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 Epitopix, 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 Epitopix, 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.

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