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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

EPITOPIX, LLC d/b/a VAXXINOVA US, Plaintiff, v. ZOETIS INC., Defendant.	Case No. **2:23-cv-02467** **COMPLAINT FOR PATENT INFRINGEMENT** JURY TRIAL DEMANDED

Plaintiff Epitopix, LLC d/b/a Vaxxinova US, for its complaint against Defendant Zoetis Inc., hereby states and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement. Epitopix d/b/a Vaxxinova US is the owner of U.S. Patent No. 8,637,048 titled "Immunizing Compositions and Methods of Use," which issued on January 28, 2014. Zoetis has made, used, offered for sale, and sold in the United States multiple product lines that infringe the '048 patent. Some of the infringing products are believed to be legacy products from Pfizer Animal Health. Vaxxinova has at multiple times had commercial agreements

and negotiations with Pfizer and Zoetis about Vaxxinova's proprietary SRP® technology that is embodied in the '048 patent and other patents owned by Vaxxinova. Upon information and belief, Zoetis incorporated the technology it obtained from Vaxxinova, beyond the scope of any license rights, into products that infringe at least the '048 patent.

THE PARTIES

2. Epitopix, LLC d/b/a Vaxxinova US 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.

3. Zoetis Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 10 Sylvan Way, Parsippany, New Jersey 07054. Zoetis was formerly a subsidiary of Pfizer Inc. doing business under the name Pfizer Animal Health. Upon information and belief, Zoetis became an independent company in 2013.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction pursuant to 35 U.S.C. §§ 1331 and 1338(a), as this action arises under the Acts of Congress relating to patents, namely, 35 U.S.C. §§ 271, 281-285.

5. This Court has personal jurisdiction over Zoetis because Zoetis resides within this judicial district.

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

FACTUAL BACKGROUND

7. 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.

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. Vaxxinova has protected its valuable SRP® vaccine technology through a robust family of patents. The U.S. Patent and Trademark Office 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 is the patent at issue in this case, identified specifically below, although Vaxxinova believes that as it learns more about Zoetis' production methods there may be additional Vaxxinova patents that Zoetis is infringing.

15. Vaxxinova is the owner by assignment of U.S. Patent No. 8,637,048 to Emery, et al., titled "Immunizing Compositions and Methods of Use" ("the '048 patent"), and has all rights to enforce and collect damages and remedies for infringement of the '048 patent. The '048 Patent was duly issued by the U.S. Patent and Trademark Office on January 28, 2014, to inventors Daryll A. Emery and Darren E. Straub and assignee Epitopix, LLC. All applicable maintenance fees were paid for the '048 patent. The patent expired at the end of its term on or about January 3, 2022. A true and correct copy of the '048 Patent is attached hereto as **Exhibit A**.

16. Vaxxinova produces its own lines of vaccine products utilizing the SRP® technology that is the subject of the '048 patent 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*.

17. Over the years, Vaxxinova has discussed its proprietary SRP® technology with Zoetis and, formerly, Pfizer Animal Health. At various times

between about 2003-2019, Zoetis and Pfizer Animal Health engaged in discussions with Epitopix concerning potential business opportunities relating to SRP® technology. Both Zoetis and Pfizer Animal Health were aware of Vaxxinova's SRP® patent portfolio (including the '048 patent) and applicability to Zoetis' products and methods.

18. For example, in or about October 2003, Epitopix scientists met with Pfizer and even prepared a draft term sheet that would allow Pfizer to develop vaccines utilizing Epitopix's SRP® technology, including the technology in the same family as the '048 patent.

19. In 2004, Epitopix and Pfizer signed a confidentiality agreement to discuss Epitopix's SRP® technology, new product development, and a potential supply and marketing relationship.

20. In 2009, Pfizer regulatory and manufacturing representatives visited Epitopix to conduct full due diligence on Epitopix's SRP® technology. The parties drafted a non-binding term sheet and began drafting a commercialization and supply agreement. Pfizer requested, and Epitopix supplied, a full list of Epitopix's patents covering its SRP® technology, which includes the family from which the '048 patent issued.

21. In or about May 2010, Pfizer and Epitopix entered into a Development, Commercialization, and Supply Agreement, which provided Pfizer a limited license to use Epitopix's SRP® technology for two USDA-licensed products.

22. In or about April 2012, Pfizer conducted a full on-site audit of Epitopix's manufacturing of products incorporating SRP® technology.

23. In or about September 2012, the parties assigned on consent the Development, Commercialization, and Supply Agreement to Zoetis, following its spinoff from Pfizer.

24. In or about December 2015, the parties entered into a First Amendment to the Development, Commercialization, and Supply Agreement.

25. In or about December 2018, following Vaxxinova International's acquisition of Epitopix, the parties executed an Amended and Restated Development, Commercialization, and Supply Agreement related to Vaxxinova's SRP® technology.

26. The Development, Commercialization, and Supply Agreement terminated effective January 1, 2021.

27. At no time were the infringing products identified herein licensed to use the patented SRP® technology.

28. Despite prior commercialization and license agreements between the parties, Zoetis proceeded to use Vaxxinova's patented SRP® technology in new products beyond the scope of the limited commercialization rights.

29. Upon information and belief, Zoetis' actions include incorporating Vaxxinova's SRP® technology into existing product lines to improve their efficacy. At various times Zoetis has modified its promotional and regulatory literature to

tout improvements in its products, all temporally correlated with Zoetis' acquisition of Vaxxinova's SRP® technology.

30. For example, in or about February 2012, Zoetis (then Pfizer Animal Health) announced a re-launch of their *E. coli* J-5 bacterin (acquired from Upjohn) under the new name Enviracor® J-5. Zoetis' promotional literature stated that the J-5 master seed organism was requalified in a new efficacy study.

31. Thus, while Zoetis may have sold various products under the same brand names as those infringing products in this action, Zoetis' incorporation of the infringing SRP® technology post-dates Vaxxinova's patent rights.

32. Upon information and belief, Zoetis' unauthorized use of Vaxxinova's patented SRP® technology has been intentional and willful.

33. At present, Vaxxinova is aware of five Zoetis product lines that infringe the patented SRP® technology: One Shot®; Poulvac® E. coli; Poulvac® ST; Somubac®; and Enviracor J-5. Vaxxinova has analyzed Zoetis' products in each of these product lines and confirmed infringement of one or more claims of the '048 patent, as exemplified below.

34. The following is a claim chart illustrating how Zoetis' One Shot® products infringe at least claim 4 of the '048 patent.

'048 Patent, Claim 4	**One Shot®**
A composition comprising: an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:	One Shot® is a whole cell bacterin of *Mannheimia haemolytica*, which is a gram negative microbe.

at least two siderophore receptor polypeptides (SRPs) expressed by the gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl; and	One Shot® includes at least the following SRPs: Transferrin Binding Protein TbpA (106 kDa) Hemoglobin Receptor Protein (93kDa) OMR Hemoglobin Receptor Protein (79kDa) Outer Membrane Siderophore Receptor (78kDa) Ferric Enterobactin Receptor Protein (77kDa)
at least two porins; and	One Shot® includes at least the following porins: OMP P2 (41kDa) OMP Heat Modifiable PomA (40 kDa)
a pharmaceutically acceptable carrier.	One Shot® is prepared in a formulation for administration to animals which includes a pharmaceutically acceptable carrier.

35. The following is a claim chart illustrating how Zoetis' Poulvac® E. coli products infringe at least claim 4 of the '048 patent.

'048 Patent, Claim 4	**Poulvac® E. coli**
A composition comprising: an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:	Poulvac® E. coli is an Aro-A deletion modified live vaccine (whole cell) of *Escherichia coli*, which is a gram negative microbe.
at least two siderophore receptor polypeptides (SRPs) expressed by the gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl; and	Poulvac® E. coli includes at least the following SRPs: Ferrienterobactin receptor protein (FepA) (82 kDa)

	Catecholate siderophore receptor protein (Fiu) (82 kDa) Fe(3+) dicitrate transport protein (FecA) (85 kDa) TonB-dependent receptor (YncD) (77 kDa) Ferrichrome outer membrane receptor protein (FhuA) (82 kDa)
at least two porins; and	Poulvac® E. coli includes at least the following porins: OMP A (37 kDa) OMP C (41 kDa)
a pharmaceutically acceptable carrier.	Poulvac® E. coli is prepared in a formulation for administration to animals which includes a pharmaceutically acceptable carrier.

36. The following is a claim chart illustrating how Zoetis' Poulvac® ST products infringe at least claim 4 of the '048 patent.

'048 Patent, Claim 4	**Poulvac® ST**
A composition comprising: an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:	Poulvac® ST is an Aro-A modified live vaccine (whole cell) of *Salmonella typhimurium*, which is a gram negative microbe.
at least two siderophore receptor polypeptides (SRPs) expressed by the gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl; and	Poulvac® ST includes at least the following SRPs: FepA (82.1 kDa) FhuA (82.2 kDa) CirA (73.9 kDa)
at least two porins; and	Poulvac® ST includes at least the following porins:

	OMP D (39.7 kDa) OMP A (37.5 kDa)
a pharmaceutically acceptable carrier.	Poulvac® ST is prepared in a formulation for administration to animals which includes a pharmaceutically acceptable carrier.

37. The following is a claim chart illustrating how Zoetis' Somubac® products infringe at least claim 4 of the '048 patent.

'048 Patent, Claim 4	**Somubac®**
A composition comprising: an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:	Somubac® is a whole cell bacterin of *Haemophilus somnus*, which is a gram negative microbe.
at least two siderophore receptor polypeptides (SRPs) expressed by the gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl; and	Somubac® includes at least the following SRPs: Iron-regulated outer membrane protein (FrpB) (76 kDa) Iron-dicitrate transporter binding Protein (FecB) (34 kDa) TonB-dependent lactoferrin and transferrin protein (85kDa) Iron-sulfur binding protein (52 kDa) TonB-dependent receptor protein (83 kDa)
at least two porins; and	Somubac® includes at least the following porins: Major outer membrane protein (41 kDa) Outer membrane efflux protein (51 kDa) Magnesium/cobalt efflux protein (34 kDa)

	Outer membrane-stress sensor protein 37 kDa Iron-sulfur cluster carrier protein (40 kDa)
a pharmaceutically acceptable carrier.	Somubac® is prepared in a formulation for administration to animals which includes a pharmaceutically acceptable carrier.

38. The following is a claim chart illustrating how Zoetis' Enviracor® J-5 products infringe at least claim 4 of the '048 patent.

'048 Patent, Claim 4	**Enviracor® J-5**
A composition comprising: an isolated whole cell preparation of gram negative microbes, wherein the gram negative microbes comprise:	Enviracor® J-5 is a whole cell bacterin of *Escherichia coli* mutant, which is a gram negative microbe.
at least two siderophore receptor polypeptides (SRPs) expressed by the gram negative microbe when the gram negative microbe is grown in the presence of 2,2-dipyridyl; and	Enviracor® J-5 includes at least the following SRPs: FhuA (82.2 kDa) Fiu (82.0 kDa) FhuE (81.2 kDa) CirA (73.9 kDa)
at least two porins; and	Enviracor® J-5 includes at least the following porins: OmpC (40.5 kDa) OmpA (37.2 kDa)
a pharmaceutically acceptable carrier.	Enviracor® J-5 is prepared in a formulation for administration to animals which includes a pharmaceutically acceptable carrier.

39. 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/ (last visited May 4, 2023).

40. Vaxxinova notified Zoetis of its infringement via letter dated November 29, 2022. Thereafter, the parties engaged in preliminary discussions concerning this matter. Zoetis and Vaxxinova entered into a tolling agreement effective January 24, 2023. Zoetis has ceased further discussions with Vaxxinova, necessitating this lawsuit.

COUNT I
Infringement of U.S. Patent No. 8,637,048

41. Vaxxinova incorporates by reference the allegations in the preceding paragraphs.

42. Zoetis has made, used, offered for sale, and sold in the United States products that infringe every limitation of one or more claims of the '048 patent.

43. As set forth above, Zoetis' One Shot® products satisfy every limitation of at least claim 4 of the '048 patent. In particular, the One Shot® products comprise an isolated whole cell preparation of gram negative microbes, wherein the microbes comprise at least two SRPs when grown under iron restriction and at least two porins, and a pharmaceutically acceptable carrier.

44. As set forth above, Zoetis' Poulvac® E. coli product satisfies every limitation of at least claim 4 of the '048 patent. In particular, the Poulvac® E. coli products comprise an isolated whole cell preparation of gram negative microbes,

wherein the microbes comprise at least two SRPs when grown under iron restriction and at least two porins, and a pharmaceutically acceptable carrier.

45. As set forth above, Zoetis' Poulvac® ST product satisfies every limitation of at least claim 4 of the '048 patent. In particular, the Poulvac® ST products comprise an isolated whole cell preparation of gram negative microbes, wherein the microbes comprise at least two SRPs when grown under iron restriction and at least two porins, and a pharmaceutically acceptable carrier.

46. As set forth above, Zoetis' Somubac® product satisfies every limitation of at least claim 4 of the '048 patent. In particular, the Somubac® products comprise an isolated whole cell preparation of gram negative microbes, wherein the microbes comprise at least two SRPs when grown under iron restriction and at least two porins, and a pharmaceutically acceptable carrier.

47. As set forth above, Zoetis' Enviracor® J-5 product satisfies every limitation of at least claim 4 of the '048 patent. In particular, the Enviracor® J-5 products comprise an isolated whole cell preparation of gram negative microbes, wherein the microbes comprise at least two SRPs when grown under iron restriction and at least two porins, and a pharmaceutically acceptable carrier.

48. Zoetis has had actual knowledge of the '048 patent, and Vaxxinova's SRP® technology in general, since at least as early as the issue date of the '048 patent through Zoetis' former commercial and patent licensing relationship with Vaxxinova. Upon information and belief, Zoetis had actual knowledge of the '048 patent through these prior relationships. Vaxxinova believes that Zoetis 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 '048 patent.

49. Zoetis has had constructive knowledge of the '048 patent through Vaxxinova's compliance with the notice provision of the Patent Act, 35 U.S.C. § 287.

50. Vaxxinova has been damaged by Zoetis' infringement of the '048 patent.

PRAYER FOR RELIEF

Vaxxinova respectfully requests that the Court award the following relief:

A. Entry of judgment in favor of Vaxxinova and against Zoetis that Zoetis has infringed U.S. Patent No. 8,637,048;

B. An award to Vaxxinova of damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by Zoetis, together with interest and costs as fixed by the court, pursuant to 35 U.S.C. § 284;

C. An order directing Zoetis to pay Vaxxinova its reasonable attorney fees in connection with this action pursuant to 35 U.S.C. § 285; and,

D. Such other and further relief as the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all issues so triable.

Respectfully submitted,

FISHERBROYLES, LLP

Dated: May 4, 2023

By: *s/ Christopher R. Kinkade*

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LOCAL CIVIL RULE 11.2 VERIFICATION

The undersigned hereby certifies that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Respectfully submitted,

Dated: May 4, 2023

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