

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF CONNECTICUT

BOEHRINGER INGELHEIM VETMEDICA, INC.,

Plaintiff,

v.

MERIAL, LTD. and  
PROTEIN SCIENCES CORPORATION

Defendants.

CIVIL ACTION NO.

**COMPLAINT FOR DECLARATORY JUDGMENT**

Plaintiff, Boehringer Ingelheim Vetmedica, Inc. (“Vetmedica”), hereby brings this action for declaratory judgment against Merial Limited (“Merial”) and Protein Sciences Corporation (“Protein Sciences”) and states as follows:

**PARTIES**

1. Vetmedica is a corporation organized and existing under the laws of the State of Delaware and maintains its headquarters at 2621 North Belt Highway, St. Joseph, Missouri. Vetmedica is currently the defendant in an action by Merial which is actively pending in the Middle District of Georgia, Athens Division, Civil Case No. 3:08-cv-116 (CDL).

2. On information and belief, Defendant Merial Limited is a company of limited shares registered in England and Wales, with a registered office in England, and is incorporated under the laws of the state of Delaware as Merial LLC. On information and belief, Merial’s North America Operational Headquarters is located at 3239 Satellite Boulevard, Duluth, Georgia. On information and belief, Merial Limited also sells and/or offers for sale veterinary pharmaceuticals or vaccines in this judicial district.

3. On information and belief, Defendant Protein Sciences Corporation is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 1000 Research Parkway, Meriden, Connecticut. On information and belief, Protein Sciences also sells and/or offers for sale the *expresSF+*<sup>®</sup> insect cell line and other veterinary research products in this judicial district.

### NATURE OF ACTION

4. This is a declaratory judgment action seeking a determination that Vetmedica has a license under a September 1, 2004 License Agreement between Vetmedica and Protein Sciences (“the 2004 License”) to practice the claims of U.S. Patent No. 6,224,882 (“the ’882 Patent”) insofar as required to make, use, sell and/or offer to sell Vetmedica’s INGELVAC<sup>®</sup> CircoFLEX<sup>®</sup> and INGELVAC<sup>®</sup> CircoFLEX–MycoFLEX<sup>™</sup> Combo Pack (collectively “Vetmedica’s CircoFLEX<sup>®</sup> Products”), and thereby does not infringe. A true and correct copy of the 2004 License, with confidential financial terms redacted, is attached hereto as Exhibit A. A true and correct copy of the ’882 Patent is attached hereto as Exhibit B.

5. In the alternative, this is a declaratory judgment action seeking a determination that the manufacture, importation, use, offer for sale, and/or sale of Vetmedica’s CircoFLEX<sup>®</sup> Products do not infringe any valid and enforceable claim of the ’882 Patent under 35 U.S.C. § 271 and that the claims of the ’882 Patent are invalid under 35 U.S.C. §§ 101 *et seq.*

### JURISDICTION AND VENUE

6. This action for declaratory judgment arises under Title 35 of the United States Code with a specific remedy sought based upon laws authorizing actions for declaratory judgment in the courts of the United States, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction over the claims in this action, which arises under the patent laws of the United States, pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201. In addition, the Court has supplemental subject matter jurisdiction over the claims in this action which arise under state law, under 28 U.S.C. § 1367, because those claims are so related to the claims brought under the patent laws of the United States.

8. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391(b) and (c). On information and belief, Merial has conducted continuous and systematic commercial activity in this judicial district. In addition, on information and belief, Protein Sciences is a resident of this judicial district.

### **BACKGROUND**

9. Vetmedica's CircoFLEX<sup>®</sup> Products are vaccines against Porcine Circovirus, which is associated with post-weaning multisystemic wasting syndrome ("PMWS") in pigs. PMWS normally affects piglets between 6 and 14 weeks of age and is considered to be one of the most significant problems of the last decade affecting feeder pigs, which are raised for human consumption. Effects of PMWS include chronic wasting, skin lesions, respiratory difficulties, diarrhea, poor coordination, and jaundice. There is no effective treatment for the virus, once contracted, and mortality rates are high. As a result, the economic consequences of PMWS to swine producers can be severe.

10. Vetmedica is part of the Boehringer Ingelheim group of companies. Vetmedica serves food-producing and companion animals and has become a center of biological research, development, and manufacturing for the animal health business. Vetmedica has developed a vaccine, the INGELVAC<sup>®</sup> CircoFLEX<sup>®</sup> vaccine product, which can be used to immunize pigs against PMWS. In addition, Vetmedica markets this vaccine in a INGELVAC<sup>®</sup> CircoFLEX-

MycoFlex™ Combo Pack, which can be used to simultaneously immunize pigs against PMWS and another major swine disease caused by *Mycoplasma hyopneumoniae*, which is a species of bacteria known to cause the disease Porcine Enzootic Pneumonia, a highly contagious and chronic disease affecting pigs.

11. In September 2004, Protein Sciences and Vetmedica entered into the 2004 License, by which Vetmedica is licensed to use the *expresSF+*® insect cell line, ostensibly covered by the claims of U.S. Patent No. 6,103,526 (“the ’526 Patent”), to develop, manufacture, use, sell and/or offer for sale Porcine Circovirus vaccine products, such as Vetmedica’s CircoFLEX® Products. *See* Exhibit A at 2, 8.

12. On information and belief, in 2004 Protein Sciences owned the ’526 Patent and the ’882 Patent. A true copy of the ’526 Patent is attached as Exhibit C.

13. On information and belief, the ’526 Patent issued on August 15, 2000 and is entitled “*Spodoptera Frugiperda* Single Cell Suspension Cell Line In Serum-Free Media, Methods Of Producing And Using.”

14. The 2004 License grants Vetmedica a license to use the purported inventions claimed in the ’882 Patent to the extent required to develop, manufacture, use and/or sell Porcine Circovirus vaccine products, such as Vetmedica’s CircoFLEX® Products, using the *expresSF+*® insect cell line ostensibly covered by the claims of the ’526 patent. *See* Exhibit A at 2, 8.

15. On information and belief, the ’882 Patent issued on May 1, 2001 and is entitled “*Insect Cell or Fractions as Adjuvant for Antigens.*”

16. On information and belief, the purported inventions claimed in the ’882 Patent were made by Gale Eugene Smith, of Wallingford, Connecticut; James DeBartolomeis, of Madison, Connecticut; and Andre Igorevitch Voznesenski, of West Hartford, Connecticut.

17. On information and belief, the named inventors of the '882 Patent assigned the rights to their purported invention to Protein Sciences of Meridien, Connecticut.

18. Pursuant to the 2004 License, Vetmedica developed, manufactured, used, sold and/or offered for sale Vetmedica's CircoFLEX<sup>®</sup> Products developed using the *expresSF+*<sup>®</sup> insect cell line ostensibly covered by the claims of the '526 Patent.

19. The 2004 License contains a provision that: "Any disputes, controversies or claims which arise under, out of, in connection with, or relating to this Agreement shall be governed by and interpreted in accordance with the laws of the State of Connecticut, without regard to choice of law, and the parties agree that all disputes, controversies or claims which arise under, out of, in connection with, or relating to this Agreement shall be brought in the Courts situated in the State of Connecticut for the resolution thereof, and the parties therefore submit to the exclusive jurisdiction of the State and Federal Courts situated in the State of Connecticut for resolution of all disputes, controversies or claims which arise under, out of, in connection with, or relating to, this Agreement." *See* Exhibit A at 6.

20. The 2004 License states that it "shall extend to and be binding upon the successors and legal representatives and assigns of LICENSOR." *See* Exhibit A at 4.

21. On or about October 2006, the U.S. Animal and Plant Health Inspection Service approved Vetmedica's marketing of the INGELVAC<sup>®</sup> CircoFLEX<sup>®</sup> vaccine product to protect pigs against Porcine Circovirus.

22. On or about August 2008, the U.S. Animal and Plant Health Inspection Service approved Vetmedica's marketing of the INGELVAC<sup>®</sup> CircoFLEX-MycoFlex<sup>™</sup> Combo Pack to protect pigs against both Porcine Circovirus and *Mycoplasma hyopneumoniae*.

23. On information and belief, on December 3, 2008, Merial recorded with the U.S. Patent and Trademark Office an assignment of rights to the '882 Patent from Protein Sciences, which is located at Reel 021912 and Frame 0488.

#### **EXISTENCE OF AN ACTUAL CONTROVERSY**

24. There is an actual and justiciable controversy between Vetmedica and Merial regarding whether the manufacture, use, sale and/or offer for sale of Vetmedica's CircoFLEX<sup>®</sup> Products infringes one or more claims of the '882 Patent. There is also an actual and justiciable controversy between Vetmedica and Protein Sciences regarding whether Vetmedica has a license to practice the claims of the '882 Patent insofar as required to make, use, sell and/or offer for sale Vetmedica's CircoFLEX<sup>®</sup> Products, and therefore, does not infringe one or more claims of the '882 Patent.

25. On December 8, 2008, Merial filed a Complaint for Patent Infringement against Vetmedica in the United States District Court for the Middle District of Georgia (3:08-cv-116), alleging that Vetmedica infringes, contributes to infringement of, and/or induces infringement of one or more claims of the '882 Patent by making, using, selling, and/or offering to sell Vetmedica's CircoFLEX<sup>®</sup> Products. In addition, Merial alleged that this infringement has been willful and requested injunctive relief. A true and correct copy of the complaint filed by Merial is attached as Exhibit D.

26. Vetmedica denies infringement of the '882 Patent and asserts as a defense that Vetmedica has a license to practice the claims of the '882 Patent insofar as is required to develop, manufacture, use and/or sell a Porcine Circovirus vaccine using the *expresSF+*<sup>®</sup> insect cell line ostensibly covered by the claims of the '526 Patent. In the alternative, Vetmedica

denies infringement of any valid and enforceable claim of the '882 Patent and asserts that the claims of the '882 Patent are invalid.

27. Concurrent with the filing of this Complaint for Declaratory Judgment, Vetmedica is filing a motion in the District Court for the Middle District of Georgia, requesting transfer of the litigation filed by Merial to the United States District Court for the District of Connecticut.

**FIRST COUNT**

**DECLARATORY JUDGMENT OF LICENSE TO PRACTICE THE '882 PATENT**

28. Vetmedica hereby restates and realleges the allegations set forth in paragraphs 1 through 27 above and incorporates them by reference.

29. Any use of the technology purportedly claimed in the '882 Patent during the manufacture, use, sale and/or offer for sale of Vetmedica's CircoFLEX® Products by Vetmedica or Vetmedica's customers or affiliates is licensed under the 2004 License.

**SECOND COUNT**

**DECLARATORY JUDGMENT OF PATENT NONINFRINGEMENT**

30. Vetmedica hereby restates and realleges the allegations set forth in paragraphs 1 through 29 above and incorporates them by reference.

31. In the alternative, Vetmedica has not at any time infringed, induced others to infringe, and/or committed acts of contributory infringement of any of the claims of the '882 Patent either literally or under the doctrine of equivalents.

### THIRD COUNT

#### DECLARATORY JUDGMENT OF PATENT INVALIDITY

32. Vetmedica hereby restates and realleges the allegations set forth in paragraphs 1 through 31 above and incorporates them by reference.

33. The claims of the '882 Patent are invalid because the claimed invention does not satisfy the requirements for patentability under Title 35 of the United States Code, including without limitation 35 U.S.C. §§ 101 *et seq.*

#### PRAYER FOR RELIEF

WHEREFORE, Vetmedica requests that the Court enter judgment:

(a) Declaring that any use of the technology claimed in the '882 Patent during the manufacture, use sale and/or offer for sale of Vetmedica's CircoFLEX<sup>®</sup> Products by Vetmedica or Vetmedica's customers or affiliates, is licensed under the 2004 License;

(b) In the alternative, declaring that Plaintiff Vetmedica does not infringe any claim of the '882 Patent;

(c) Declaring invalid the claims of the '882 Patent;

(d) Finding that, pursuant to 35 U.S.C. § 285 and/or other applicable laws, Merial's conduct renders this an exceptional case and that Vetmedica be awarded costs of the action and its attorneys' fees to the extent permitted by law;

(e) Finding that, pursuant to 35 U.S.C. § 285 and/or other applicable laws, Protein Sciences' conduct renders this an exceptional case and that Vetmedica be awarded costs of the action and its attorneys' fees to the extent permitted by law; and

(f) Granting such other and further relief as the Court deems just and proper.

Dated: February 4, 2009

Respectfully submitted,

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