later filed as U.S. Pub. No. 2011/0244026 (published Oct. 6, 2011); Frédéric Martinon et al., *Induction of virus-specific cytotoxic T lymphocytes* in vivo *by liposome-entrapped mRNA*, 23 EUR. J. IMMUNOLOGY 1719-22 (1993); Austin Bailey & Pieter Cullis, *Modulation of Membrane Fusion by Asymmetric Transbilayer Distributions of Amino Lipids*, 33 BIOCHEMISTRY 12573-80 (1994); Ronald Soong & Peter Macdonald, *PEG molecular weight and lateral diffusion of PEG-ylated lipids in magnetically aligned bicelles*, 1768 BIOCHIMICA ET BIOPHYSICA ACTA 1805-14 (2007); E. Jane Manning & G.C. Millson, *Infectivity of Liposomally Encapsulated Nucleic Acids Isolated from EMC Virus and Scrapie-Infected Mouse Brain*, 20 INTERVIROLOGY 164-68 (1983); Tazewell Wilson et al., *The Introduction of Poliovirus RNA into Cells via Lipid Vesicles (Liposomes)*, 17 CELL 77-84 (May 1979); Sean Semple *et al*., *Rational design of cationic lipids for siRNA delivery*, 28 NATURE BIOTECH. 172-76 (2010); Escriou, WO 2002/095023 (published Nov. 28, 2002); and José Mario Barichello et al., *Complexation of siRNA and pDNA with Cationic Liposomes: The Important Aspects in Lipoplex Preparation*, METHODS IN MOLECULAR BIOLOGY, 605, 461-72 (2010).

129. The claims of the ’467 Patent are also invalid for lack of written description and for lack of enablement pursuant to 35 U.S.C. § 112, including because the specification does not describe, or enable a person of ordinary skill in the art to make and use a formulation like Acuitas’s mRNA-LNP formulations, including the mRNA-LNP formulation in Comirnaty®. For example, to the extent GSK reads its claims to cover lipids like those in Comirnaty®, the disclosure in the specification does not describe or enable such lipids.

130. The claims of the ’467 Patent are also invalid for indefiniteness pursuant to 35 U.S.C. § 112 as the specification fails to inform, with reasonable certainty, those of skill in the art about the scope of the invention.

131. As explained above, without a declaratory judgment of invalidity, Acuitas has and will continue to suffer uncertainty and unquantifiable financial and business risks because of GSK’s infringement allegations with respect to Comirnaty® and the Patents-in-Suit.

132. Acuitas hereby seeks a declaration that the claims of the ’467 Patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Acuitas respectfully requests that this Court enter judgment in favor of Acuitas against GSK and grant the following relief:

A. Judgment be entered declaring that the manufacture, use, offer to sell, sale of Comirnaty® in the United States, and the importation of Comirnaty® into the United States, does not infringe any valid and enforceable claims of any of the Patents-in-Suit;

B. Judgment be entered declaring that all the claims of each of the Patents-in-Suit are invalid;

C. Judgment be entered declaring this an exceptional case and awarding Acuitas its attorneys’ fees pursuant to 35 U.S.C. § 285;

D. Costs and expenses in this action; and

E. Such other and further relief as this Court may deem just and proper.

YOUNG CONAWAY STARGATT & TAYLOR, LLP

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