IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NANEXA AB Plaintiff, v. VITRIVAX, INC., Defendant.	Civil Action No. 21-764-CFC JURY TRIAL DEMANDED

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Nanexa AB ("Plaintiff" or "Nanexa"), by and through its undersigned counsel, for its complaint against Defendant VitriVax, Inc. ("Defendant" or "VitriVax"), hereby alleges and states the following:

PARTIES

1. Plaintiff Nanexa AB is a Swedish corporation with a principal place of business at Virdings Allé 32B, SE-75450, Uppsala, Sweden.

2. Plaintiff is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,166,198 (the "'198 Patent") entitled Solid Nanoparticle with Inorganic Coating, a copy of which is attached hereto as Exhibit A.

3. Plaintiff is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,478,402 (the "'402 Patent") entitled Solid Nanoparticle with Inorganic Coating, a copy of which is attached hereto as Exhibit B.

4. Plaintiff is the owner by assignment of the entire right, title and interest in and to U.S. Patent No. 10,864,171 (the "'171 Patent," and together with the '198 Patent and the

'402 Patent, the "Patents-in-Suit") entitled Solid Nanoparticle with Inorganic Coating, a copy of which is attached hereto as Exhibit C.

5. Upon information and belief, Defendant VitriVax is a United States corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 3415 Colorado Avenue, Boulder, Colorado 80303.

6. Upon information and belief, VitriVax was founded, at least in part, by Dr. Robert Garcea and Dr. Theodore Randolph.

JURISDICTION AND VENUE

7. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq.*

8. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Defendant because it has, directly or through its agents and/or intermediaries, committed acts within Delaware giving rise to this action and/or Defendant has established minimum contacts with Delaware such that the exercise of jurisdiction would not offend traditional notions of fair play and substantial justice, including without limitation, the incorporation of VitriVax in the State of Delaware.

10. Upon information and belief, Defendant regularly conducts business in Delaware, and purposefully avails itself of the privileges of conducting business in Delaware, including without limitation, through the incorporation of VitriVax in the State of Delaware. Further, upon information and belief, Defendant and/or its agents and/or intermediaries has at least made, used, or offered the Accused Products for sale in a manner that could be sufficiently directed to Delaware to give rise to personal jurisdiction, which would require discovery to further confirm.

11. Upon information and belief, and as further described herein, Defendant has infringed and continues to infringe the '198 Patent, the '402 Patent, and the '171 Patent, which has led to foreseeable harm and injury to Plaintiff.

12. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b), (c) and/or (d), and 28 U.S.C. § 1400(b).

THE PATENTS-IN-SUIT

A. The '198 Patent

13. The '198 Patent was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on January 1, 2019, to listed inventors Jan-Otto Carlsson, Anders Johansson, and Mårten Rooth.

14. Plaintiff is the owner by assignment of all right, title and interest in and to the '198 Patent. Plaintiff is listed on the face of the '198 Patent as assignee.

15. The '198 Patent is directed to a nanoparticle (as broadly defined in that patent) having a solid core comprising a biologically active substance, the core being enclosed by an inorganic coating, a method of preparing the nanoparticle and coating, and use of the nanoparticle in therapy.

16. As an example, Claim 14 of the '198 Patent provides:

> A controlled or delayed release pharmaceutical composition in a form of a sterile injectable or infusible suspension of particles, the composition comprising:
> i. a plurality of coated particles of a size that is from 0.1 μm to 50 μm, said coated particles having a solid core comprising a drug, said solid core being enclosed by one or more metal oxide materials to enable a therapeutically effective controlled or delayed release of the drug from the coated particles in said pharmaceutical composition; and
> ii. a pharmaceutically and parentally acceptable diluent,
> the pharmaceutical composition being prepared according to a process comprising the sequential steps of:

> (1) applying a coating of at least one metal oxide to said solid cores in an atomic layer deposition reactor;
> (2) discharging the coated particles from the reactor and subjecting the coated particles to agitation to disaggregate particle aggregates formed during step (1);
> (3) reintroducing the disaggregated, coated particles from step (2) into an atomic layer deposition reactor and applying a further coating of at least one metal oxide to the reintroduced particles;
> (4) optionally repeating steps (2) and (3) one or more times to increase a total thickness of the one or more metal oxide materials that enclose said solid core; and
> (5) admixing said coated particles obtained from step (3) or step (4) with said pharmaceutically and parenterally acceptable diluent to form said pharmaceutical composition wherein the controlled or delayed release of the drug from the coated particles is provided by the process steps (1) to (3) and (4), if performed.

See Exhibit A, 23:61-24:25.

B. <u>The '402 Patent</u>

17. The '402 Patent was duly and lawfully issued by the USPTO on November 19, 2019, to listed inventors Jan-Otto Carlsson, Anders Johansson, and Mårten Rooth.

18. Plaintiff is the owner by assignment of all right, title and interest in and to the '402 Patent. Plaintiff is listed on the face of the '402 Patent as assignee.

19. The '402 Patent is directed to a nanoparticle (as broadly defined in that patent) having a solid core comprising a biologically active substance, the core being enclosed by an inorganic coating, a method of preparing the nanoparticle and coating, and use of the nanoparticle in therapy.

20. As an example, Claim 15 of the '402 Patent claims:

> A controlled or delayed release pharmaceutical composition comprising:
> i. a plurality of coated particles of a size that is from 0.1 μm to 50 μm, said coated particles having a solid core comprising a biologically active substance, said solid core being enclosed by one or more metal oxide materials to enable a therapeutically effective

> controlled or delayed release of the biologically active substance from the coated particles in said pharmaceutical composition; and
> ii. a pharmaceutically acceptable carrier,
> the pharmaceutical composition being prepared according to a process comprising the sequential steps of:
> (1) applying a coating of at least one metal oxide to said solid cores in an atomic layer deposition reactor;
> (2) discharging the coated particles from the reactor and subjecting the coated particles to agitation to disaggregate particle aggregates formed during step (1);
> (3) reintroducing the disaggregated, coated particles from step (2) into an atomic layer deposition reactor and applying a further coating of at least one metal oxide to the reintroduced particles;
> (4) optionally repeating steps (2) and (3) one or more times to increase total thickness of the one or more metal oxide materials that enclose said solid core; and
> (5) admixing said coated particles obtained from step (3) or step (4) with said pharmaceutically acceptable carrier to form said pharmaceutical composition wherein the controlled or delayed release of the biologically active substance from the coated particles is provided by the process steps (1) to (3) and (4), if performed.

See Exhibit B, 24:1-35.

C. The ’171 Patent

21. The ’171 Patent was duly and lawfully issued by the USPTO on December 15, 2020, to listed inventors Jan-Otto Carlsson, Anders Johansson, and Mårten Rooth.

22. Plaintiff is the owner by assignment of all right, title and interest in and to the ’171 Patent. Plaintiff is listed on the face of the ’171 Patent as assignee.

23. The ’171 Patent is directed to a nanoparticle (as broadly defined in that patent) having a solid core comprising a biologically active substance, the core being enclosed by an inorganic coating, a method of preparing the nanoparticle and coating, and use of the nanoparticle in therapy.

24. As an example, Claim 15 of the ’171 Patent claims:

> A controlled or delayed release pharmaceutical composition comprising:

> i. a plurality of coated particles of a size that is from 0.1 µm to 50 µm, said coated particles having a solid core comprising a buffering agent, said solid core being enclosed by one or more metal oxide materials to enable a therapeutically effective controlled or delayed release of the buffering agent from the coated particles in said pharmaceutical composition; and
> ii. a pharmaceutically acceptable carrier,
> the pharmaceutical composition being prepared according to a process comprising the sequential steps of:
> (1) applying a coating of at least one metal oxide to said solid cores in an atomic layer deposition reactor;
> (2) discharging the coated particles from the reactor and subjecting the coated particles to agitation to disaggregate particle aggregates formed during step (1);
> (3) reintroducing the disaggregated, coated particles from step (2) into an atomic layer deposition reactor and applying a further coating of at least one metal oxide to the reintroduced particles;
> (4) optionally repeating steps (2) and (3) one or more times to increase total thickness of the one or more metal oxide materials that enclose said solid core; and
> (5) admixing said coated particles obtained from step (3) or step (4) with said pharmaceutically acceptable carrier to form said pharmaceutical composition;
> wherein the controlled or delayed release of the buffering agent from the coated particles is provided by the process steps (1) to (3) and (4), if performed.

See Exhibit C, 23:66-24:28.

THE ACCUSED PRODUCTS

25. Upon information and belief, and based on VitriVax's public statements detailed below, VitriVax makes, uses, sells and/or offers for sale in the United States one or more products that meet the characteristics and have the attributes of products made using the process described in the article Garcea, R.L., *et al.*, "Single-administration, Thermostable Human Papillomavirus Vaccines Prepared with Atomic Layer Deposition Technology," *NPJ Vaccines* 5:45, https://doi.org/10.1038/s41541-020-0195-4 (published online 2 June 2020) ("Garcea Article"), a copy of which is attached hereto as Exhibit D. Two primary authors of the Garcea Article are Dr. Robert Garcea and Dr. Theodore Randolph, who are listed as co-founders

of VitriVax. *See* https://vitrivaxbio.com/about, a copy of which is attached hereto as Exhibit E. VitriVax also admits that the technology disclosed in the Garcea Article is exclusively licensed to VitriVax. *See* Exhibit H.

26. One Accused Product is the human papillomavirus ("HPV") vaccine formulation that is described in Garcea Article ("HPV Vaccine"). The Garcea Article and VitriVax's public statements detailed below confirm the existence and infringing characteristics of VitriVax's HPV Vaccine.

27. Based on publicly available information, VitriVax admits that the HPV Vaccine is described in Garcea Article. *See* Single-Shot HPV Vaccine Study Published in the *Nature* Journal "NPJ Vaccines," dated June 2, 2020, available at https://vitrivax.com, a copy of which is attached hereto as Exhibit F ("June 2 Press Release"). Specifically, the HPV Vaccine described in Garcea Article is identified in the June 2 Press Release as the "***VitriVax*** formulated HPV vaccine" (emphasis added). *See* Exhibit F.

28. VitriVax admits in the June 2 Press Release that "[t]he data [in the Garcea Article] demonstrate the effectiveness in mice of a single-shot human papillomavirus (HPV) vaccine using ***VitriVax's groundbreaking vaccine formulation platform***" (emphasis added). *See* Exhibit F. This is a reference to the process disclosed in the Garcea Article.

29. Further, VitriVax admits in the June 2 Press Release that "The ***VitriVax formulated HPV vaccine*** demonstrated in this study [i.e, the Garcea Article] is thermostable at over 50°C (122°F) for months without loss of efficacy. Further, because the VitriVax combined dose technology provides timed release of a booster dose weeks after injection, only a single injection [of] ***the VitriVax HPV vaccine formulation*** is required for full immunization" (emphasis added). *See* Exhibit F.

30. All of these VitriVax statements in the June 2 Press Release confirm that the "VitriVax formulated HPV vaccine" is a product made using the process disclosed in the Garcea Article, making that HPV Vaccine product an Accused Product. VitriVax's public statements also confirm that VitriVax is at least, *inter alia*, making, selling, or offering for sale, that Accused Product, and thereby infringing the Asserted Patents, as detailed below.

31. VitriVax also admits that it is making additional vaccine products that would qualify as Accused Products beyond its HPV Vaccine.

32. In a July 7, 2021 press release, VitriVax publicly described its vaccine production process as "the ALTA™ platform". *See* VitriVax Announces Series A Financing to Further Demonstrate Feasibility of Its Thermostable, Single-dose Vaccine Technology, Aiming to Make Life-saving Biologics Widely Accessible to Underserved Populations Globally, dated July 7, 2021, available at https://vitrivax.com, a copy of which is attached hereto as Exhibit G ("July 7 Press Release").

33. In its July 7 Press Release, VitriVax describes the ALTA™ platform as involving both a spray-drying process for manufacture of antigen- and adjuvant-containing spray-dried microparticles, and an atomic layer deposition (ALD) process to apply nanometer-thick, precision coatings of protective metal oxides on the surface of antigen- and adjuvant-containing spray-dried microparticles. *See* Exhibit G, p. 1.

34. In describing its ALTA™ platform, VitriVax admits that it "…uses a spray drying process to embed antigens and adjuvants in a sugar-glass matrix, protecting them against thermal and chemical degradation at temperatures as high as 70° Celsius (158° Fahrenheit) for months, as demonstrated in multiple mouse studies using HPV capsomeres as a model antigen, as well as in multiple studies with commercial partners" and that it uses "atomic layer deposition (ALD)

to apply nanometer-thick, precision coatings of protective metal oxides on the surface of antigen- and adjuvant-containing spray-dried microparticles", which "provides timed release of doses up to six months after injection, also demonstrated in the same studies." *See* Exhibit G, p. 1. This is a description of the process disclosed in the Garcea Article and uses terminology the same as or similar to the Garcea Article, confirming that other products made using VitriVax's ALTA™ platform would be Accused Products. The July 7 Press Releases expressly references VitriVax's HPV Vaccine (*see* Exhibit G, p. 1.), providing further confirmation that the HPV Vaccine is an infringing Accused Product. Further, the July 7 Press Release confirms that different vaccine products made by the ALTA™ platform with different antigens would be additional Accused Products.

35. Upon information and belief, VitriVax has further utilized the process described in the Garcea Article and/or its ALTA™ platform to make vaccines using antigens other than HPV capsomeres. Such vaccines, made using its ALTA™ platform and containing other antigens, are additional Accused Products.

36. VitriVax states in the June 2 Press Release that: "The VitriVax platform's ability to eliminate vaccine cold chain requirements, and to deliver multi-dose vaccines in a single injection can make an enormous impact for common public health vaccines like HPV, and it can also provide huge benefits in the fight against COVID-19 and other future pandemics" and "***VitriVax is actively engaging in trials with multiple partners*** to demonstrate thermostability and combined doses f***or a variety of different antigens and disease targets, in both human and animal health***." *See* Exhibit F, p. 1 (emphasis added). These statements are in accord with and track the attributes of the process disclosed in the Garcea Article and VitriVax's descriptions of its ALTA™ platform.

37. VitriVax has published information about these efforts on other antigens on its website. *See* Exhibit E. Specifically, VitriVax identifies its "platform technology for thermostable, single-dose vaccine regimens [as having] already been successfully applied to a variety of antigen types, including Anthrax, Botulinum toxin, Ebola glycoprotein, HPV16 L1 capsomere, Trivalent HPV16/18/31 L1 capsomeres, Mouse polyomavirus and Ricin toxin A." *See* Exhibit E, p. 1. The "HPV16 L1 capsomere" is the antigen in the HPV Vaccine, *i.e*. the "VitriVax formulated HPV vaccine" Accused Product described above. Upon information and belief, the other vaccine products described above containing any of these six additional antigens (or antigen combinations) constitute additional Accused Products.

38. Upon information and belief, VitriVax is also actively seeking to collaborate with other pharmaceutical companies to incorporate its Accused Products and technology covered by the claims of the Patents-in-Suit into their pharmaceutical products. Upon information and belief, any such additional incorporated products would constitute additional Accused Products.

39. Based on the Garcea Article and in the above-noted public statements of VitriVax, the Accused Products include any products made using the VitriVax's ALTA™ platform, including the HPV Vaccine, *i.e*. the "VitriVax formulated HPV vaccine," as described in the Garcea Article and in Exhibits F and G; the vaccine products containing Anthrax, Botulinum toxin, Ebola glycoprotein, Trivalent HPV16/18/31 L1 capsomeres, Mouse polyomavirus, or Ricin toxin A as described in Exhibit E; as well as any other products made by VitriVax for "trials with multiple partners to demonstrate thermostability and combined doses for a variety of different antigens and disease targets" as described in Exhibit E.

40. VitriVax has provided a detailed public description of its HPV Vaccine Accused Product, i.e. the "VitriVax formulated HPV vaccine," as described in the Garcea Article and in VitriVax's other public statements. Discovery would be needed to detail additional Accused Products by name or antigen beyond those discussed in this First Amended Complaint, but VitriVax's public statements to date confirm the existence of at least the above Accused Products and expressly indicate that they are made using the process described in the Garcea Article. Upon information and belief, only VitriVax or potentially its commercial partners have additional detailed information on any additional Accused Products and their manner of manufacture beyond VitriVax's public statements. However, those public statements to date confirm the existence of at least the above-described Accused Products.

41. The above Accused Products meet the limitations of at least Claim 14 of the '198 Patent, Claim 15 of the '402 Patent, and Claim 15 of the '171 Patent, as set forth below.

INFRINGEMENT BY THE ACCUSED PRODUCTS

42. As described above, VitriVax admits that the Accused Products are made using the process described in the Garcea Article, including without limitation, by VitriVax's ALTA™ platform. *See* Exhibits D to H.

43. The process for making the Accused Products as detailed in the Garcea Article, and as confirmed by VitriVax's public statements noted above, meets the limitations recited in the above-noted claims of the Asserted Patents.

44. Upon information and belief, the Accused Products are an injectable, controlled or delayed release pharmaceutical composition that includes a suspension of particles in a suitable carrier, a limitation in each of the above-noted claims of the Asserted Patents.

45. For example, the Garcea Article states:

> When the alumina-coated antigen particles are injected in vivo, the coating dissolves slowly, providing a time-delayed booster dose of antigen.
>
> . . .
>
> We show that these ALD-coated antigen preparations elicit a prime-boost immune response to the L1 antigen after a single administration, with antibody titers meeting or exceeding those seen with a standard, alum-adsorbed two-dose immunization of the L1 protein.
>
> . . .
>
> Because the time-release characteristics depend on the number of layers applied, the time between prime and boost doses can be controlled by applying precise numbers of coating layers.

See Exhibit D, pp. 1, 2, 5.

46. Upon information and belief, the Accused Products contain a pharmaceutically and parentally acceptable diluent (carrier) and a plurality of coated particles, which particles have a solid core and a metal oxide coating, which are limitations in each of the above-noted claims of the Asserted Patents.

47. For example, the Garcea Article states

> Particles were coated with alumina (aluminum oxide, (Al_2O_3)) layers by ALD in a custom-built, low pressure fluidized bed reactor. . . . ALD-coated particles were suspended in 54 mM histidine HCl with 15 w/v% endotoxin-free trehalose, 2.5% w/v HES, 40 mM NaCl, 0.02 mM Tween 80 immediately prior to injection.

See Exhibit D, pp. 6, 7.

48. Upon information and belief, the Accused Products' solid cores include an antigen/adjuvant formulation containing glass-forming polymers and trehalose, which are first spray-dried to form a solid, glassy microparticle. The presence of a solid core containing a drug or biologically active substance, such as a vaccine, is a limitation in the above-noted claims of the Asserted '198 and '402 Patents.

49. For example, the Garcea Article states: "In the current study . . . mixtures of alum and HPV capsomere protein were spray-dried together with trehalose and hydroxyethyl starch added as glass transition temperature (T_g) modifiers." *See* Exhibit D, p. 2.

50. Upon information and belief, the Accused Products' HPV16 L1 capsomeres, Anthrax, Botulinum toxin, Ebola glycoprotein, Trivalent HPV16/18/31 L1 capsomeres, Mouse polyomavirus, or Ricin toxin A constitute a biologically active substance, or drug, which are limitations in the above-noted claims of the Asserted '198 and '402 Patents.

51. For example the Garcea Article states: "In the current study we have used the human papillomavirus type 16 (HPV16) L1 capsid protein as a model antigen for evaluating these technologies." *See* Exhibit D, p. 2.

52. As a further example, in Exhibit E VitriVax states that its "platform technology for thermostable, single-dose vaccine regimens … has already been successfully applied to a variety of antigen types, including Anthrax, Botulinum toxin, Ebola glycoprotein, HPV16 L1 capsomere, Trivalent HPV16/18/31 L1 capsomeres, Mouse polyomavirus and Ricin toxin A." *See* Exhibit E, p. 1.

53. Upon information and belief, the Accused Products' coated particles are microparticles (specifically of a size that is from 1 to 5 μm), meeting a limitation in each of the above-noted claims of the Asserted Patents.

54. For example, the Garcea Article states: "The resulting microparticles were spherical, with the majority of the particles ranging in diameter from 1 to 5 μm as measured by flow imaging microscopy (Figs 1a, 2)." *See* Exhibit D, p. 2.

55. Upon information and belief, the Accused Products' method of preparation for the coated particles practices ALD according to steps (1) to (4) in the '198, '402, and '171 Patents, including intermittently disaggregating by sieving.

56. For example, the Garcea Article states: "We then utilized ALD in a custom-built fluidized bed reaction chamber to apply conformal alumina coats of desired thickness to the spherical spray-dried microparticles"; and "Particles were coated with alumina (aluminum oxide, (Al_2O_3)) layers by ALD in a custom-built, low pressure fluidized bed reactor. . . . To further decrease agglomeration, the reaction was interrupted every 70−100 cycles and the particles were sieved to remove or break agglomerates." *See* Exhibit D, pp. 2, 6-7.

57. The Garcea Article expressly describes a process in which ALD is interrupted periodically in order to carry out intermittent sieving. Plaintiff is unaware of any commercially-available ALD reactor design that would allow coated particles to be passed through a sieve while remaining inside an ALD reactor. Thus, based on that fact and the fact that there is nothing in the Garcea Article to suggest that the sieving is being done inside the ALD reactor, upon information and belief, the sieving process described in the Garcea Article is occurring outside the ALD reactor.

58. Upon information and belief, the Accused Products' method of preparation includes admixing the coated particles with the diluent/carrier to form the pharmaceutical composition, a limitation in each of the above-noted claims of the Asserted Patents.

59. For example, the Garcea Article states: "ALD-coated particles were suspended in 54 mM histidine HCl with 15 w/v% endotoxin-free trehalose, 2.5% w/v HES, 40 mM NaCl, 0.02 mM Tween 80 immediately prior to injection." *See* Exhibit D, p. 7.

60. Upon information and belief, the Accused Products' solid core includes a buffering agent as one part of an antigen/adjuvant formulation containing glass-forming polymers and trehalose, which are first spray-dried to form a glassy microparticle. The presence of a buffering agent in the solid core is a limitation in the above-noted claim of the '171 Patent.

61. For example, the Garcea Article states:

> In the current study . . . mixtures of alum and HPV capsomere protein were spray-dried together with trehalose and hydroxyethyl starch added as glass transition temperature (T_g) modifiers. . . . Prior to spray-drying, 0.5 mg/mL HPV16 L1 capsomeres . . . were formulated in 54mM histidine HCl with 15 w/v% endotoxin-free trehalose, 2.5% w/v HES, 40mM NaCl, 0.02 mM Tween 80. Some formulations also contained 0.5 mg/mL aluminum from Alhydrogel® (alum) with a final pH of 6.0.

See Exhibit D, pp. 2, 6.

62. As a further example, the Garcea Article states: "Before formulation, fractions containing L1 were exchanged by size exclusion chromatography into a 100 mM histidine buffer pH 7.1." *See* Exhibit D, p. 6.

63. Upon information and belief, the Accused Products use histidine HCl as a buffering agent, a limitation in the above-noted claim of the '171 Patent. *See* Exhibit D, pp. 2, 6.

64. The above analysis addresses all the limitations of Claim 14 of the '198 Patent, Claim 15 of the '402 Patent, and Claim 15 of the '171 Patent. As a result of the foregoing, upon information and belief, the Accused Products meet the limitations of at least Claim 14 of the '198 Patent, at least Claim 15 of the '402 Patent, and at least Claim 15 of the '171 Patent.

VITRIVAX WAS ON NOTICE OF ITS INFRINGEMENT

65. On August 11, 2020, David Westberg, Plaintiff's CEO, sent an email to Robert Garcea of VitriVax to inform him of the '198 Patent and the '402 Patent and the fact that, based on the information in the Garcea Article, the Accused Products are made using the process

claimed in the '198 Patent and the '402 Patent, which would naturally mean that the Accused Products infringed those patents. A copy of the August 11, 2020 email and emails relating thereto is attached as Exhibit H.

66. This email communication was passed on to Matthew Raider, VitriVax's CEO, who replied on August 13, 2020, and the parties subsequently held a conference call. During that conference call, Mr. Raider stated, in sum and substance, that VitriVax was not worried about the '198 Patent or the '402 Patent, meaning that he understood that Plaintiff was asserting that VitriVax was practicing the '198 Patent and the '402 Patent without authorization, but that VitriVax was not worried about that issue. Plaintiffs' August 11, 2020 communication and VitriVax's response make clear that Vitrivax was aware of the '198 Patent and the '402 Patent, was aware that Plaintiff was asserting that VitriVax was practicing those patents without authorization, and that VitriVax had determined not to alter its conduct. As a result, Defendant has persisted in its infringements despite this knowledge, these communications, and being on notice.

COUNT I

(DIRECT INFRINGEMENT OF THE '198 PATENT)

67. Plaintiff incorporates by reference the preceding paragraphs as if set forth fully herein.

68. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§ 271, *et seq.*

69. Defendant makes, uses, offers to sell, sells, imports, promotes and/or demonstrates the Accused Products in the United States.

70. Defendant possesses knowledge of, and is aware of, the '198 patent.

71. Defendant has been and is now directly infringing, literally and/or under the doctrine of equivalents at least claim 14 of the ’198 patent.

72. Upon information and belief, Defendant intends to, and continues to intend to, directly infringe the ’198 Patent through making, using, offering to sell, selling, importing, promoting and/or demonstrating the Accused Products.

73. Defendant knew or should have known of the ’198 Patent and its infringement of the ’198 Patent, and has acted and continued to act, in an egregious and wanton manner by infringing the ’198 Patent in a willful manner.

74. Despite knowing that its actions constituted infringement of the ’198 Patent and/or despite knowing that there was a high likelihood that its actions constituted infringement of the patent, Defendant nevertheless continued its infringing actions, and continues to make, use, and/or sell the Accused Products.

75. Defendant’s acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

76. Defendant’s actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market.

77. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

COUNT II

(DIRECT INFRINGEMENT OF THE ’402 PATENT)

78. Plaintiff incorporates by reference the preceding paragraphs as if set forth fully herein.

79. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§ 271, *et seq.*

80. Defendant makes, uses, offers to sell, sells, imports, promotes and/or demonstrates the Accused Products in the United States.

81. Defendant possesses knowledge of, and is aware of, the ’402 patent.

82. Defendant has been and is now directly infringing, literally and/or under the doctrine of equivalents at least claim 15 of the ’402 patent.

83. Upon information and belief, Defendant intends to, and continues to intend to, directly infringe the ’402 Patent through making, using, offering to sell, selling, importing, promoting and/or demonstrating the Accused Products.

84. Defendant knew or should have known of the ’402 Patent and its infringement of the ’402 Patent, and has acted and continues to act, in an egregious and wanton manner by infringing the ’402 Patent in a willful manner.

85. Despite knowing that its actions constituted infringement of the ’402 Patent and/or despite knowing that there was a high likelihood that its actions constituted infringement of the patent, Defendant nevertheless continued its infringing actions, and continues to make, use, and/or sell, the Accused Products.

86. Defendant’s acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

87. Defendant’s actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market.

88. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

COUNT III

(DIRECT INFRINGEMENT OF THE '171 PATENT)

89. Plaintiff incorporates by reference the preceding paragraphs as if set forth fully herein.

90. This cause of action arises under the patent laws of the United States, and in particular, 35 U.S.C. §§ 271, *et seq.*

91. Defendant makes, uses, offers to sell, sells, imports, promotes and/or demonstrates the Accused Products in the United States.

92. Defendant has been and is now directly infringing, literally and/or under the doctrine of equivalents at least claim 15 of the '171 patent.

93. Upon information and belief, Defendant intends to, and continues to intend to, directly infringe the '171 Patent through making, using, offering to sell, selling, importing, promoting and/or demonstrating the Accused Products.

94. Despite knowing that there was a high likelihood that its actions constituted patent infringement, from a date not later than Defendant learning of the filing of the original Complaint, Defendant has nevertheless continued its infringing actions, and continues to make, use, and/or sell, the Accused Products.

95. Defendant's acts of infringement have injured and damaged Plaintiff and will continue to injure and damage Plaintiff.

96. Defendant's actions have caused Plaintiff to suffer irreparable harm resulting from the loss of its lawful patent rights and the loss of its ability to exclude others from the market.

97. Upon information and belief, Defendant will continue these infringing acts unless enjoined by this court.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury for all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter:

A. A judgment in favor of Plaintiff that Defendant has infringed the '198 Patent, the '402 Patent, and the '171 Patent;

B. An order of this Court permanently enjoining Defendant and its officers, directors, agents, affiliates, employees, divisions, branches, subsidiaries, parents, and all others in active concert therewith from infringing the '198 Patent, the '402 Patent, and the '171 Patent;

C. A judgment and order requiring Defendant to pay Plaintiff its damages, costs, expenses, and pre-judgment and post-judgment interest for Defendant's infringement of the '198 Patent, the '402 Patent, and the '171 Patent, as provided under 35 U.S.C. § 284;

D. A judgment and order requiring Defendant to pay treble damages as provided under 35 U.S.C. § 284;

E. A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285, and awarding to Plaintiff its reasonable attorneys' fees; and

F. Any and all other relief to which Plaintiff may show itself to be entitled and/or as the Court may deem just and proper.

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Dated: July 30, 2021

Respectfully submitted,

/s/ James H. S. Levine

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