IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

ACUITAS THERAPEUTICS INC., MICHAEL HOPE, YING TAM, PAULO LIN, and BARBARA MUI	)	
Plaintiffs,	)	
v.	)	C.A. No. 2:23-cv-567
CUREVAC SE	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY JUDGMENT OF INVENTORSHIP

Plaintiffs Acuitas Therapeutics Inc. ("Acuitas"), Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui, for their Complaint against Defendant CureVac SE ("CureVac"), allege as follows:

NATURE OF THE ACTION

1. This is an action pursuant to 35 U.S.C. § 256 to correct the inventorship of four United States patents: U.S. Patent No. 11,241,493; U.S. Patent No. 11,471,525; U.S. Patent No. 11,576,966; and U.S. Patent No. 11,596,686 (collectively the "'493 Patent Family," and each of them a member of the '493 Patent Family). Copies of the members of the '493 Patent Family are attached as Exhibits A through D, respectively. The '493 Patent Family is assigned to CureVac SE. Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch are named inventors on each member of the '493 Patent Family, and the '493 Patent and the '525 Patent also identify Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek as inventors.

2. The named inventors on the '493 Patent Family, however, should also include Acuitas's scientists: Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui. By this action, Plaintiffs seek to add Acuitas's scientists as inventors to those patents. While CureVac's scientists

contributed to the work leading to those patents, they did not do so and could not have done so alone. Instead, they worked hand in hand with Acuitas's scientists, who invented and taught CureVac's scientists significant elements of each claimed invention in the '493 Patent Family. CureVac surreptitiously filed the applications that led to the '493 Patent Family, deliberately omitting Acuitas's inventors despite their essential role in significant elements of those claimed inventions.

3. Acuitas is a world leader in developing lipid nanoparticle ("LNP") technology that is used in mRNA vaccines as well as other therapeutics under development. Indeed, Acuitas's research and development resulted in its lipids and LNP technology being used to deliver the mRNA payload in the Pfizer/BioNTech COVID-19 vaccine, Comirnaty®. mRNA vaccines like Comirnaty® work by introducing mRNA into a person's body, such that the body makes a viral protein from the mRNA. The body will recognize the viral protein as foreign and will develop an immune response to it, such that if a person is later infected by that particular virus, then his immune system is primed to protect against the viral infection. mRNA, however, is exceptionally fragile, breaking down quickly in the body, and is too large to enter human cells by itself. LNPs serve as the delivery system that protects and delivers mRNA into the body and importantly into cells where the mRNA works. The components of the LNP are carefully chosen and tested to have the best safety and efficacy profiles.

4. Acuitas and CureVac have been collaborating on therapeutics that use Acuitas's LNP technology since at least 2014.[1] Much of that collaboration has been directed to vaccine development, including vaccines against rabies and coronaviruses. Acuitas and CureVac entered

[1] *See, e.g.*, Andreas Thess *et al.*, *Sequence-engineered mRNA Without Chemical Nucleoside Modifications Enables an Effective Protein Therapy in Large Animals*, 23(9) MOLECULAR THERAPY 1456 (2015) (received Jan. 30, 2015).

into a series of contracts to provide a framework for their collaboration. As part of the collaboration, CureVac provided the mRNA, and Plaintiffs provided their expertise in lipids and LNP technology and created mRNA-LNP formulations using CureVac's mRNA. The collaboration resulted in joint patent applications, such as PCT/EP2017/077517, which published as WO 2018/078053 ("WO'053").

5. At the start of the COVID-19 pandemic, in or around January 2020, Acuitas reached out to CureVac, offering to work together under their existing contractual framework to develop an mRNA vaccine for COVID-19. CureVac agreed. CureVac provided mRNA based on the COVID-19 sequence available from published scientific literature, and Plaintiffs formulated it using their proprietary LNP technology. Their collaboration relied upon and built on the research and findings from their previous joint collaboration and the internal research conducted by Acuitas's scientists over many years.

6. Without Plaintiffs' knowledge, CureVac then applied for and obtained the '493 Patent Family based on its joint work with Acuitas but deliberately omitted Acuitas's scientists as inventors. Acuitas's scientists, however, conceived the LNP technology and helped design and formulate the mRNA-LNP vaccine claimed in the '493 Patent Family. The claims in this patent family explicitly recite Acuitas's scientists' contributions, including the lipids and mRNA-LNP formulations that Acuitas provided, explained, and taught to CureVac, in addition to the mRNA. The common specification of these patents includes working examples and experimental results of mRNA-LNP vaccines formulated by Acuitas's scientists using Acuitas's lipids and LNP technology. These results were jointly generated by Plaintiffs and CureVac. The disclosed examples and results are necessary to describe and enable the inventions claimed in the '493 Patent

Family. Thus, Acuitas's scientists significantly contributed to conception of what is claimed in the '493 Patent Family.

7. Plaintiffs seek correction of the inventorship of the '493 Patent Family pursuant to 35 U.S.C. § 256.

THE PARTIES

8. Plaintiff Acuitas is a leading biotechnology company that collaborates with partner companies, non-governmental organizations, and academic institutions to develop new therapies to address unmet clinical needs. It is a private 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.

9. Plaintiffs Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui are pioneering scientists in the lipid and LNP technology field. All four have been with Acuitas for many years and, in some cases, worked together prior to joining Acuitas, collaborating together for decades in total. All four have also assigned their inventorship rights to Acuitas. Dr. Hope, an expert in lipid research and an author on over 100 publications in peer-reviewed journals, is one of the founders of Acuitas. Dr. Hope, along with Acuitas co-founders Drs. Thomas Madden and Pieter Cullis, received the Governor General's Innovation Award for his contribution to developing the LNP used in Comirnaty® and for the development of other important therapeutics, including anticancer drugs. Dr. Tam is an expert in nanotechnology and immunology and serves as the Chief Scientific Officer of Acuitas, where he oversees Acuitas's research programs internally and with external partners. Dr. Lin is the Director of Formulation Development at Acuitas and is responsible for the creation and testing of LNPs as well as the mechanism of action associated with LNPs. Dr. Mui is a Senior Scientist at Acuitas and has been working with lipids

and LNP technology for decades. She worked extensively on perfecting the molar ratios of various lipids in Acuitas's LNP technology. She, along with Drs. Hope, Tam, and Lin, were instrumental in the research that resulted in the LNP used in Comirnaty®.

10. Plaintiffs design and synthesize novel lipids and formulate them into LNPs encapsulating mRNA. Plaintiffs optimize such formulations and extensively characterize these LNPs to ensure they have the most advantageous safety and efficacy profiles, and Acuitas licenses these lipids and LNP technology to companies, like Pfizer and BioNTech, that manufacture mRNA-LNP vaccines—most notably Comirnaty® against COVID-19.

11. Plaintiffs also partnered with CureVac to develop mRNA-LNP vaccines, including the COVID-19 mRNA-LNP vaccine that is the subject of the '493 Patent Family.

12. Acuitas's business model is to pioneer the research and development of lipids and LNP technology and to collaborate with partners to create novel therapeutics using such LNP technology. When a partner wishes to take a novel therapeutic into clinical development, it licenses Acuitas lipids and LNP technology for that clinical product. It is essential to this business model that intellectual property arising from such collaborations and reflecting each party's contribution to the collaboration be jointly owned. This avoids either party to the collaboration being able to block the other collaborator from use of its own technology.

13. As such, it is antithetical to Acuitas's business model that any one of its partners, including CureVac, should be able to file patent applications claiming subject matter that includes Acuitas's scientific know-how and inventive contributions, and then assert any resulting patents against another Acuitas partner. Acuitas's business would be irretrievably harmed if any Acuitas partner, including CureVac, could sue and prevail over another Acuitas partner based on patents claiming subject matter that includes Acuitas's inventions.

14. Drs. Hope, Tam, Lin, and Mui all worked with CureVac during its collaboration with Acuitas, and each contributed significantly to the work done between Acuitas and CureVac. Their work has resulted in, for example, the 2017 patent application published as WO'053, which lists Drs. Hope, Tam, Lin, and Mui as inventors along with CureVac scientists and is titled "Lipid Nanoparticle mRNA Vaccines."

15. On information and belief, CureVac is a publicly listed and traded corporation on Nasdaq and exists under the laws of Germany with a principal place of business at Friedrich-Miescher-Strasse 15, 72076 Tübingen, Germany. CureVac has offices worldwide, including in Switzerland, Belgium, the Netherlands, and the United States with an office in Boston, Massachusetts. CureVac employs approximately one thousand people.

16. CureVac is the assignee of the '493 Patent Family.

JURISDICTION AND VENUE

17. This Court has subject matter and personal jurisdiction under 28 U.S.C. §§ 1331, 1338(a), and 2201 and 35 U.S.C. § 293.

18. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) and 35 U.S.C. § 293.

FACTUAL BACKGROUND

19. Acuitas's scientists, including Drs. Michael Hope, Ying Tam, Paulo Lin, Barbara Mui, and others, have been conducting groundbreaking research and development of lipids and LNP formulations for decades. Acuitas's scientists, including Drs. Hope, Tam, Lin, and Mui, elucidated the mechanism by which ionizable and pegylated lipids, and LNPs employing those lipids, safely and effectively deliver fragile mRNA to cells *in vivo* with minimal side effects. They use this insight to develop newer and better lipids and LNPs. Plaintiffs developed these lipids and

LNPs after decades of hard work and after painstaking design and testing of thousands of lipids and LNP candidates. For this reason, Acuitas's lipids and LNPs are the most advanced in the LNP field. Acuitas licenses its lipids and LNP technology to many partners, including Pfizer, BioNTech, and CureVac. Acuitas's lipids and LNP technology are used to deliver the mRNA in Comirnaty®—the first FDA-approved COVID-19 vaccine.

20. As part of its collaboration with its partners described above, Acuitas formulates the partner's mRNA using its proprietary lipids and LNP technology to jointly develop the resulting mRNA-LNP products. A partnership with Acuitas is the only way to access Plaintiffs' expertise and Acuitas's LNP technology. CureVac is one such partner.

21. Since at least 2014, CureVac and Acuitas have been working together on developing therapeutics that use Acuitas's LNPs and LNP technology for the formulation and delivery of CureVac's mRNA. CureVac and Plaintiffs have been, and still are, collaborators on developing mRNA-LNP vaccines. As part of this collaboration, Acuitas's scientists researched, developed, and characterized novel lipids and LNPs using Acuitas's LNP technology while CureVac provided the mRNA that was encapsulated by Acuitas's LNPs using its LNP technology. In general, during the initial development stage, Plaintiffs would not provide to CureVac the LNP formulation details, including the lipids used, the amounts of each component in the formulation, or the characteristics of the formulation (such as mean diameter of the LNP), and CureVac would not provide to Plaintiffs the mRNA sequence or other technical information relating to the mRNA. Only after the project had progressed to identifying promising clinical candidates, for which CureVac would take a license, would the LNP formulation details be disclosed to CureVac by Acuitas. As a consequence, in an mRNA-LNP formulation, CureVac provided the mRNA, and did not provide any input into (1) the lipids Plaintiffs designed and synthesized, (2) the non-mRNA

components Plaintiffs selected for their mRNA-LNP formulation (including the cryoprotectant sucrose), (3) the amounts of each of the components Plaintiffs selected for their mRNA-LNP formulation, or (4) the characteristics of the mRNA-LNP formulation such as the LNP's mean particle size. Between 2014 and 2020, using various mRNA constructs from CureVac, Plaintiffs formulated hundreds of mRNA-LNPs using their proprietary lipids—including ALC-315 and ALC-159—and LNP technology. This collaboration resulted in potential mRNA-LNP vaccines against many viruses, including rabies and coronaviruses.

22. CureVac and Plaintiffs' joint work resulted in a number of joint patent filings. For example, on October 26, 2017, Acuitas and CureVac filed an International Application No. PCT/EP2017/077517 entitled "Lipid Nanoparticle mRNA Vaccines," which lists inventors from both CureVac and Acuitas and was published on May 3, 2018 as WO'053; the international application was also filed in the United States and was published on May 28, 2020 as U.S. Patent App. Pub. No. 2020/0163878 ("the '878 publication"). The Acuitas inventors listed are Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui.

23. The invention disclosed in WO'053 "relates to mRNA comprising lipid nanoparticles useful as mRNA-based vaccines . . . for use in the prophylaxis or treatment of infectious diseases, tumour or cancer diseases, allergies or autoimmune diseases." WO'053 at 1:3–7. WO'053 discloses lipids invented by Acuitas—including ALC-315 and ALC-159—and mRNA-LNP formulations that use LNP technology invented by Acuitas and "an mRNA sequence encoding at least one antigenic peptide or protein" from CureVac. WO'053 at 115:1–121:35 (Table 7), 127:5–132:35 (Table 8), 135:25–140:35 (Table 9) (disclosing ALC-315 as No. III-3), 144:9–151:14 (disclosing ALC-315 as a cationic lipid and structure of ALC-159 as a PEG lipid of "formula (IVa)" in a preferred embodiment in addition to component ratio for an mRNA-LNP

formulated by Acuitas e.g., "preferably 47.5:10:40.8:1.7"). For example, WO'053 discloses that the antigen may be derived from "SARS coronavirus" including "spike glycoprotein S . . . SARS coronavirus, SARS (Severe Acute Respiratory Syndrome)." WO'053 at 22:15, 32:27–28. Accordingly, WO'053 includes several claims to an LNP comprising Acuitas's lipids—including ALC-315 and ALC-159—and "an mRNA sequence encoding at least one antigenic peptide or protein." WO'053 at 141:20. CureVac did not dispute that Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui co-invented the claimed subject matter in WO'053.

24. By early January 2020, the COVID-19 pandemic was emerging and several groups who were interested in developing a rapid response had approached Acuitas. On or around January 22, 2020, Thomas Madden, Acuitas's President and CEO, reached out to Ulrich Kruse at CureVac to see if CureVac would be interested in participating with Acuitas in the effort to develop an mRNA-LNP vaccine for SARS-CoV-2, the virus responsible for COVID-19. On or around January 27, 2020, Dr. Ying Tam followed up and emailed Patrick Baumhof at CureVac about Acuitas's interest in developing an mRNA-LNP vaccine against the 2019-nCOV (subsequently termed COVID-19), the new emergent coronavirus from Wuhan, and asked to speak to assess whether CureVac had an interest in potentially participating in such endeavor. By the end of January, Acuitas and CureVac had agreed to work together to develop an mRNA-LNP vaccine directed at the new Coronavirus. [redacted]

[redacted]

25. As with their prior dealings, CureVac developed the mRNA and Acuitas—specifically, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui—designed and developed the LNP formulations and LNP technology that protect and deliver the mRNA into the body for use in mRNA-LNP vaccines. [redacted]

26. While the parties were jointly developing an mRNA-LNP vaccine against the COVID-19 virus, unbeknownst to Plaintiffs, CureVac filed a series of provisional patent applications—the first of them on February 4, 2020—for the '493 Patent Family claiming Plaintiffs and CureVac's joint work on the same vaccine. These applications relied on Plaintiffs' lipids, Plaintiffs' LNP technology, and/or the joint experimental results. The specification of the '493 Patent Family specifically refers to lipids invented by Plaintiffs such as ALC-315 and ALC-159 and LNP technology invented and developed by Plaintiffs, including the non-mRNA components of the formulation (including the lipids and the cryoprotectant sucrose), the relative proportion each lipid within the formulation, the ratio of lipid to mRNA in the formulation ("N/P ratio"), and the characteristics of the mRNA-LNP (including the mean particle size). Moreover, while the first provisional application, filed on February 4, 2020, relied only on so-called

"prophetic" examples, by the May 29, 2020 provisional patent application, CureVac had included examples and data using mRNA-LNP formulations that Acuitas's scientists had designed and created using Acuitas's LNP technology to encapsulate CureVac's mRNA. *See, e.g.*, '493 Patent at Figs. 5A–11G, Exs. 1.4 (at 181:51–182:67), 6–8 (at 192:31–198:9), Tables A (at 183:1–39), 11–13 (at 192:49–67, 194:51–195:14, 197:29–43); '525 Patent at Figs. 5A–11G, Exs. 1.4 (at 181:31–182:48), 6–8 (at 189:36–194:58), Tables A (at 182:49–183:29), 11–13 (at 189:53–67, 191:34–59, 194:11–28); '966 Patent at Figs. 5A–11G, Exs. 1.4 (at 183:1–34), 6–8 (at 194:46–200:16), Tables A (at 185–88), 11–13 (at 195:1–14, 197:1–23, 199:43–54); '686 Patent at Figs. 5A–11G, Exs. 1.4 (at 183:1–184:8), 6–8 (at 193:1–198:49), Tables A (at 184:9–48), 11–13 (at 193:17–29, 195:14–37, 198:6–19). CureVac subsequently filed several additional provisional applications relying on more examples and data that Plaintiffs contributed to and helped generate. *See, e.g.*, '493 Patent at Figs. 14A–16C, Exs. 11–14 (at 204:58–269:39), Tables 16–20 (at 205:20–268:41); '525 Patent at Figs. 14A–16C, Exs. 11–14 (at 201:20–264:21), Tables 16–20 (at 201:50–263:19); '966 Patent at Figs. 14A–16C, Exs. 11–14 (at 206:56–272:23), Tables 16–20 (at 207:18–271:19); '686 Patent at Figs. 14A–16C, Exs. 11–14 (at 205:15–269:67), Tables 16–20 (at 205:45–269:14). These examples and data form the basis of, and provide support for, the claims in the '493 Patent Family. But, despite Acuitas's scientists' significant contributions to the conception of the inventions claimed in the '493 Patent Family, CureVac did not name any Acuitas inventors, including Drs. Hope, Tam, Lin, or Mui, on any of the patents in the '493 Patent Family.

27. Plaintiffs therefore file this action to seek correction of inventorship of each of the patents of the '493 Patent Family and to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as joint inventors pursuant to 35 U.S.C. § 256.

COUNT I

(CORRECTION OF INVENTORSHIP OF THE '493 PATENT)

28. Plaintiffs incorporate by reference herein all of the allegations of the preceding paragraphs.

29. The '493 Patent is entitled "Coronavirus Vaccine." On its face, the '493 Patent names Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch as inventors and CureVac AG as applicant and assignee. The '493 Patent does not name Drs. Hope, Tam, Lin, or Mui as inventors. The '493 Patent issued on February 8, 2022. A copy of the '493 Patent is attached to this Complaint as Exhibit A.

30. CureVac AG assigned the '493 Patent to CureVac SE in a change of name conveyance executed on September 26, 2022, and recorded on March 2, 2023.

31. Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek executed assignment of their rights to the '493 Patent's underlying application, U.S. Patent Application No. 17/231,261, and their assignment was recorded on March 24, 2023.

32. On March 24, 2023, CureVac petitioned the USPTO to add Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek as inventors of the '493 Patent. On August 1, 2023, the USPTO issued a Certificate of Correction adding Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek as inventors of the '493 Patent.

33. The '493 Patent is based on U.S. Patent Application No. 17/231,261, which was filed on April 15, 2021. U.S. Patent Application No. 17/231,261 is a continuation of U.S. Patent Application No. 17/276,788, which was filed as PCT/EP2021/052455 on February 3, 2021. The '493 Patent cites to a foreign patent application PCT/EP2020/052775 filed on February 4, 2020,

and a number of provisional applications, Provisional App. Nos. 63/112,106, 63/113,159, 63/119,390, and 63/129,395, that rely on CureVac and Plaintiffs' joint work.

34. The '493 Patent contains one independent claim, claim 1, which states:

> A composition comprising a mRNA comprising:
> (a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising a pre-fusion stabilizing K986P and V987P mutation;
> (b) at least one heterologous untranslated region (UTR); and
> (c) at least one pharmaceutically acceptable carrier,
> wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:
> (i) at least one cationic lipid according to formula III-3: [Plaintiffs' ALC-315];
> (ii) at least one neutral lipid, comprising 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC);
> (iii) at least one steroid, comprising cholesterol; and
> (iv) at least one PEG-lipid according to formula IVa: [Plaintiffs' ALC-159]
> wherein n has a mean value ranging from 30 to 60,
> wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-15% PEG-lipid.

35. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each significantly contributed to the conception of the subject matter claimed in the '493 Patent and are therefore co-inventors of the '493 Patent. CureVac provided the mRNA and Acuitas provided the LNP encapsulating the mRNA resulting in the claimed mRNA-LNP compositions.

36. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each contributed to the conception of at least claim element (c) of claim 1.

37. As discussed above in paragraphs 21–26, Acuitas conceived of the cationic lipid according to formula III-3 and the PEG-lipid according to formula IVa, and, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids.

38. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each contributed to the conception of dependent claims 15–16 and 19–22.

39. As discussed above in paragraphs 21–26, Acuitas conceived of the PEG-lipid according to formula IVa, and, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids (claim 15), conceived of and formulated mRNA-LNP compositions having the claimed mean particle diameter (claim 16), conceived of and formulated mRNA-LNP compositions with the cryoprotectant sucrose (claims 19–20), conceived of and formulated mRNA-LNP compositions with the claimed N/P ratios (claim 21), and conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids (claim 22).

40. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui to the subject matter claimed in the ’493 Patent are not insignificant when measured against the dimension of the full invention.

41. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui amounted to more than merely explaining well-known concepts and/or the current state of the art.

42. Through error, the ’493 Patent does not name Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as joint inventors.

43. Pursuant to 35 U.S.C. § 256(a), the ’493 Patent should be corrected to include omitted joint inventors Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors.

44. Plaintiffs request that the court order correction of the patent and that the Director of the U.S. Patent and Trademark Office issue a certificate, pursuant to 35 U.S.C. § 256(b), to

include Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors of the '493 Patent.

COUNT II

(CORRECTION OF INVENTORSHIP OF THE '525 PATENT)

45. Plaintiffs incorporate by reference herein all of the allegations of the preceding paragraphs.

46. The '525 Patent is entitled "Coronavirus Vaccine." On its face, the '525 Patent names Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch as inventors and CureVac AG as applicant and assignee. The '525 Patent does not name Drs. Hope, Tam, Lin, or Mui as inventors. The '525 Patent issued on October 18, 2022. A copy of the '525 Patent is attached to this Complaint as Exhibit B.

47. CureVac AG assigned the '525 Patent to CureVac SE in a change of name conveyance executed on September 26, 2022, and recorded on March 2, 2023.

48. Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek executed assignment of their rights to the '525 Patent's underlying application, U.S. Patent Application No. 17/546,414, and their assignment was recorded on March 24, 2023.

49. On March 24, 2023, CureVac petitioned the USPTO to add Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek as inventors of the '525 Patent. On August 1, 2023, the USPTO issued a Certificate of Correction adding Patrick Baumhof, Regina Heidenreich, and Mariola Fotin-Mleczek as inventors of the '525 Patent.

50. The '525 Patent is in the same patent family as the '493 Patent. The '525 Patent is based on U.S Patent Application No. 17/546,414, which was filed on December 9, 2021. U.S. Patent Application No. 17/546,414 is a continuation of U.S. Patent Application No. 17/276,788,

which was filed as PCT/EP2021/052455 on February 3, 2021. The '525 Patent cites to the same provisional applications, Provisional App. Nos. 63/112,106, 63/113,159, 63/119,390, and 63/129,395, that rely on CureVac and Plaintiffs' joint work as the '493 Patent.

51. The '525 Patent contains two independent claims, claims 1 and 25. Both claim 1 (below) and claim 25 cover Acuitas's lipids and LNP technology:

> A method of stimulating an immune response in a subject, the method comprising administering to the subject an effective amount of a composition comprising:
> (I) a mRNA comprising
> (a) at least one coding sequence which is at least 80% identical to SEQ ID NO: 137 encoding a severe acute respiratory syndrome coronavirus type 2 (SARS-CoV-2) spike protein (S) at least 90% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S stab) comprising a pre-fusion stabilizing K986P and V987P mutation and comprising a D614G amino acid substitution; and
> (b) a 5' heterologous untranslated region (UTR) and a heterologous 3' UTR, said heterologous 3' UTR comprising a terminal poly(A) sequence of 30 to 200 adenosine nucleotides; and
> (II) at least one pharmaceutically acceptable carrier,
> wherein the mRNA is complexed with lipid nanoparticles (LNP) and wherein the LNP comprise:
> (i) at least one cationic lipid according to formula III-3: [Plaintiffs' ALC-315];
> (ii) at least one neutral lipid, comprising 1,2-distearoyl-sn-glycero-3-phosphocholine (DSPC);
> (iii) at least one steroid, comprising cholesterol; and
> (iv) at least one polyethylene glycol (PEG)-lipid according to formula IVa: [Plaintiffs' ALC-159]
> wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-5% PEG-lipid,
> wherein the composition is administered by intramuscular injection.

52. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each significantly contributed to the conception of at least claim element no. (II) of claims 1 and 25 of the '525 Patent. CureVac provided the mRNA and Acuitas provided the LNP encapsulating the mRNA resulting in the claimed mRNA-LNP compositions.

53. As discussed above in paragraphs 21–26, Acuitas conceived of the cationic lipid according to formula III-3 and the PEG-lipid according to formula IVa, and, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids so that the compositions would be suitable for intramuscular injection.

54. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each contributed to the conception of dependent claims 15–23 and 28–29 of the ’525 Patent.

55. As discussed above in paragraphs 21–26, Acuitas conceived of the PEG-lipid according to formula IVa, and, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids (claims 15–16), conceived of and formulated mRNA-LNP compositions with the cryoprotectant sucrose (claims 17–18), conceived of and formulated mRNA-LNP compositions with the claimed N/P ratios (claim 19), conceived of and formulated mRNA-LNP compositions having the claimed mean particle diameter (claims 20, 28), and conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids and claimed amount of mRNA (claims 21–23, 29).

56. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui to the subject matter claimed in the ’525 Patent are not insignificant when measured against the dimension of the full invention.

57. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui amounted to more than merely explaining well-known concepts and/or the current state of the art.

58. Through error, the ’525 Patent does not name Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as joint inventors.

59. Pursuant to 35 U.S.C. § 256(a), the ’525 Patent should be corrected to include omitted joint inventors Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors.

60. Plaintiffs request that the court order correction of the patent and that the Director of the U.S. Patent and Trademark Office issue a certificate, pursuant to 35 U.S.C. § 256(b), to include Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors of the ’525 Patent.

COUNT III

(CORRECTION OF INVENTORSHIP OF THE ’966 PATENT)

61. Plaintiffs incorporate by reference herein all of the allegations of the preceding paragraphs.

62. The ’966 Patent is entitled “Coronavirus Vaccine.” On its face, the ’966 Patent names Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch as inventors and CureVac SE as applicant and assignee. The ’966 Patent does not name Drs. Hope, Tam, Lin, or Mui as inventors. The ’966 Patent issued on February 14, 2023. A copy of the ’966 Patent is attached to this Complaint as Exhibit C.

63. The ’966 Patent is in the same patent family as the ’493 Patent. The ’966 Patent is based on U.S. Patent Application No. 17/526,912, which was filed on November 15, 2021. U.S. Patent Application No. 17/526,912 is a continuation of U.S. Application No. 17/276,788, which was filed as PCT/EP2021/052455 on February 3, 2021. The ’966 Patent cites to the same provisional applications, Provisional App. Nos. 63/112,106, 63/113,159, 63/119,390, and 63/129,395, that rely on CureVac and Plaintiffs’ joint work as the ’493 Patent.

64. The ’966 Patent contains two independent claims, claims 1 and 26. Both claim 1 (below) and claim 26 cover Acuitas’s lipids and LNP technology:

> A composition comprising a mRNA comprising:
> (a) at least one coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S stab) comprising K986P and V987P stabilizing mutations and H69del, V70del, S477N, T478K, E484A, N501Y, and D614G amino acid substitutions relative to SEQ ID NO: 10;
> (b) at least one heterologous untranslated region (UTR); and
> (c) at least one pharmaceutically acceptable carrier,
> wherein the mRNA is complexed or associated with lipid nanoparticles (LNP) and wherein the LNP comprises:
> (i) at least one cationic lipid;
> (ii) at least one neutral lipid;
> (iii) at least one steroid or steroid analogue; and
> (iv) at least one PEG-lipid,
> wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-10% PEG-lipid.

65. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each significantly contributed to the conception of at least claim element (c) of claims 1 and 26 of the ’966 Patent. CureVac provided the mRNA and Acuitas provided the LNP encapsulating the mRNA resulting in the claimed mRNA-LNP compositions.

66. As discussed above in paragraphs 21–26, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids.

67. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each contributed to the conception of dependent claims 3, 13–17, 20, 23–24 of the ’966 Patent.

68. As discussed above in paragraphs 21–26, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed lipids and relative proportions of the lipids (claims 3, 20), conceived of and formulated mRNA-LNP compositions with the cryoprotectant sucrose such that

at least 80% of the mRNA is intact at least about two weeks after storage as a liquid at temperatures of about 5ºC (claims 13–14), conceived of and formulated mRNA-LNP compositions that had high encapsulation of mRNA such that there was less than 20% free mRNA (claim 15), conceived of and formulated mRNA-LNP compositions having the claimed mean particle diameter (claims 16, 24), and conceived of and formulated mRNA-LNP compositions with the claimed N/P ratios (claim 17).

69. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui to the subject matter claimed in the ’966 Patent are not insignificant when measured against the dimension of the full invention.

70. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui amounted to more than merely explaining well-known concepts and/or the current state of the art.

71. Through error, the ’966 Patent does not name Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as joint inventors.

72. Pursuant to 35 U.S.C. § 256(a), the ’966 Patent should be corrected to include omitted joint inventors Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors.

73. Plaintiffs request that the court order correction of the patent and that the Director of the U.S. Patent and Trademark Office issue a certificate, pursuant to 35 U.S.C. § 256(b), to include Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors of the ’966 Patent.

COUNT IV

(CORRECTION OF INVENTORSHIP OF THE '686 PATENT)

74. Plaintiffs incorporate by reference herein all of the allegations of the preceding paragraphs.

75. The '686 Patent is entitled "Coronavirus Vaccine." On its face, the '686 Patent names Susanne Rauch, Hans Wolfgang Große, and Benjamin Petsch as inventors and CureVac SE as applicant and assignee. The '686 Patent does not name Drs. Hope, Tam, Lin, or Mui as inventors. The '686 Patent issued on March 7, 2023. A copy of the '686 Patent is attached to this Complaint as Exhibit D.

76. The '686 Patent is in the same patent family as the '493 Patent. The '686 Patent is based on U.S. Patent Application No. 17/818,699, which was filed on August 9, 2022. U.S. Patent Application No. 17/818,699 is a continuation of U.S. Application No. 17/526,966, which issued as the '966 Patent. The '966 Patent is based on U.S. Patent Application No. 17/526,912, which was filed November 15, 2021. U.S. Patent Application No. 17/526,912 is a continuation of U.S. Application No. 17/276,788, which was filed as PCT/EP2021/052455 on February 3, 2021. The '686 Patent cites to the same provisional applications, Provisional App. Nos. 63/112,106, 63/113,159, 63/119,390, and 63/129,395, that rely on CureVac and Plaintiffs' joint work as the '493 Patent.

77. The '686 Patent contains two independent claims, claims 1 and 26. Claims 1, 14, 18, and 19 state:

> 1. A purified mRNA comprising:
> (a) a 5' cap structure
> (b) a heterologous 5' untranslated region (UTR);
> (c) a coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing substitutions

and further comprising a D614G amino acid substitution relative to SEQ ID NO: 10; and
(d) a heterologous 3' UTR,
wherein the mRNA optionally comprises a nucleotide substitution at one or more uracil position(s) selected from a 1-methylpseudouridine or a pseudouridine substitution.

14. A pharmaceutical composition comprising the purified mRNA of claim 1 and at least one pharmaceutically acceptable carrier.

18. The composition of claim 14, wherein the mRNA is complexed or associated with lipid nanoparticles (LNPs).

19. The composition of claim 18, wherein the LNPs comprises:
(i) at least one cationic lipid;
(ii) at least one neutral lipid;
(iii) at least one steroid or steroid analogue; and
(iv) at least one PEG-lipid,
wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-10% PEG-lipid.

78. Similarly, claims 26 and 27 state:

26. A composition comprising:
(I) a purified mRNA comprising:
(a) a 5' cap structure;
(b) a heterologous 5' untranslated region (UTR);
(c) a coding sequence encoding a SARS-CoV-2 spike protein (S) at least 95% identical to SEQ ID NO: 10 that is a pre-fusion stabilized spike protein (S_stab) comprising K986P and V987P stabilizing substitutions and further comprising a D614G amino acid substitution relative to SEQ ID NO: 10; and
(d) a heterologous 3' UTR, comprising a terminal poly(A) sequence of 30 to 200 adenosine nucleotides, wherein 100% of the uracil positions in the mRNA are replaced with 1-methylpseudouridine; and
(II) at least one pharmaceutically acceptable carrier, wherein the mRNA is complexed or associated with lipid nanoparticles (LNPs).

27. The composition of claim 26, wherein the LNPs comprises:
(i) at least one cationic lipid;
(ii) at least one neutral lipid;
(iii) at least one steroid or steroid analogue; and
(iv) at least one PEG-lipid,
wherein (i) to (iv) are in a molar ratio of about 20-60% cationic lipid, 5-25% neutral lipid, 25-55% sterol, and 0.5-5% PEG-lipid.

79. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each significantly contributed to the conception of claims 19 and 27 of the ’686 Patent.

80. As discussed above in paragraphs 21–26, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids.

81. Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui each contributed to the conception of dependent claims 20, 23–25 of the ’686 Patent.

82. As discussed above in paragraphs 21–26, using the mRNA conceived by CureVac, Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui conceived of and formulated mRNA-LNP compositions with the claimed relative proportions of the lipids (claim 20), conceived of and formulated mRNA-LNP compositions having the claimed mean particle diameter (claim 23), conceived of and formulated mRNA-LNP compositions with the claimed N/P ratios (claim 24), and conceived of and formulated mRNA-LNP compositions with the cryoprotectant sucrose (claim 25).

83. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui to the subject matter claimed in the ’686 Patent are not insignificant when measured against the dimension of the full invention.

84. The contributions of Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui amounted to more than merely explaining well-known concepts and/or the current state of the art.

85. Through error, the ’686 Patent does not name Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as joint inventors.

86. Pursuant to 35 U.S.C. § 256(a), the ’686 Patent should be corrected to include omitted joint inventors Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors.

87. Plaintiffs request that the court order correction of the patent, and that the Director of the U.S. Patent and Trademark Office issue a certificate, pursuant to 35 U.S.C. § 256(b), to include Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as named inventors of the ’686 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in favor of Plaintiffs against CureVac and grant the following relief:

A. Judgment be entered declaring correction of inventorship of the ’493 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

B. Judgment be entered declaring correction of inventorship of the ’525 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

C. Judgment be entered declaring correction of inventorship of the ’966 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

D. Judgment be entered declaring correction of inventorship of the ’686 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

E. Enter an order pursuant to 35 U.S.C. § 256 requiring the Director of the United States Patent and Trademark Office to issue a Certificate to correct the inventorship of the ’493 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

F. Enter an order pursuant to 35 U.S.C. § 256 requiring the Director of the United States Patent and Trademark Office to issue a Certificate to correct the inventorship of the '525 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

G. Enter an order pursuant to 35 U.S.C. § 256 requiring the Director of the United States Patent and Trademark Office to issue a Certificate to correct the inventorship of the '966 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

H. Enter an order pursuant to 35 U.S.C. § 256 requiring the Director of the United States Patent and Trademark Office to issue a Certificate to correct the inventorship of the '686 Patent to add Drs. Michael Hope, Ying Tam, Paulo Lin, and Barbara Mui as inventors;

I. Judgment be entered declaring this is an exceptional case and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. § 285;

J. Costs and expenses in this action; and

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

Acuitas Therapeutics Inc.,
Michael Hope, Ying Tam,
Paulo Lin, and Barbara Mui.

By Counsel

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**Pro hac vice* applications forthcoming

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