IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF KANSAS

BIOMUNE COMPANY Declaratory Judgment Plaintiff, v. MERIAL LIMITED and MERIAL LLC, Declaratory Judgment Defendants.	Civil Action No. _____ **Jury trial not requested** **Place of trial: Kansas City**

COMPLAINT

Biomune Company, Inc. ("Biomune" or "Plaintiff") submits this Complaint for Declaratory Judgment of patent invalidity and noninfringement against Merial Limited and Merial LLC (collectively "Merial" or "Defendants"). Specifically, Biomune seeks a declaration that the manufacture, importation, use, offer for sale, or sale of Biomune's Porcine Circovirus Vaccine, Type-2, Killed Virus-Mycoplasma Hyopneumonia Bacterin (referred to here as Biomune's "Vaccine") does not infringe any valid claim of Merial's U.S. Patent Nos. 6,660,272 ("the '272" patent") and 7,122,192 ("the '192 patent") (collectively, the "patents in suit"), and that the claims of those patents are invalid under the patent laws. Biomune's Vaccine is one of the foundational pieces of the company's development of a swine immunology and vaccine business in the United States. Biomune will build on this product to research and develop additional products for the swine industry, as well as other food animal and companion animal industries. For this reason, Biomune's Vaccine is critical to the company's continued investment in growing its U.S. business. Biomune alleges as follows:

THE PARTIES

1. Biomune is a company involved in, *inter alia*, the research and development of products that aid in preventing and treating diseases of food-producing animals, including diseases of swine, and is a leading manufacturer of animal vaccines in the United States. Biomune is organized under the laws of the state of Delaware and has its principal place of business at 8906 Rosehill Road, Lenexa, Kansas 66215. Biomune is part of the Kansas City Animal Health Corridor business development effort, and employs 268 workers in Kansas, including scientists, researchers and technicians.

2. Biomune is a wholly-owned subsidiary of Ceva Santé Animale S.A., a veterinary pharmaceutical company organized under the laws of France that researches, develops, manufactures and markets pharmaceutical products and vaccines for companion and food production animals, including products for swine. Biomune's Vaccine is a product of research and development conducted by scientists employed in Biomune's Kansas facility and Ceva Santé Animale's European facilities.

3. On information and belief, Defendant Merial Limited is a company limited by shares registered in England and Wales. For the purposes of doing business in the U.S., Merial Limited has domesticated itself as a limited liability company in the state of Delaware under the name Merial LLC. Merial Limited has its North American headquarters at 3239 Satellite Boulevard, Building 500, Duluth, Georgia 30096. Merial Limited is a multi-billion dollar company that makes and sells animal health products.

4. On information and belief, Merial LLC, the U.S. arm of Merial Limited, is a limited liability company organized under the laws of Delaware that has its principal office at 1209 Orange Street Wilmington, Delaware.

5. On information and belief, Merial LLC has a registered office in Kansas at The Corporation Company, Inc., 515 S. Kansas Avenue, Topeka, Kansas 66603. Merial LLC submitted an application for authority to transact business in Kansas on or about December 18, 1997. In that application, Merial irrevocably submitted to personal jurisdiction in this district pursuant to K.S.A. § 17-7301(b)(7) and described the nature of its business as "Research, Development, Manufacture, Sales and Marketing of Animal Health and Poultry Genetics Products."

THE PATENTS AT ISSUE

6. Merial's '192 patent indicates that it was issued by the United States Patent and Trademark Office on October 17, 2006. The '192 patent is entitled "Porcine Circoviruses, Vaccines, and Diagnostic Reagents," and it includes claims to compositions containing, *inter alia*, PCV-2 virus. On information and belief, the '192 patent is owned by Merial SAS, which is a simplified joint-stock company having its principal place of business at 29 Avenue Tony Garnier 69007, Lyon, France. Merial SAS is identified as the assignee on the face of the '192 patent. A copy of the '192 patent is attached as Exhibit A.

7. Merial's '272 patent indicates that it was issued by the Patent Office on December 9, 2003. The '272 patent is also entitled "Porcine Circoviruses, Vaccines, and Diagnostic Reagents," and it contains claims to isolated porcine circoviruses and compositions containing, *inter alia*, porcine circoviruses. The '272 patent is assigned on its face to Merial, The Queen's University of Belfast, and the University of Saskatchewan. On information and belief, the Queen's University of Belfast and University of Saskatchewan assigned their rights in the '272 patent to Merial SAS; thus, Merial SAS owns the '272 patent. A copy of the '272 patent is attached as Exhibit B.

8. On information and belief, the owner of the patents—Merial SAS—has granted Merial Limited an irrevocable, exclusive, worldwide right and license to the '192 and '272 patents. The license grants Merial Limited the right to conduct any and all activities with respect to the patents, including the right to bring suit for patent infringement and the right to settle disputes regarding the patents in any proceeding at Merial Limited's sole discretion. On information and belief, Merial Limited and its U.S. arm Merial LLC own all substantial rights in the '192 and '272 patents.

JURISDICTION

9. This Court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202, as this declaratory judgment action raises a case of actual controversy arising under the patent laws of the United States (35 U.S.C. § 1, *et seq.*).

10. On August 31, 2012, Biomune submitted an application to the USDA for approval of its Vaccine. The application was filed pursuant to the Act of Congress approved 1913, 21 U.S.C. §§ 151-158.

11. Biomune's Vaccine is a combination vaccine that combines an "inactivated," i.e., killed, vaccine against PCV-2 with a bacterial vaccine (a "bacterin") against an organism known as *Mycoplasma hyopneumonia*, or "*M. hyo*." PCV-2 and *M. hyo* are two of the most prevalent and important pathogenic organisms found in pigs. PCV-2 is associated with a number of disease syndromes in pigs, which are collectively referred to as "Porcine Circovirus Associated Disease" (PCVAD). Among other possible signs of illness, PCVAD pigs commonly exhibit difficulty breathing and wasting, i.e., losing weight or exhibiting poor growth. *M. hyo* causes the respiratory disease Porcine Enzootic Pneumonia in pigs of similar age to those affected by PCV-2, and the two organisms are commonly found together in affected herds. Losses from these

organisms result both from dying pigs and the failure of the pigs to thrive and gain weight efficiently; these losses cause tremendous economic hardship to farmers and other members of the pork industry.

12. Even though Biomune does not yet have USDA approval to manufacture or market its Vaccine, by statute, the submission of an application to the USDA for a license to market a veterinary biological product under 21 U.S.C. §§ 151-158 is a technical act of patent infringement. *See* 35 U.S.C. § 271(e)(2)(B). On information and belief, Merial will allege that Biomune's Vaccine and the use of the Vaccine are covered by the '192 and '272 patents, and that the submission of Biomune's application to the USDA is a technical act of patent infringement.

13. Moreover, Biomune has taken concrete steps in Kansas to enter the vaccine market. Biomune spent years planning and developing its Vaccine before submitting its application to the United States Department of Agriculture for a license to market the product in the United States on August 31, 2012. Since that time Biomune's staff in Kansas has diligently worked conducting the trials necessary to obtain approval.

14. Biomune has invested significant employee resources and money into developing its vaccine, submitting it to the U.S.D.A., and conducting the trials necessary to pursue approval. In the past five years, more than 100 Biomune and Ceva employees have collectively worked over 60,000 hours researching, developing, and preparing Biomune's Vaccine for approval and commercialization in the United States animal health market.

15. To date, Biomune has invested more than $4.2 million in developing its Vaccine. Biomune estimates that an additional $15 million will be invested in the real estate, facilities, research, development, manufacture, production, and commercialization of Biomune's Vaccine within the next four years.

16. Biomune anticipates that it will begin manufacturing, producing, and selling its Vaccine in the United States as soon as it is approved. Biomune anticipates receiving approval for its vaccine before the end of 2015.

17. Merial has a history of aggressively asserting its PCV-2-related patents to stop competitors from bringing PCV-2 vaccine products to market. In 2005, Merial initiated suit in the Northern District of Georgia against Intervet, Inc.'s sale of its PCV-2 vaccine on the basis of a patent from the same patent family as the '192 and '272 patents. *Merial Ltd. et al. v. Intervet, Inc*., 430 F. Supp. 2d 1357 (N.D. Ga. 2006) (infringement action on the basis of U.S. Patent No. 6,368,601 seeking a temporary restraining order, preliminary and permanent injunction, and damages). After that action was transferred to the District of Columbia, Merial brought suit against Intervet in the D.C. District Court on an additional patent seeking damages and injunctive relief. *Merial Ltd. et al. v. Intervet, Inc*., No. 07-630 (D.D.C. filed Apr. 4, 2007). In 2008 and 2009, Merial brought additional actions against Intervet, and later Boehringer Ingelheim, Inc., in the Northern District of Georgia seeking preliminary and permanent injunctive relief against Intervet's and Boehringer's PCV-2 vaccines on yet another patent that it asserted covered the defendants' products. *Merial Ltd. v. Intervet, Inc.*, No. 08-121 (M.D. Ga. filed Dec. 10, 2008); *Merial Ltd. v. Boehringer Ingelheim Vetmedica, Inc.*, No. 08-116 (M.D. Ga. filed Dec. 8, 2009).

18. Merial also has a history of enforcing its patents against Biomune. Merial sued Biomune's parent company Ceva Santé Animale's subsidiary Horizon Valley Generics, Inc. alleging infringement of patents related to flea control products. Horizon Valley Generics, Inc. filed a declaratory judgment action in the District of Delaware, where Horizon Valley Generics, Inc. is incorporated, and Merial successfully transferred its patent infringement case against

Horizon Valley Generics, Inc. to the Northern District of Georgia on basis of the first-filed case doctrine.

19. On or about October 24, 2011, Ceva Santé Animale employee Bernard Emery contacted Merial's Vice President of Business Development, Mr. Peter Selover, to discuss a potential license with respect to Merial's patent rights related to PCV-2 in an effort to remove any uncertainty concerning Biommune's vaccine. On or about November 3, 2011, Merial, by and through its representative, Mr. Selover, refused to enter into license negotiations with Ceva related to Merial's PCV-2 products.

20. Based on Merial's history of aggressively litigating its patent rights, Merial's behavior toward Ceva with respect to other products and PCV-2 vaccines, Biomune has a reasonable apprehension that Merial will assert its patents against Biomune and seek to enjoin further development and ultimately the sale of Biomune's Vaccine.

21. A case of actual controversy exists here. To the extent that Merial's '192 and '272 patents are valid and are interpreted to embrace Biomune's Vaccine, the submission of Biomune's USDA application constitutes an act of infringement. Merial's aggressive litigation history with respect to other PCV-2 vaccine products, its behavior toward Biomune's parent company with respect to other products, and its refusal to enter into license negotiations with Ceva Santé Animale regarding PCV-2, Biomune has a reasonable apprehension that Merial will utilize the same aggressive litigation tactics against Biomune in an attempt to prevent Biomune from developing and ultimately selling its Vaccine product. This apprehension and the cloud that it raises over Biomune's business is harming Biomune by undermine's the company's ability to continue to invest in its Vaccine and to grow its business in Kansas and beyond.

22. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b) as a substantial part of the events giving rise to the claim occurred in Kansas, the defendants are subject to personal jurisdiction in Kansas, and the defendants have an established place of business within this district.

23. On information and belief, defendants are subject to personal jurisdiction in this district. K.S.A. § 17-7301 provides that no foreign corporation may transact business within the state without, inter alia, "an irrevocable written consent of the foreign corporation that actions may be commenced against it in the proper court of any county where there is proper venue by service of process on the secretary of state . . . ." K.S.A. § 17-7301(b)(7). This irrevocable written consent is sufficient to confer personal jurisdiction over the foreign corporation, and such jurisdiction does not violate the Due Process Clause. *See Merriman v. Crompton Corp.*, 282 Kan. 433, 445, 455, 146 P.3d 162, 171, 176-77 (2006). Defendants gave their irrevocable written consent to jurisdiction in Kansas as part of their application for a Certificate of Authority to transact business in the State of Kansas, filed with the Secretary of State on December 22, 1997, and are therefore subject to jurisdiction in this district.

24. Moreover, on information and belief, defendants are also subject to personal jurisdiction in this district pursuant to the Kansas long-arm statute. K.S.A. § 60-308. On information and belief, defendants have had systematic and continuous contacts with this judicial district as a result of their conducting business in the state, including the research and development, marketing, and sales of their veterinary and animal health products in Kansas.

COUNT I
(Non-Infringement of U.S. Patent No. 6,660,272)

25. Biomune repeats and realleges each and every allegation contained in paragraphs 1–25 of this Complaint as though fully set forth herein.

26. Biomune's Vaccine and its submission of U.S.D.A. Application No. 41K5.20 for the purpose of obtaining a license to market Biomune's Vaccine does not infringe, induce others to infringe, or contribute to the infringement of the claims of the '272 patent under 35 U.S.C. § 271 because Biomune's Vaccine does not meet each and every limitation of the '272 patent claims either literally or under the doctrine of equivalents.

27. The making, using, selling, or offering to sell Biomune's Vaccine does not infringe, induce others to infringe, or contribute to the infringement of any valid claim of the '272 patent either literally or under the doctrine of equivalents.

COUNT II
(Invalidity of U.S. Patent No. 6,660,272)

28. Biomune repeats and realleges each and every allegation contained in paragraphs 1–28 of this Complaint as though fully set forth herein.

29. Each of the claims of the '272 patent is invalid for failure to comply with one or more sections of the patent laws of the United States, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

30. The claims of the '272 patent are invalid under 35 U.S.C. § 101 because they are directed to unpatentable products of nature.

31. Each of the claims of the '272 patent is invalid under 35 U.S.C. §§ 102 and 103 because the prior art available prior to the time the inventors made the claimed invention anticipated and/or rendered those claims obvious. The prior art to the '272 patent disclosed PCV-2 –and taught that it was linked to disease in pigs. The skilled person would have been motivated to isolate that virus, and make the immunogenic compositions covered by the claims and would have had a reasonable expectation of succeeding. It would have been obvious to a

person of ordinary skill in the art to make the claimed compositions and the claims of the '272 patent are therefore invalid as obvious under 35 U.S.C. § 103.

32. Moreover, the applications to which the '272 patent claims priority fail to provide adequate written description of the claimed inventions.

COUNT III
(Non-Infringement of U.S. Patent No. 7,122,192)

33. Biomune repeats and realleges each and every allegation contained in paragraphs 1–33 of this Complaint as though fully set forth herein.

34. Biomune's Vaccine and its submission of U.S.D.A. Application No. 41K5.20 for the purpose of obtaining a license to market Biomune's Vaccine does not infringe, induce others to infringe, or contribute to the infringement of the claims of the '192 patent under 35 U.S.C. § 271 because Biomune's Vaccine does not meet each and every limitation of the '192 patent claims either literally or under the doctrine of equivalents.

35. The making, using, selling, or offering to sell Biomune's Vaccine does not infringe, induce others to infringe, or contribute to the infringement of any valid claim of the '192 patent either literally or under the doctrine of equivalents.

COUNT IV
(Invalidity of U.S. Patent No. 7,122,192)

36. Ceva repeats and realleges each and every allegation contained in paragraphs 1–45 of this Complaint as though fully set forth herein.

37. Each of the claims of the '192 patent are invalid for failure to comply with one or more sections of the patent laws of the United States, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and 112.

38. The claims of the '192 patent are invalid under 35 U.S.C. § 101 because they are directed to unpatentable products of nature.

39. Each of the claims of the '192 patent is invalid under 35 U.S.C. §§ 102 and 103 because the prior art available prior to the time the inventors made the claimed invention anticipated and/or rendered those claims obvious. The prior art to the '192 patent disclosed PCV-2, and taught that it was linked to disease in pigs. The skilled person would have been motivated to isolate that virus, and make the immunogenic compositions covered by the claims, including combining an isolated PCV-2 virus with an additional porcine pathogen, such as *Mycoplasm hyopneumonia*, and would have had a reasonable expectation of succeeding. It would have been obvious to a person of ordinary skill in the art to make the claimed compositions and the claims of the '192 patent are therefore invalid as obvious under 35 U.S.C. § 103.

40. Moreover, the applications to which the '192 patent claims priority fail to provide adequate written description of the claimed inventions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs requests that the Court enter judgment as follows:

(a) Declaring invalid each and every claim of U.S. Patent Nos. 6,660,272 and 7,122,192;

(b) Declaring that Biomune does not infringe either directly or indirectly by inducing or contributing to the inducement of, any valid claim of U.S. Patent Nos. 6,660,272 and 7,122,192;

(c) Declaring that Merial and its officers, agents, representatives, counsel, and all persons in active concert or participation with them are enjoined from instituting or continuing

any action for infringement of U.S. Patent Nos. 6,660,272 and 7,122,192 against Biomune, its suppliers, customers, distributors, or users of its products;

(d) Declaring this case exceptional under 35 U.S.C. § 285;

(e) Awarding Biomune its costs and reasonable attorney's fees; and

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

DEMAND FOR JURY TRIAL

Plaintiff does not demand a jury trial in connection with this action,

DESIGNATION OF PLACE OF TRIAL

Plaintiff designates its choice for place of trial: Kansas City, Kansas.

Dated: November 3, 2014

Respectfully submitted,

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