

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

MERIAL, INC. and MERIAL S.A.S.,

Plaintiffs,

vs.

C.A. No. 16-171-UNA

CEVA U.S. HOLDINGS, INC.,  
CEVA SANTÉ ANIMALE S.A. a/k/a CEVA  
ANIMAL HEALTH,  
CEVA ANIMAL HEALTH, LLC and  
BIOMUNE COMPANY a/k/a CEVA BIOMUNE,

Defendants.

**JURY TRIAL DEMANDED**

**AMENDED COMPLAINT**

Plaintiffs Merial, Inc. and Merial S.A.S. (collectively, “Merial”), complain and allege as follows against Defendants Ceva U.S. Holdings, Inc., Ceva Santé Animale S.A. a/k/a Ceva Animal Health, Ceva Animal Health, LLC and Biomune Company a/k/a Ceva Biomune (collectively, “Ceva”).

**NATURE OF ACTION**

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code.

**JURISDICTION AND VENUE**

2. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 (federal question) and 1338 (patents).

3. An actual and justiciable controversy exists between Merial and Ceva requiring resolution by this Court.

4. Personal jurisdiction over Ceva is proper in this District. Ceva's domestic U.S. entities are incorporated in Delaware, and its foreign parent controls those Delaware entities. Ceva is present in this District, it has availed itself of the rights and benefits of the laws of Delaware, and it has had systematic and continuous business contacts with Delaware at all relevant times. Ceva's infringing activities are causing injury to Merial within this District. Merial is informed and believes that Ceva expects its actions to have consequences within this District, and that Ceva derives substantial revenue from interstate and international commerce. Ceva maintains several interactive web sites to conduct business with residents of this District, including <https://www.facebook.com/CevaSanteAnimaleGlobal>, [https://twitter.com/Ceva\\_USA](https://twitter.com/Ceva_USA), <https://www.linkedin.com/company/ceva-sante-animale> (last visited March 17, 2016).

5. Indeed, on February 26, 2016, at the Civic Theater in New Orleans, Louisiana, Ceva held a "Swine U.S. Launch & Scientific Symposium" and made several presentations, available on YouTube at <https://www.youtube.com/playlist?list=PL-MftmYZJVXAg4HpLsqeXAQtJRboFrbS5> (last visited March 17, 2016). In one presentation, Marc Prikazsky, Chairman of the Board of Ceva Santé Animale S.A. depicted the various Ceva entities as operating as a "Network," including with the slide provided below:



That the various Ceva entities are all inter-related and function in a coordinated unitary fashion, as a network, led by Ceva Santé Animale S.A., was confirmed in a presentation by Gary Robertson, Director, U.S. Swine Business Unit, Ceva Animal Health, including with the following slide:



6. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and 1400(b).

### PARTIES

7. Merial, Inc. is a Georgia corporation having a place of business at 3239 Satellite Boulevard, Duluth, Georgia 30096.

8. Merial S.A.S. is a société par actions simplifiée of France, located in Lyon, France.

9. On information and belief, Ceva U.S. Holdings, Inc. is a Delaware corporation and has its principal place of business at 8735 Rosehill Road, #300, Lenexa, Kansas 66215.

10. On information and belief, Ceva Santé Animale S.A. a/k/a Ceva Animal Health is a French Société Anonyme and has its principal place of business at 10 Avenue de la Ballastière, 33500 Libourne, France.

11. On information and belief, Ceva Animal Health, LLC is a Delaware limited liability company and has its principal place of business at 8735 Rosehill Road, #300, Lenexa, Kansas 66215.

12. On information and belief, Biomune Company d/b/a Ceva Biomune is a Delaware corporation and has its principal place of business at 8735 Rosehill Road, #300, Lenexa, Kansas 66215. Biomune Company is a wholly-owned subsidiary of Ceva Santé Animale S.A.

## FACTS

### I. Merial's Innovations and Asserted Patents

13. Merial is a world-leading, innovation-driven animal health company, providing a comprehensive range of products to enhance the health, well-being and performance of a wide range of animals. Merial employs approximately 6,900 people and operates in more than 150 countries. Merial is the Animal Health subsidiary of Sanofi-Aventis.

14. In the field of swine health (or porcine health), Merial scientists have been on the leading edge of the fight against porcine circovirus and the significant animal health and

economic losses associated with it. Porcine circovirus is not only responsible for PMWS (Post-Weaning Multi-Systemic Wasting Syndrome), but also has been associated with problems in porcine reproduction including such reproductive failures as abortions, return to estrus, delayed parturitions, mummified porcine fetuses and stillbirths. Merial, through vast investment over many years, as well as the skill of its scientists and researchers, has led the field in porcine circovirus vaccines, including with the product **Circovac®**, an inactivated porcine circovirus type 2 vaccine, marketed in the U.S. by Merial.

15. Through intellectual property rights, Merial has protected its investment in these innovations.

**A. The '272 Patent**

16. Exhibit A hereto is a true and correct copy of United States Patent Number 6,660,272 B2 (“the ‘272 Patent”), entitled “Porcine Circoviruses, Vaccines and Diagnostic Reagents,” which was duly and legally issued on December 9, 2003.

17. On information and belief, the Ceva swine vaccines being launched in the U.S. infringe multiple claims of the ‘272 Patent, including, but not limited to, Claims 23 and 31, which depend from Claim 12. On information and belief, the Ceva swine vaccines contain each limitation of at least these claims. These claims describe and define Merial’s property rights in its invention as follows: an immunogenic composition comprising an isolated porcine circovirus type II [Claim 12]; the immunogenic composition of claim 12, wherein the isolated porcine circovirus type II comprises an inactivated porcine circovirus [claim 23]; and the immunogenic composition of claim 23, wherein the porcine circovirus has been inactivated by a chemical agent [claim 31].

18. All rights in, to and under the '272 Patent have been assigned to Merial, and Merial has the exclusive worldwide right to enforce the '272 Patent.

**B. The '192 Patent**

19. Exhibit B hereto is a true and correct copy of United States Patent Number 7,122,192 B2 ("the '192 Patent"), also entitled "Porcine Circoviruses, Vaccines and Diagnostic Reagents," which was duly and legally issued on October 17, 2006.

20. On information and belief, the Ceva swine vaccines being launched in the U.S. infringe multiple claims of the '192 Patent, including, but not limited to, Claims 20, 22, 26 and 28, which depend from Claim 1. These claims describe and define Merial's property rights in its invention as follows: an immunogenic composition comprising an isolated porcine circovirus type II (PCV2) and an additional porcine pathogen, wherein the PVC2 is inactivated or attenuated [Claim 1]; the immunogenic composition of claim 1, comprising about  $10^6 - 10^8$  TCID<sub>50</sub> of inactivated PCV2 [Claim 20]; the immunogenic composition of claim 1, wherein the PCV2 has been inactivated by a chemical agent [Claim 22]; the immunogenic composition of any one of claims 1-7, wherein the additional porcine pathogen is selected from the group consisting of Porcine Reproductive and Respiratory Syndrome (PRRS) virus, *Mycoplasma hyopneumonia*, *Actinobacillus pleuropneumoniae*, *Escherichia coli*, *Pasteurella multocida* Pseudorabies virus, Swine Fever virus and Swine Influenza virus [Claim 26]; and the immunogenic composition of claim 26, wherein the additional porcine pathogen is *Mycoplasma hyopneumonia* [Claim 28].

21. All rights in, to and under the '192 Patent have been assigned to Merial, and Merial has the exclusive worldwide right to enforce the '192 Patent.

## II. Ceva's Infringing Activities and Products

22. Ceva has announced a 2016 "launch" of its U.S. swine business, with the following announcement on its website:

### **LAUNCHING THE SWINE BUSINESS IN THE UNITED STATES**

Ceva is a global swine health company founded by veterinarians and led by industry experts focusing in the areas of reproduction, emerging diseases, grow/finish products and unmet needs. Ceva is dedicated to the swine industry, passionate about pigs and focused on providing solutions to the challenges customers are facing.

During the 2016 annual meeting of the American Association of Swine Veterinarians, Ceva hosted a symposium introducing the company and its approach to meeting the health needs of the pork industry. [<http://www.ceva.us/Swine/About-Ceva-Swine>] (last visited March 17, 2016).

23. The "symposium" to "introduce[e] the company and its approach" was titled the "2016 Ceva Swine U.S. Launch & Scientific Symposium" and was held in New Orleans, Louisiana on February 26, 2016. The materials from the symposium that Ceva has published on YouTube make clear that Ceva has made extensive preparations to launch, and has launched or will launch, a vast sales and marketing campaign for swine health care technologies and products that, on information and belief, have been patented by Merial, including, on information and belief, a porcine circovirus, type 2 ("PCV2") vaccine within the claims of Merial's '272 Patent and '192 Patent, as indicated herein. Thus, rather than develop its own swine health innovations, Ceva has chosen to copy Merial's.

24. At the presentations at this symposium, Ceva made direct references to introducing vaccines and PCV2 as an "endemic" pig pathogen, including with slides as set forth below, that Ceva posted on YouTube:

**North American Business Vision: **A**mbition**

**Companion Animal**

- Parasiticides
- Behavior
- Pain & Mobility
- Cardiology
- Anti-infectives
- Dermatology

**Poultry**

- Vaccines
- Equipment
- Services

**Swine**

- Vaccines
- Reproduction
- Services

**Ruminants**

- Reproduction
- Udder Health

2016 Ceva Swine U.S. Launch & Scientific Symposium

- 1 Dr. Marc Prikazsky - Introduction to Ceva
- 2 Dr. Kent Schwartz - Disease Interventions: Are We Doing as Good as We Know?
- 3 Panel Discussion - Swine Industry Expectations, Innovations & Transformations
- 4 Dr. David Hurley - The Chaos of Vaccine Responses: The Importance of Tissue-Level Activity
- 5 Craig Wallace - Ceva U.S. Business
- 6 Gary Robertson - Ceva U.S. Swine Business

Craig Wallace - Ceva U.S. Business

**CONCEPT: Many swine "pathogens" are ENDEMIC**

**Susceptible Host**  
"immunity, nutrition, genetics"

**Conducive Environment**  
"facilities, management"

**Pathogen**  
"infectious diseases"  
Dose x Virulence

**Disease**

**Potential Pathogens**

- MHP
- Pasteurella
- Streptococcus
- Haemophilus
- Salmonella
- Lawsonia
- PCV2
- Rotaviruses
- Coccidia

**These don't HAVE TO cause disease!**

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- 4 Dr. David Hurley - The Chaos of Vaccine Responses: The Importance of Tissue-Level Activity
- 5 Craig Wallace - Ceva U.S. Business
- 6 Gary Robertson - Ceva U.S. Swine Business

Dr. Kent Schwartz - Disease Interventions: Are We Doing as Good as We

**"Welcome to the Masquerade Ball  
The Many Faces of PCV2" (B. Arruda)**

**ENTEROCOLITIS**

**IHC POSITIVE**

**APES**

**PDNS**

**HEPATITIS**

**PNEUMONIA TBLN**

**REPRODUCTIVE**

**EDEMA**

**WASTING**

**VARIATION !!!**

2016 Ceva Swine U.S. Launch & Scientific Symposium

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- 6 Gary Robertson - Ceva U.S. Swine Business

Dr. Kent Schwartz - Disease Interventions: Are We Doing as Good as We



25. Importantly, Ceva announced that not only is it entering the swine vaccine business, with reference to PCV2, but it has a swine vaccine production facility in the United States that is fully operational, with “[a]nticipate[d] [U.S. Department of Agriculture (“USDA”)] approval of commercial vaccines” in 2016, including with slides as set forth below:



26. Notably, as mentioned herein, a clinical condition of the pig pathogen PCV2 is “PMWS” or “Post-Weaning Multisystemic Wasting Syndrome” and hence the anticipated “Product Categories” of “Breed-to-Wean” and “Wean-to-Finish,” especially with references in presentations to PCV2 as an “endemic” pig pathogen, indicate that Ceva intends to market in the United States a PCV2 vaccine. On information and belief, that CEVA has announced and intends to soon launch in the United States a combination vaccine containing inactivated PCV2 and *Mycoplasma hyopneumonia* bacterin (“PCV2+M.hyo”), and thereafter, but also in 2016, a stand-alone or single antigen PCV2 vaccine containing inactivated PCV2, makes this all the more clear and undeniable.

27. On information and belief, to obtain USDA approval to market these products, Ceva has conducted or is conducting animal testing. Such animal testing and ancillary supporting activities for such testing can be in the United States. Such animal testing in the United States infringes the claims of Merial’s ‘272 Patent and ‘192 Patent, as indicated herein, including as such is an unauthorized use of Merial’s patented invention.

28. On information and belief, Ceva plans to supply the United States market with the aforementioned infringing PCV2 vaccines (the PCV2+M.hyo combination and PCV stand-alone) through the U.S. facility announced on February 26, 2016, and this too constitutes at least, on information and belief, the making of a product that infringes the claims of Merial’s ‘272 Patent and ‘192 Patent, as indicated herein, especially as, on information and belief, Ceva would need or needed to demonstrate to the USDA that the U.S. facility can produce vaccines in a fashion satisfactory to the USDA. For instance, the above-depicted slide from its Swine Symposium makes clear that Ceva has gone through this process and has apparently received

USDA approval for its facility, stating, “Received first U.S. license for the swine market [in 2015].”

29. Ceva’s announcement of a U.S. launch and the extensive preparatory activities admitted in its Swine Symposium, or necessarily implied by it, demonstrate, on information and belief, extensive past and current infringement of the claims of Merial’s ‘272 Patent and ‘192 Patent, as well as an intention to increase dramatically the scope, scale and severity of such infringement in 2016, starting with the U.S. Swine Business product launch three weeks ago.

30. Given the vast expansion of such infringement by Ceva, going on now or due to be inflicted on Merial imminently, the damage and injury to Merial is vast and irreparable. Merial is being damaged in a fashion that cannot be adequately compensated with monetary relief, as, among other things, Merial will suffer immediate market and price erosion by such a launch. Thus, Ceva’s U.S. Swine Business product launch needs to be immediately enjoined.

31. Finally, this is certainly not the first time Ceva and its affiliated companies have heard of Merial’s ‘272 Patent and ‘192 Patent. Cognizant that its planned swine health products are infringing or would infringe, Defendant Biomune Company brought a declaratory action against certain Merial entities in the U.S. District Court for the District of Kansas on November 10, 2014 seeking a declaration of noninfringement of Merial’s ‘272 Patent and ‘192 Patent by products that, on information and belief, are the same swine health products at issue here. On motion by Merial, the court dismissed that action for lack of subject matter jurisdiction, thus declining to provide the requested declaration of noninfringement. *See* Case No. 14 Civ. 2567 (D. Kan.).

32. But the allegations in the complaint filed by Biomune establish, all but conclusively, the infringements pleaded here.

33. Exhibit C hereto is a true and correct copy of the declaratory judgment complaint filed by Biomune.

34. As explained in that complaint:

(a) On August 31, 2012, Ceva submitted an application to the USDA for approval of its Porcine Circovirus Vaccine, Type-2 Killed Virus-*Mycoplasma Hyopneumonia* Bacterin vaccine (the "Vaccine"). The application was filed pursuant to the Act of Congress approved 1913, 21 U.S.C. §§ 151-158.

(b) Ceva'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.

(c) Even though Ceva 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). Ceva anticipated that Merial would allege that

Ceva's Vaccine and the use of the Vaccine are covered by the '192 and '272 patents, and that the submission of Ceva's application to the USDA is a technical act of patent infringement.

Moreover, Ceva had taken concrete steps in Kansas to enter the vaccine market. Ceva 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 Ceva's staff in Kansas diligently worked conducting the trials necessary to obtain approval.

(d) Ceva anticipated that it would begin manufacturing, producing and selling its Vaccine in the United States as soon as it was approved. At the time of the declaratory judgment action, Ceva anticipated receiving approval for its vaccine before the end of 2015.

35. On information and belief, Ceva has infringed and continues to infringe Merial's patent rights by making, using, testing and offering for sale products in the United States and elsewhere that embody or use the inventions claimed in Merial's patents. Specifically, Ceva plans to sell the Vaccine. Ceva has stated its intent to build on this product to research and develop additional products for the swine industry, as well as other food animal and companion animal industries.

36. As Ceva admitted in the declaratory judgment complaint filed by Biomune, at Ceva's direction, Ceva personnel have worked over an extended period in the U.S. to qualify the Vaccine for approval and commercialization in the United States animal health market, including activities in the U.S. that, on information and belief, infringe Merial's '272 Patent and '192 Patent.

37. As Ceva admitted in the declaratory judgment complaint, in connection with Ceva seeking USDA approval for its entrance into the swine healthcare market, Ceva has

conducted animal testing of its proposed products. As part of this testing, Ceva has directed others to conduct animal tests in a manner that, on information and belief, infringes Merial's '272 Patent and '192 Patent and does so willfully, knowing that the testers' actions constituted infringement.

38. Ceva submitted an application to the USDA for a license to market its infringing veterinary biological product under 21 U.S.C. §§ 151-158. This too constituted an act of patent infringement under 35 U.S.C. § 271, as Ceva acknowledged in the declaratory judgment complaint and on other grounds as well.

39. On information and belief, Ceva has been and is inducing infringement of Merial's patent rights by actively and knowingly inducing others to make, use, offer for sale or import products that embody or use the inventions claimed in Merial's asserted patents.

40. Ceva has known of the existence of Merial's asserted patents. On information and belief, Ceva's acts of infringement have been willful and in disregard of Merial's intellectual property rights and without any reasonable basis for believing that it had a right to engage in the infringing conduct. In particular, Ceva's U.S. Chief Executive Officer, Craig Wallace has boasted that "[e]ntering the swine business is a strategic and intentional move." *See* <http://www.ceva.us/Swine/About-Ceva-Swine> (last visited March 17, 2016). Further, Merial is informed and believes that Ceva's infringement has been willful because it had knowledge of Merial's intellectual property rights through direct or indirect communications with Merial (including, on information and belief, multiple requests for a license from Merial), as well as Ceva's admission of making a "strategic and intentional" decision to enter the swine health industry in the U.S.

41. On information and belief, Ceva's infringement of Merial's '272 Patent and '192 Patent provides Ceva with unique functionality and benefits that are the result of Merial's innovation—not Ceva's.

42. Ceva has not obtained permission from Merial to use its inventions.

43. According to Ceva, "Ceva Swine is developing a pipeline of science-based solutions for the market that will be available in 2016."

44. In connection with the U.S. roll-out of Ceva's Vaccine, Ceva created a media campaign and hosted a conference, as discussed herein.

45. Ceva's sales and marketing activities are impacting the stream of commerce, to the severe and irreparable harm of Merial.

### **FIRST CLAIM FOR RELIEF**

#### **INFRINGEMENT OF THE '272 PATENT**

46. Merial incorporates and realleges the preceding paragraphs.

47. Ceva has infringed and continues to infringe, directly and indirectly through contributory and/or induced infringement, one or more claims of the '272 Patent.

48. Ceva's infringing acts have not been authorized by Merial.

49. Merial is informed and believes that Ceva's infringement has been and continues to be knowing, intentional and willful.

50. Merial has suffered damages as a direct and proximate result of Ceva's infringement.

51. Merial will suffer and is suffering irreparable harm from Ceva's infringement. Merial lacks an adequate remedy at law and is entitled to an injunction against Ceva's

continuing infringement of the '272 Patent. Unless enjoined, Ceva will continue its infringing conduct.

52. This case is exceptional. Therefore, Merial is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

**SECOND CLAIM FOR RELIEF**  
**INFRINGEMENT OF THE '192 PATENT**

53. Merial incorporates and realleges the preceding paragraphs.

54. Ceva has infringed and continues to infringe, directly and indirectly through contributory and/or induced infringement, one or more claims of the '192 Patent.

55. Ceva's infringing acts have not been authorized by Merial.

56. Merial is informed and believes that Ceva's infringement has been and continues to be knowing, intentional and willful.

57. Merial has suffered damages as a direct and proximate result of Ceva's infringement.

58. Merial will suffer and is suffering irreparable harm from Ceva's infringement. Merial lacks an adequate remedy at law and is entitled to an injunction against Ceva's continuing infringement of the '192 Patent. Unless enjoined, Ceva will continue its infringing conduct.

59. This case is exceptional. Therefore, Merial is entitled to an award of attorneys' fees pursuant to 35 U.S.C. § 285.

**RELIEF REQUESTED**

WHEREFORE, Merial requests that the Court:



- (a) issue a judgment that each of Merial's asserted patents is valid and enforceable;
- (b) issue a judgment that Ceva has infringed, contributorily infringed, and/or induced infringement of one of more claims of each of Merial's asserted patents;
- (c) issue an injunction preliminarily and permanently enjoining Ceva, its employees, agents, officers, directors, attorneys, successors, affiliates, subsidiaries and assigns, and all of those in active concert and participation with any of the foregoing persons or entities from infringing, contributing to the infringement of, or inducing infringement of Merial's asserted patents;
- (d) require Ceva to account and pay damages adequate to compensate Merial for Defendant's infringement, with the maximum pre-judgment and post-judgment interest and costs, as provided by 35 U.S.C. § 284;
- (e) rule that the damages award be increased up to three times the actual amount assessed, as provided by 35 U.S.C. § 284;
- (f) declare this case exceptional, in accordance with 35 U.S.C. § 285;
- (g) award Merial its attorneys' fees, costs and expenses, and
- (h) grant any further relief that may be necessary to achieve justice.

**JURY TRIAL DEMAND**

Merial requests a trial by jury of all issues so triable raised in this Complaint.

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Dated: March 21, 2016

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