

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION**



Epitopix, LLC d/b/a Vaxxinova US,)	
)	
Plaintiff,)	
)	
v.)	Cause No.
)	
Elanco Animal Health, Inc.,)	JURY TRIAL DEMANDED
)	
Defendant.)	

COMPLAINT

Plaintiff Epitopix, LLC d/b/a Vaxxinova US (“Plaintiff” or “Vaxxinova”), by its undersigned attorneys, for its complaint against Elanco Animal Health, Inc. (“Defendant” or “Elanco”), hereby states and alleges as follows:

The Parties

1. Vaxxinova is a limited liability company organized and existing under the laws of the State of Minnesota and has a principal place of business at 1801 Biotech Avenue NE, Willmar, Minnesota 56201. Vaxxinova is a wholly owned subsidiary of Vaxxinova International BV, a company organized and existing under the laws of The Netherlands.

2. Elanco is a corporation organized and existing under the laws of the State of Indiana and has a principal place of business at 2500 Innovation Way, Greenfield, Indiana 46140.

3. Upon information and belief, Elanco was originally a division of Eli Lilly and Company and later became a subsidiary of Eli Lilly and Company. Through the 2000s and 2010s, Elanco engaged in a series of acquisitions, including acquiring Lohmann Animal Health

and Novartis Animal Health in or about 2014-2015. In 2018, Elanco announced that it would go public and separate from Eli Lilly. In 2019, Elanco became a publicly traded company and was fully divested from Eli Lilly.

Jurisdiction

4. This is a claim of patent infringement arising under the Acts of Congress relating to patents, namely, 35 U.S.C. §§ 271, 281-285.

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

6. This Court has personal jurisdiction over Elanco because Elanco is incorporated in the State of Indiana and resides within this judicial district.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) because Elanco resides within, and has a physical place of business within, this judicial district.

Factual Background

8. Vaxxinova is a privately held animal health research and development company, specializing in the discovery and development of veterinary vaccines to improve animal health and food safety.

9. Vaxxinova began as the laboratory service division of Willmar Poultry Company (“WPC”) in Willmar, Minnesota. During the 1980s, in an effort to combat bacterial and viral infections and improve the health of its turkey breeding stock, WPC created a USDA-licensed vaccine laboratory and selected a premier team of scientists to pioneer novel vaccine technology. Through many years of research, the WPC (now Vaxxinova) team developed groundbreaking technology in the form of siderophore receptor protein (“SRP”) vaccines, which immunize against bacterial infections utilizing a cell-free purified extract of SRPs.

10. Epitopix, LLC was formed in 2002 to continue developing and commercialize SRP® technology, and to discover new vaccine technologies that improve animal health and human food safety. In 2018, Epitopix was acquired by Vaxxinova International to develop and distribute products in the United States. Vaxxinova continues its discovery and development today, to bring novel vaccine products to additional markets including livestock, poultry, and companion animals.

11. Vaxxinova's proprietary SRP® vaccines work by starving bacteria of iron, which is an essential element for bacterial growth and survival. To compete with the host animal for iron, bacteria utilize special transport proteins called siderophore receptors ("siderophore" comes from Greek, meaning "iron carrier") located on the outer surfaces of the bacterial cells. Siderophore receptors are a class of tube-shaped proteins called porins, which transport nutrients through the bacterial cell wall.

12. Many bacterial species have identical siderophore receptor proteins, even though the rest of their exterior structures are unique. Vaxxinova thus targeted SRPs for vaccine development because the commonality enables the production of a single vaccine that combats multiple types of bacteria.

13. Vaxxinova developed methods of extraction to harvest SRPs and porins from bacterial fermentations. Using these extracted proteins, Vaxxinova developed proprietary SRP extract compositions that form the core of Vaxxinova's SRP® vaccine technology. The vaccines work by generating an antibody mediated immune response in the host animal, whose immune cells then target any bacterial infection having the common SRPs used in the vaccine.

14. Additionally, Vaxxinova's SRP® technology includes processes to reduce the concentration of lipopolysaccharides, which are endotoxins present on the cell membranes of

bacteria. This reduction of endotoxins results in vaccines that are less likely to negatively impact the animals following vaccination.

15. Vaxxinova has protected its valuable SRP® vaccine technology through a robust family of patents. The U.S. Patent and Trademark Office (“USPTO”) has awarded Vaxxinova no fewer than 13 issued patents covering various aspects of Vaxxinova’s novel SRP® technology, which claim priority to provisional applications filed in January 2001. These issued patents include U.S. Patent Nos. 7,138,124; 7,138,125; 7,147,857; 7,341,732; 7,160,549; 7,371,393; 7,943,150; 7,943,151; 8,637,048; 8,282,941; 8,425,916; 8,575,315; and 8,993,252. Among this patent family are the patents at issue in this case, identified specifically below, although Vaxxinova believes that as it learns more about Elanco’s production methods there may be additional Vaxxinova patents that Elanco is infringing.

16. Vaxxinova is the owner by assignment of U.S. Patent No. 8,282,941, titled “Immunizing Compositions and Methods of Use” (“the ’941 Patent”), and has all rights to enforce and collect damages and remedies for infringement of the ’941 Patent. The ’941 Patent was duly issued by the U.S. Patent and Trademark Office on October 9, 2012 to inventors Daryll A. Emery and Darren E. Straub and assignee Eptopix, LLC and is in full force and effect. A true and correct copy of the ’941 Patent is attached hereto as **Exhibit A**.

17. Vaxxinova is the owner by assignment of U.S. Patent No. 7,943,150, titled “Immunizing Compositions and Methods of Use” (“the ’150 Patent”), and has all rights to enforce and collect damages and remedies for infringement of the ’150 Patent. The ’150 Patent was duly issued by the U.S. Patent and Trademark Office on May 17, 2011 to inventors Daryll A. Emery and Darren E. Straub and assignee Eptopix, LLC and is in full force and effect. A true and correct copy of the ’150 Patent is attached hereto as **Exhibit B**.

18. Vaxxinova is the owner by assignment of U.S. Patent No. 7,943,151, titled “Immunizing Compositions and Methods of Use” (“the ’151 Patent”), and has all rights to enforce and collect damages and remedies for infringement of the ’151 Patent. The ’151 Patent was duly issued by the U.S. Patent and Trademark Office on May 17, 2011 to inventors Daryll A. Emery and Darren E. Straub and assignee Epitopix, LLC and is in full force and effect. A true and correct copy of the ’151 Patent is attached hereto as **Exhibit C**.

19. Vaxxinova produces its own lines of vaccine products utilizing the SRP® technology that are the subject of the ’941, ’150, and ’151 Patents and related patents. These products include vaccines for cattle, poultry, and swine. Vaxxinova’s vaccines target bacteria such as *E. coli*, *Salmonella*, *Klebsiella*, and *Pasteurella*.

20. Over the years, Vaxxinova has discussed its proprietary SRP® technology with Elanco and Novartis Animal Health (subsequently acquired by Elanco, as set forth above). At various times between about 2005-2011, Elanco and Novartis Animal Health engaged in discussions with Epitopix concerning potential business opportunities relating to SRP® technology. Both Elanco and Novartis were aware of Vaxxinova’s SRP® patent portfolio (including the ’941, ’150, and ’151 patents) and applicability to Elanco’s products and methods.

21. For example, in June 2008, Vaxxinova shared with Elanco some of the SRP® patent portfolio, including patents in the same family as the patents-at-issue in this action.

22. Additionally, between about 2008-2010, Vaxxinova was engaged in active collaborative negotiations with Elanco, including disagreements about ownership of intellectual property rights. These negotiations ceased in or about May 2010.

23. Despite rebuffing any license or other business arrangement with Vaxxinova, Elanco proceeded to develop and acquire (through Novartis Animal Health) technology that infringes upon Vaxxinova's SRP® technology and patents.

24. Upon information and belief, Elanco's and Novartis Animal Health's unauthorized use of Vaxxinova's patented SRP® technology has been intentional and willful. Furthermore, as the successor in interest to Novartis Animal Health, Elanco is responsible for the wrongdoings of the acquired entity and all acquired infringing products and methods.

25. At present, Vaxxinova is aware of two Elanco products that infringe or are likely to infringe the patented SRP® technology. Vaxxinova has analyzed Elanco's Nuplura PH product and confirmed that it infringes one or more claims of at least the '941, '150, and '151 patents, as detailed below.

26. On or about March 4, 2021, Elanco announced the launch of a new product family called Nuplura PH+. This announcement came after Elanco had engaged in discussions with Vaxxinova concerning Vaxxinova's infringement allegations, and thus was with full knowledge of Vaxxinova's allegations and the asserted SRP® patents. Upon information and belief, Nuplura PH+ products infringe one or more claims of at least the '941, '150, and '151 patents for the same reasons identified below with respect to Nuplura PH.

27. As set forth in the claim charts below, Nuplura PH is representative of Elanco's infringing products. Nuplura PH contains at least two siderophore receptor polypeptides, at least two porins, and lipopolysaccharide concentration below that of the reference composition according to the claims of the '941, '150, and '151 Patents.

28. Elanco’s own marketing materials are consistent with Vaxxinova’s bases of infringement set forth herein. Non-limiting examples of Elanco’s marketing admissions are noted in the claim charts below.

29. The following is a claim chart detailing how Nuplura PH infringes at least claim 9 of the ’941 Patent:

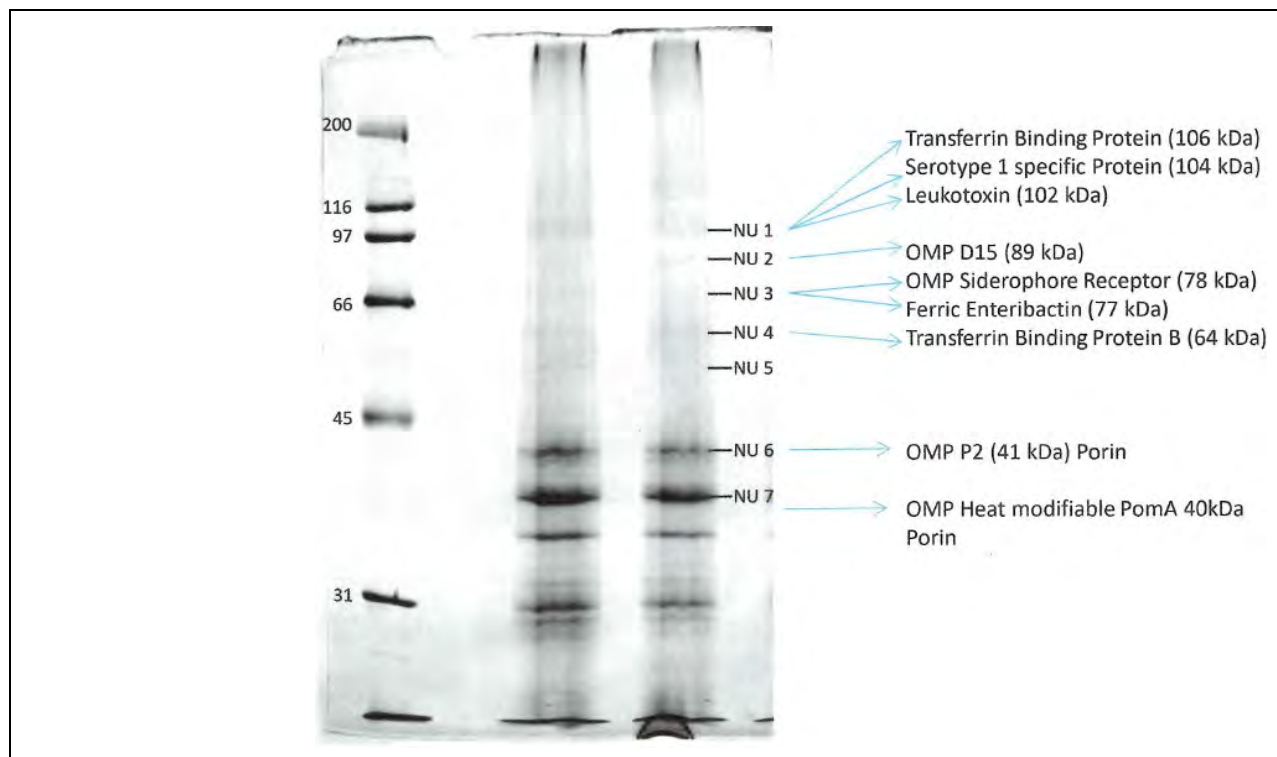
'941 Patent, Claim 9	NUPLURA PH
A siderophore receptor polypeptide (SRP) composition comprising:	NUPLURA PH is indicated “for use in healthy cattle, 3 months of age and older, as an aid in the prevention of respiratory disease caused by <i>M. haemolytica</i> .” As explained below, NUPLURA PH contains SRPs.
at least two SRPs isolated from a gram negative microbe; and	<p>The NUPLURA PH product label states that it “contains <i>Mannheimia haemolytica</i> Outer Membrane Proteins and recombinant leukotoxin.”</p> <p>NUPLURA PH contains at least two SRPs, confirmed by western blot analysis, as depicted in the following image of an SDS-PAGE gel run with a NUPLURA PH sample.</p>
<p>The image shows an SDS-PAGE gel with molecular weight markers on the left (200, 116, 97, 66, 45, 31 kDa) and seven lanes labeled NU 1 through NU 7. Arrows on the right point to specific bands in the lanes:</p> <ul style="list-style-type: none"> NU 1: Transferrin Binding Protein (106 kDa) NU 2: Serotype 1 specific Protein (104 kDa) NU 3: Leukotoxin (102 kDa) NU 4: OMP D15 (89 kDa) NU 5: OMP Siderophore Receptor (78 kDa) NU 6: Ferric Enteribactin (77 kDa) NU 7: Transferrin Binding Protein B (64 kDa) NU 7: OMP P2 (41 kDa) Porin NU 7: OMP Heat modifiable PomA 40kDa Porin 	

<p>lipopolysaccharide (LPS) at a concentration of no greater than the concentration of LPS in a reference composition comprising: the at least two siderophore receptor polypeptides isolated from the gram negative microbe and lipopolysaccharide; wherein the reference composition is produced by a process comprising:</p> <p>providing the gram negative microbe;</p> <p>disrupting the gram negative microbe in a buffer;</p> <p>solubilizing the disrupted gram negative microbe for greater than about 24 hours in a solution comprising sarcosine to result in solubilized and insoluble cellular material, wherein a ratio of the sarcosine to gram weight of disrupted gram negative microbe is between about 0.8 gram sarcosine per about 4.5 grams of disrupted gram negative microbe and about 1.2 grams sarcosine per about 4.5 grams of disrupted gram negative microbe; and</p> <p>isolating molecules of the gram negative microbe, wherein the isolated molecules comprise the at least two SRPs and LPS.</p>	<p>NUPLURA PH contains a reduced concentration of endotoxin compared to a reference sample produced according to the claimed method. Upon information and belief, the concentration of LPS in NUPLUA PH is nearly 1000 times lower than that of the claimed reference sample.</p> <p>According to Elanco’s “Tech Specs,” the “outer membrane proteins have been extracted and purified.” Elanco has publicized: “By using outer membrane proteins and not the complete cell wall, the volume of endotoxin is reduced”; and, “the extraction and purification processing of outer membrane proteins reduces the amount of endotoxin.” Additionally, Elanco scientists have stated that “the outer membrane proteins are extracted from the bacterial cell walls of a wild-type isolate using filtration processes.”</p>
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30. The following is a claim chart detailing how Nuplura PH infringes at least claim

23 of the ’150 Patent:

’150 Patent, Claim 23	NUPLURA PH
<p>A method for inducing the production of an antibody that specifically binds at least one SRP or at least one porin in an animal, the method comprising administering to an animal an effective amount of a composition comprising:</p>	<p>NUPLURA PH is indicated “for use in healthy cattle, 3 months of age and older, as an aid in the prevention of respiratory disease caused by <i>M. haemolytica</i>.” As explained below, NUPLURA PH induces antibody production for binding SRPs or porins.</p>
<p>at least two siderophore receptor polypeptides (SRPs) isolated from a gram negative microbe;</p>	<p>The NUPLURA PH product label states that it “contains <i>Mannheimia haemolytica</i> Outer Membrane Proteins and recombinant leukotoxoid.”</p>
<p>at least two porins isolated from the gram negative microbe;</p>	<p>NUPLURA PH contains at least two SRPs and at least two porins, confirmed by western blot analysis, as depicted in the following image of an SDS-PAGE gel run with a NUPLURA PH sample.</p>



lipopolysaccharide (LPS) at a concentration of no greater than the concentration of LPS in a reference composition comprising: the at least two siderophore receptor polypeptides isolated from the gram negative microbe and lipopolysaccharide; wherein the reference composition is produced by a process comprising:

- providing the gram negative microbe;
- disrupting the gram negative microbe in a buffer;
- solubilizing the disrupted gram negative microbe for greater than about 24 hours in a solution comprising sarcosine to result in solubilized and insoluble cellular material, wherein a ratio of the sarcosine to gram weight of disrupted gram negative microbe is between about 0.8 gram sarcosine per about 4.5 grams of disrupted gram negative microbe and about 1.2 grams sarcosine per about 4.5 grams of disrupted gram negative microbe; and
- isolating molecules of the gram negative microbe, wherein the isolated molecules comprise the at least two SRPs and LPS; and

a pharmaceutically acceptable carrier, wherein the composition induces in the animal antibody that specifically binds at least one SRP or at least one porin.

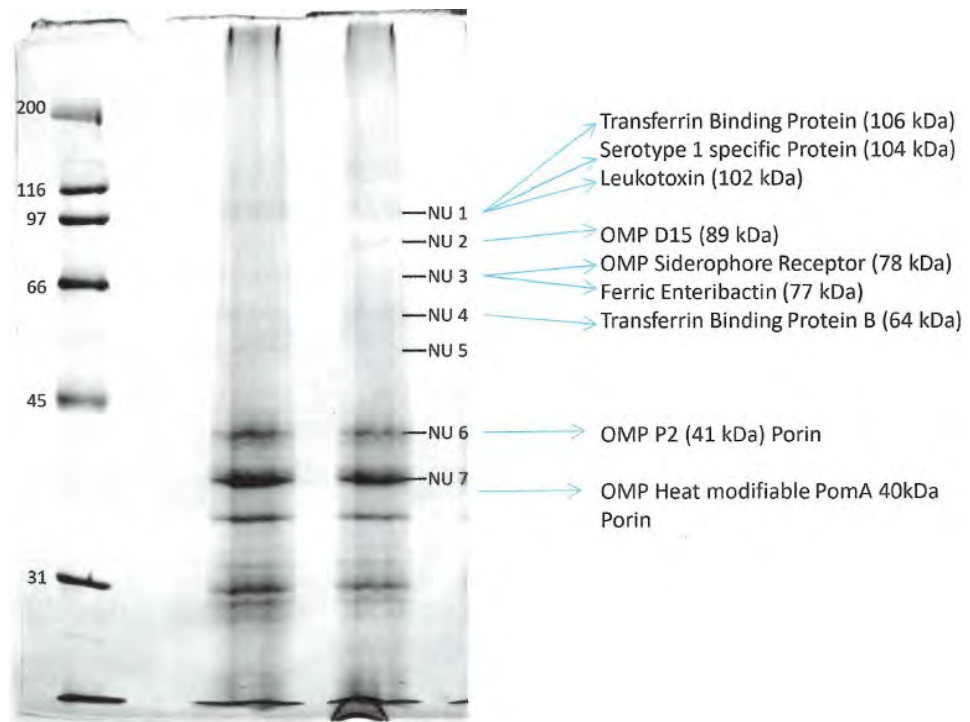
NUPLURA PH contains a reduced concentration of endotoxin compared to a reference sample produced according to the claimed method. Upon information and belief, the concentration of LPS in NUPLUA PH is nearly 1000 times lower than that of the claimed reference sample.

According to Elanco’s “Tech Specs,” the “outer membrane proteins have been extracted and purified.” Elanco has publicized: “By using outer membrane proteins and not the complete cell wall, the volume of endotoxin is reduced”; and, “the extraction and purification processing of outer membrane proteins reduces the amount of endotoxin.” Additionally, Elanco scientists have stated that “the outer membrane proteins are extracted from the bacterial cell walls of a wild-type isolate using filtration processes.”

NUPLURA PH is indicated for the vaccination of healthy cattle, 3 months of age and older, against respiratory disease caused by *M. haemolytica*. NUPLURA PH contains a pharmaceutically acceptable carrier suitable for subcutaneous administration. NUPLURA PH induces vaccinated cattle to produce antibodies that specifically bind at least one SRP or at least one porin.

31. The following is a claim chart detailing how Nuplura PH infringes at least claim 11 of the '151 Patent:

'151 Patent, Claim 11	NUPLURA PH
A method for inducing the production of an antibody that specifically binds at least one SRP in an animal, the method comprising administering to an animal an effective amount of a siderophore receptor polypeptide (SRP) composition comprising:	NUPLURA PH is indicated “for use in healthy cattle, 3 months of age and older, as an aid in the prevention of respiratory disease caused by <i>M. haemolytica</i> .” As explained below, NUPLURA PH contains SRPs and induces antibody production for binding SRPs.
at least two SRPs isolated from a gram negative microbe;	<p>The NUPLURA PH product label states that it “contains <i>Mannheimia haemolytica</i> Outer Membrane Proteins and recombinant leukotoxin.”</p> <p>NUPLURA PH contains at least two SRPs, confirmed by western blot analysis, as depicted in the following image of an SDS-PAGE gel run with a NUPLURA PH sample.</p>



<p>lipopolysaccharide (LPS) at a concentration of no greater than the concentration of LPS in a reference composition comprising: the at least two siderophore receptor polypeptides isolated from the gram negative microbe and lipopolysaccharide; wherein the reference composition is produced by a process comprising:</p> <p style="padding-left: 40px;">providing the gram negative microbe;</p> <p style="padding-left: 40px;">disrupting the gram negative microbe in a buffer;</p> <p style="padding-left: 40px;">solubilizing the disrupted gram negative microbe for greater than about 24 hours in a solution comprising sarcosine to result in solubilized and insoluble cellular material, wherein a ratio of the sarcosine to gram weight of disrupted gram negative microbe is between about 0.8 gram sarcosine per about 4.5 grams of disrupted gram negative microbe and about 1.2 grams sarcosine per about 4.5 grams of disrupted gram negative microbe; and</p> <p style="padding-left: 40px;">isolating molecules of the gram negative microbe, wherein the isolated molecules comprise the at least two SRPs and LPS; and</p>	<p>NUPLURA PH contains a reduced concentration of endotoxin compared to a reference sample produced according to the claimed method. Upon information and belief, the concentration of LPS in NUPLUA PH is nearly 1000 times lower than that of the claimed reference sample.</p> <p>According to Elanco’s “Tech Specs,” the “outer membrane proteins have been extracted and purified.” Elanco has publicized: “By using outer membrane proteins and not the complete cell wall, the volume of endotoxin is reduced”; and, “the extraction and purification processing of outer membrane proteins reduces the amount of endotoxin.” Additionally, Elanco scientists have stated that “the outer membrane proteins are extracted from the bacterial cell walls of a wild-type isolate using filtration processes.”</p>
<p>a pharmaceutically acceptable carrier, wherein the composition induces in the animal antibody that specifically binds at least one SRP.</p>	<p>NUPLURA PH is indicated for the vaccination of healthy cattle, 3 months of age and older, against respiratory disease caused by <i>M. haemolytica</i>. NUPLURA PH contains a pharmaceutically acceptable carrier suitable for subcutaneous administration. NUPLURA PH induces vaccinated cattle to produce antibodies that specifically bind at least one SRP.</p>

32. On or about December 23, 2020, Vaxxinova contacted Elanco concerning infringement of the '941, '150, and '151 Patents. The parties engaged in discussions; however, to date, Elanco has refused to cease its infringing activity.

33. Recently, on about March 4, 2021, Elanco announced the launch of a new product, Nuplura PH+.

34. Among other characteristics, Elanco advertises Nuplura PH+ as containing *Mannheimia haemolytica* outer membrane proteins and recombinant leukotoxoid, similar to Nuplura PH.

35. Upon information and belief, Nuplura PH+ contains outer membrane proteins, including at least two siderophore receptor polypeptides and at least two porins.

36. Upon information and belief, Nuplura PH+ is formulated and manufactured to have reduced endotoxin levels.

37. Upon information and belief, Nuplura PH+ has a lipopolysaccharide concentration below that of a reference composition as claimed in claim 9 of the '941 Patent, claim 23 of the '150 Patent, and claim 11 of the '151 Patent.

38. Vaxxinova has complied with the notice provision of the Patent Act, 35 U.S.C. § 287, including by listing its SRP® technology patents on Vaxxinova's website at <https://vaxxinova.us.com/patents/>.

COUNT I
Patent Infringement – U.S. Patent No. 8,282,941

39. Vaxxinova incorporates by reference the allegations of paragraphs 1-38 above as if fully set forth herein.

40. Elanco has made, used, sold, and offered for sale in the United States products that infringe each and every limitation of the '941 Patent. Specifically, as set forth above, Elanco's Nuplura PH product satisfies every limitation of at least Claim 9 of the '941 Patent. Additionally, upon information and belief, as set forth above, Elanco's Nuplura PH+ product satisfies every limitation of at least Claim 9 of the '941 Patent.

41. In particular, as set forth above and upon information and belief, Nuplura PH and Nuplura PH+ comprise: at least two SRPs, at least two porins, and an LPS concentration below that of the claimed reference composition.

42. Elanco has had actual knowledge of the '941 Patent since at least as early as December 23, 2020, when Vaxxinova contacted Elanco concerning its infringing products, thereby putting Elanco on notice of infringement pursuant to 35 U.S.C. § 287.

43. Upon information and belief, Elanco had actual knowledge of the '941 Patent prior to December 23, 2020. In particular, Vaxxinova believes that Elanco is and has been aware of Vaxxinova's SRP® technology and has been, or reasonably should have been, aware of Vaxxinova's patents covering its SRP® technology, including the '941 Patent.

44. Upon information and belief, Elanco had actual or constructive knowledge of the '941 Patent family and Vaxxinova's patented SRP® technology dating back to at least about 2008, based on Vaxxinova's discussion of its SRP® technology and related patent portfolio (including the '941 Patent) with Elanco and Elanco's predecessor in interest, Novartis Animal Health. Additionally, based on these prior disclosures, Elanco should reasonably have been aware of the '150 Patent upon its issuance in 2012.

45. Vaxxinova has been damaged, and will continue to be damaged, by Elanco's infringement of the '941 Patent.

46. Vaxxinova has suffered, and will continue to suffer, irreparable harm, unless Elanco is enjoined from infringing the '941 Patent.

COUNT II
Patent Infringement – U.S. Patent No. 7,943,150

47. Vaxxinova incorporates by reference the allegations of paragraphs 1-46 above as if fully set forth herein.

48. Elanco has made, used, sold, and offered for sale in the United States products that infringe each and every limitation of the '150 Patent. Specifically, as set forth above, Elanco's Nuplura PH product satisfies every limitation of at least Claim 23 of the '150 Patent.

Additionally, upon information and belief, as set forth above, Elanco's Nuplura PH+ product satisfies every limitation of at least Claim 23 of the '150 Patent.

49. In particular, as set forth above and upon information and belief, Nuplura PH and Nuplura PH+ comprise: at least two SRPs, at least two porins, and an LPS concentration below that of the claimed reference composition.

50. Elanco has had actual knowledge of the '150 Patent since at least as early as December 23, 2020, when Vaxxinova contacted Elanco concerning its infringing products, thereby putting Elanco on notice of infringement pursuant to 35 U.S.C. § 287.

51. Upon information and belief, Elanco had actual knowledge of the '150 Patent prior to December 23, 2020. In particular, Vaxxinova believes that Elanco is and has been aware of Vaxxinova's SRP® technology and has been, or reasonably should have been, aware of Vaxxinova's patents covering its SRP® technology, including the '150 Patent.

52. Upon information and belief, Elanco had actual or constructive knowledge of the '150 Patent family and Vaxxinova's patented SRP® technology dating back to at least about 2008, based on Vaxxinova's discussion of its SRP® technology and related patent portfolio (including the '150 Patent) with Elanco and Elanco's predecessor in interest, Novartis Animal Health. Additionally, based on these prior disclosures, Elanco should reasonably have been aware of the '150 Patent upon its issuance in 2009.

53. Vaxxinova has been damaged, and will continue to be damaged, by Elanco's infringement of the '150 Patent.

54. Vaxxinova has suffered, and will continue to suffer, irreparable harm, unless Elanco is enjoined from infringing the '150 Patent.

COUNT III
Patent Infringement – U.S. Patent No. 7,943,151

55. Vaxxinova incorporates by reference the allegations of paragraphs 1-54 above as if fully set forth herein.

56. Elanco has made, used, sold, and offered for sale in the United States products that infringe each and every limitation of the '151 Patent. Specifically, as set forth above, Elanco's Nuplura PH product satisfies every limitation of Claim 11 of the '151 Patent. Additionally, upon information and belief, as set forth above, Elanco's Nuplura PH+ product satisfies every limitation of Claim 11 of the '151 Patent.

57. In particular, as set forth above and upon information and belief, Nuplura PH and Nuplura PH+ comprise: at least two SRPs, at least two porins, and an LPS concentration below that of the claimed reference composition

58. Elanco has had actual knowledge of the '151 Patent since at least as early as December 23, 2020, when Vaxxinova contacted Elanco concerning its infringing products, thereby putting Elanco on notice of infringement pursuant to 35 U.S.C. § 287.

59. Upon information and belief, Elanco had actual knowledge of the '151 Patent prior to December 23, 2020. In particular, Vaxxinova believes that Elanco is and has been aware of Vaxxinova's SRP® technology and has been, or reasonably should have been, aware of Vaxxinova's patents covering its SRP® technology, including the '151 Patent.

60. Upon information and belief, Elanco had actual or constructive knowledge of the '151 Patent family and Vaxxinova's patented SRP® technology dating back to at least about 2008, based on Vaxxinova's discussion of its SRP® technology and related patent portfolio (including the '151 Patent) with Elanco and Elanco's predecessor in interest, Novartis Animal

Health. Additionally, based on these prior disclosures, Elanco should reasonably have been aware of the '151 Patent upon its issuance in 2011.

61. Vaxxinova has been damaged, and will continue to be damaged, by Elanco's infringement of the '151 Patent.

62. Vaxxinova has suffered, and will continue to suffer, irreparable harm, unless Elanco is enjoined from infringing the '151 Patent.

Prayer for Relief

WHEREFORE, Vaxxinova prays for the following relief:

A. A judgment that Elanco has directly infringed U.S. Patent Nos. 8,282,941, 7,943,150, and 7,943,151;

B. A preliminary and permanent injunction enjoining and restraining Elanco, its officers, directors, agents, employees, attorneys and all others acting under or through them, directly or indirectly, from infringing U.S. Patent Nos. 8,282,941, 7,943,150, and 7,943,151;

C. A judgment and order requiring Elanco to pay damages to Vaxxinova under 35 U.S.C. § 284, including treble damages for willful infringement, with interest;

D. A judgment and order directing Elanco to pay the costs of this action (including all disbursements) and attorney fees as provided by 35 U.S.C. § 285, with interest; and,

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

Demand for Jury Trial

Plaintiffs hereby demand a jury trial on all issues so triable.

Dated: March 24, 2021

Respectfully submitted,

FISHERBROYLES, LLP

/s Alastair J. Warr

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