

**UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION**

MERIAL LIMITED and MERIAL SAS,

Plaintiffs,

v.

HORIZON VALLEY GENERICS, INC.
and CEVA SANTÉ ANIMALE S.A.,

Defendants.

Civil Case No. 3:12-cv-00154-CDL

JURY TRIAL DEMANDED

**MERIAL LIMITED AND MERIAL SAS'S SECOND AMENDED
DECLARATORY JUDGMENT COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs Merial Limited and Merial SAS (collectively, "Merial"), pursuant to the stipulation by the parties entered on November 6, 2013 (D.I. 41), for their Amended Declaratory Judgment Complaint for Patent Infringement against Defendants Horizon Valley Generics, Inc. ("HVG") and Ceva Santé Animale S.A. (Ceva France)¹ allege as follows:

NATURE OF ACTION

1. This is an action in which Merial seeks declaratory and injunctive relief under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, for HVG's and Ceva France's intended infringement of Merial's U.S. Patent No. 6,096,329 ("the '329 Patent"). A true and correct copy of the '329 Patent is attached as Exhibit A.

2. The United States Patent and Trademark Office ("USPTO") duly and legally issued the '329 Patent on August 1, 2000. On October 4, 2011, the USPTO issued an *Ex Parte*

¹ Defendants HVG and Ceva France, along with their affiliate Ceva Animal Health, LLC ("Ceva USA"), are collectively referred to as "Ceva."

Reexamination Certificate for the '329 Patent. A true and correct copy of the *Ex Parte* Reexamination Certificate for the '329 Patent is attached as Exhibit B.

THE PARTIES

3. Merial Limited is a company limited by shares registered in England and Wales with a registered office in England. Merial Limited is domesticated in the State of Delaware as Merial LLC. Merial Limited's North American operational headquarters are in Duluth, Georgia.

4. Merial S.A.S. is a Société Par Actions Simplifiée of France with principal offices located at 29 Avenue Tony Garnier 69007 Lyon, France.

5. Ceva France is a French corporation with its principal place of business in Libourne, France.

6. HVG is incorporated under the laws of the State of Delaware. HVG represents that it has a principal place of business at 8735 Rosehill Road, Lenexa, Kansas, which is the same principal place of business as Ceva USA.

7. On information and belief, Ceva USA is the United States business unit of Ceva France. Ceva USA represents Ceva France's presence in the United States animal health industry and acts as an agent on behalf of Ceva France, including the sale of Ceva's flea and tick products in the United States.

8. Ceva USA and Ceva France have represented that Ceva USA is not a real party in interest, and instead that HVG and Ceva France are the real parties in interest in this action.

JURISDICTION AND VENUE

9. This is an action arising under the patent laws of the United States, Title 35 of the United States Code and the Declaratory Judgment Act of 1934, 28 U.S.C. §§ 2201-2202. This Court has subject matter jurisdiction under Title 28, United States Code, §§ 1331 and 1338(a).

10. HVG and Ceva France admit that this Court has personal jurisdiction over them for purposes of this litigation.

11. Venue is proper in this Court pursuant to at least Local Rule 3.4 and 28 U.S.C. §§ 1391(b) and (c) because corporations are deemed to reside in any judicial district in which they are subject to personal jurisdiction at the time the action is commenced. Ceva has continuously and systematically advertised, offered for sale, and sold animal health products, including flea and tick treatment products, in the Athens Division of this Judicial District, and, on information and belief, Ceva intends to sell infringing products in this Judicial District. Under the Patent Act, an infringement claim arises where the sale of the infringing product occurs. On information and belief, Ceva's infringing products will soon be offered for sale in the Athens Division of this Judicial District. Ceva's planned actions in the Athens Division of this Judicial District with regard to its infringing products will cause substantial injury to Merial in the Athens Division of this Judicial District.

12. Pursuant to Local Rule 3.4, venue is also proper in the Division where the plaintiff resides. Merial Limited resides in the Athens Division of this District by virtue of its substantial presence in Athens, Georgia. For example, Merial Limited has a substantial research and development facility located in Athens, Georgia, which employs approximately 400 people, and conducts testing, research and development, and regulatory licensing-related activities with

regard to, among other projects, companion animal flea and tick control products sold under the brand name FRONTLINE PLUS.

UNDERLYING FACTS

13. Merial is a world-leading animal health company. Among Merial's most successful animal health products are its FRONTLINE PLUS products. Merial's FRONTLINE PLUS products are the world's bestselling flea and tick treatment for dogs and cats. Merial's FRONTLINE PLUS products provide gentle, long-lasting, fast-acting, waterproof flea and tick control and are approved by the United States Environmental Protection Agency ("EPA") for eliminating flea and tick infestations.

14. Merial's FRONTLINE PLUS products are synergistic spot-on compositions for long lasting protection against fleas and ticks on mammals which comprise synergistic effective amounts of the insecticide fipronil and synergistic amounts of methoprene, a compound which mimics juvenile hormones, as well as customary spot-on formulation adjuvants. In particular, Merial's FRONTLINE PLUS products for dogs contain 9.8% fipronil and 8.8% (s)-methoprene, while, Merial's FRONTLINE PLUS product for cats contains 9.8% fipronil and 11.8% (s)-methoprene.

15. Merial spent substantial sums of money inventing and bringing to market its FRONTLINE PLUS products.

16. Merial's FRONTLINE PLUS products are covered by claims of the '329 Patent including, but not limited to, Claims 1, 4, 26, 77, 85, 101, and 106-108.

17. The '329 Patent is assigned to Merial S.A.S., which has granted Merial Limited an exclusive license to the '329 Patent. Merial, therefore, has all substantial rights to enforce the

'329 Patent, including all rights to recover for any and all past, present, and future infringement thereof.

18. HVG and Ceva France are aware of the '329 Patent and Merial's rights to the '329 Patent.

19. On information and belief, Ceva has taken significant, concrete steps and has made meaningful preparations, either alone or in concert with third parties, to sell, use, and offer for sale flea and tick products within the United States, including the State of Georgia, and the Athens Division of this Judicial District, that infringe one or more claims of Merial's '329 Patent.

20. On information and belief, Ceva, acting through HVG, has filed with the EPA applications to register generic FRONTLINE PLUS products, *i.e.* spot-on flea and tick products containing fipronil and methoprene as the only active ingredients. On information and belief, Ceva's applications to register the generic FRONTLINE PLUS products were made pursuant to Section 3(c)(3)(B) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). Section 3(c)(3)(B) of FIFRA permits the EPA to expeditiously review and act on an application to register a pesticide product if the product to be registered is identical or substantially similar in composition and labeling to a currently-registered pesticide product. Such applications to register a pesticide product pursuant to Section 3(c)(3)(B) of FIFRA were formerly referred to as "me-too" product registration applications, and are now referred to as "Identical/Substantially Similar" pesticide registration applications.

21. An applicant submitting an "Identical/Substantially Similar" pesticide registration to the EPA pursuant to Section 3(c)(3)(B) of FIFRA need not repeat certain safety, efficacy, and toxicity studies for the product it is seeking to register, but rather can cite to and use the existing

data previously submitted to the EPA by the registrant for the currently-registered product. The applicant seeking to register a product pursuant to Section 3(c)(3)(B) of FIFRA, *i.e.*, seeking to register an “Identical/Substantially Similar pesticide product, however, must offer to pay the registrant of the currently-registered product for the use of its data.

22. On information and belief, on September 25, 2012, Merial was sent a letter from a regulatory consulting company acting on behalf of HVG, and thus on behalf of Ceva, offering to pay Merial, as required by FIFRA regulations, for the use of Merial’s FRONTLINE PLUS data. That letter stated that (i) HVG “is applying for registration of two (2) end-use products containing fipronil and S-methoprene . . . as the active ingredients” and (ii) in support of the applications for registration, HVG, and thus Ceva, intends to rely on the acute toxicity, product performance, and companion animal safety data that Merial previously submitted to the EPA in connection with the registration of Merial’s FRONTLINE PLUS fipronil and methoprene-containing flea and tick products.

23. The products that HVG is seeking to register on behalf of Ceva and that Ceva intends to sell in the United States contain the same combinations and amounts of active ingredients, fipronil and methoprene, that are present in Merial’s FRONTLINE PLUS products. The amounts of fipronil and methoprene in Ceva’s generic FRONTLINE PLUS products are within the scope of one or more claims of Merial’s ’329 Patent. Ceva’s generic FRONTLINE PLUS products also contain at least one customary spot-on formulation adjuvant.

24. On or about November 7th, 2012, the General Counsel of Ceva France contacted Merial and informed Merial that Ceva intended to launch fipronil- and methoprene-containing spot-on flea and tick products in the United States and that Ceva therefore desired a license to the

'329 Patent in order to permit Ceva to import, offer for sale, and sell the generic FRONTLINE PLUS products in the United States without infringing Merial's patent rights.

25. The Ceva representative threatened that, if Merial refused to grant Ceva a license to the '329 Patent, Ceva would attempt to invalidate the '329 Patent. The Ceva representative also explained that, because Ceva was "far down the road" in its preparations to launch the fipronil- and methoprene-containing spot-on flea and tick products in the United States, Ceva needed to know promptly if Merial was willing to grant Ceva a license to the '329 Patent or, alternatively, Ceva would proceed to attempt to invalidate the '329 Patent. By these statements, Ceva admitted that it plans to offer for sale in the United States products that would infringe the '329 Patent, and threatened imminent litigation to attempt to invalidate the '329 patent unless Merial agreed to license the '329 Patent to Ceva.

26. On January 28, 2013, Ceva France and HVG filed a Declaratory Judgment Complaint in the United States District Court for the District of Delaware (the "Delaware Action"). In that Complaint, Ceva France and HVG alleged that they had "recently completed concrete steps to introduce [a] fipronil/methoprene product into the U.S. market as a generic alternative to Merial's FRONTLINE PLUS products," and claimed that entry was "imminent."

27. On February 19, 2013, Merial moved to dismiss the Delaware Action because, *inter alia*, this case was the first-filed legal action with regard to the subject matter of Ceva's planned infringement of Merial's '329 Patent.

28. On March 12, 2013, Ceva France and Ceva USA moved to dismiss this action for lack of personal and subject matter jurisdiction.

29. On July 23, 2013, the Delaware Court denied Merial's motion to dismiss without prejudice and stayed the Delaware Action until this Court ruled on Ceva France and Ceva USA's motion to dismiss.

30. On September 4, 2013, this Court denied Ceva France and Ceva USA's motion to dismiss. On September 30, 2013, Ceva USA and Ceva France withdrew their motion to dismiss to the extent that motion had not already been denied by the Court's September 4, 2013, Order and filed their Answer to Merial's Amended Declaratory Judgment Complaint.

31. The parties agreed to and entered a stipulation that would substitute HVG for Ceva USA in this case (*see* D.I. 41). Pursuant to that stipulation, on November 6, 2013, Ceva France and HVG filed a motion to dismiss the Delaware Action and that case has now been dismissed by the Delaware Court.

32. On information and belief, Ceva intends to begin selling its fipronil- and methoprene-containing spot-on flea and tick products, which are the subject of this lawsuit, in the United States before or during the next flea and tick season.

33. On information and belief, the offer for sale, sale, and/or use of such fipronil- and methoprene-containing spot-on flea and tick products will constitute infringement of the '329 Patent.

34. Merial is not willing to grant Ceva a license to the '329 patent or otherwise relinquish its legal right to exclude others from exploiting its patented inventions claimed in the '329 patent.

35. If Ceva is permitted to sell, use, and offer for sale its infringing flea and tick products, Merial will suffer irreparable, unquantifiable harm. Merial has made substantial investments in its FRONTLINE PLUS products, including developing its products through

research and development, marketing and establishing a strong brand, developing strong customer relationships, and remaining the exclusive supplier of the world's bestselling flea and tick treatment for dogs and cats.

36. To help protect its substantial investments, Merial has obtained patents, including the '329 Patent, that grant Merial the legal right to exclude others from using its inventions.

37. Ceva seeks to gain all the benefits of Merial's substantial investments in its flea and tick protection business, but pay none of the costs, by introducing infringing products into the marketplace. Ceva's attempt to "piggy-back" on Merial's substantial investments undermines the purpose of the patent laws of the United States, which allows Merial a period of exclusivity as an incentive to invest and innovate.

38. Ceva's infringement will inflict irreparable and irreversible harm, causing Merial to suffer lost market share, price erosion, and damage to the goodwill and reputation Merial has spent years and millions of dollars to establish. These losses are impossible to recapture and impossible to quantify and may affect sales and relationships relating to not only Merial's FRONTLINE PLUS products, but also other Merial products.

39. In view of Ceva's meaningful preparations to conduct infringing activities, and the concrete steps it has taken toward that end, there is a substantial and continuing justiciable controversy between Merial and HVG and Ceva France. Ceva's actions have created a reasonable apprehension in Merial of imminent and irreparable harm and loss.

40. In light of HVG's and Ceva France's concrete steps, meaningful preparations, and determination to register, offer to sell, and sell infringing flea and tick products in the United States, and their threats to attempt to invalidate the '329 Patent, there is a real and immediate

controversy between Merial and HVG and Ceva France concerning Ceva's infringement of the '329 Patent under 35 U.S.C. § 271.

COUNT I
(CLAIM FOR INFRINGEMENT OF THE '329 PATENT)

41. The allegations in Paragraphs 1 through 40 of this Complaint are incorporated by reference as if set forth in their entirety.

42. HVG and Ceva France have made meaningful preparations, either alone or in concert with others, to make, use, offer to sell, and/or sell within, or import into, the United States infringing generic FRONTLINE PLUS fipronil- and methoprene-containing spot-on flea and tick products. HVG's and Ceva France's making, using, offering to sell, or selling within, or importing into, the United States such products will infringe, contribute to the infringement of, and/or actively induce the infringement of one or more claims of the '329 Patent, including, but not limited to, Claims 1, 4, 26, 77, 85, 101, and 106-108.

43. Ceva France is also liable for any infringing activities of its wholly owned subsidiary, HVG.

44. HVG and Ceva France have had notice of the '329 Patent and their infringement of the '329 Patent will be deliberate and willful.

45. HVG's and Ceva France's planned infringing acts have not been authorized by Merial and will be in violation of Merial's rights in the '329 Patent.

46. As a direct result of HVG's and Ceva France's infringing acts, Merial will suffer both damages and irreparable harm.

47. Merial will have no adequate remedy at law for HVG's and Ceva France's infringing acts, and unless such infringing acts are enjoined by this Court, Merial will suffer damage and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Merial prays that the Court:

- (a) Enter a judgment that HVG's and Ceva France's planned generic FRONTLINE PLUS products infringe, either directly, by contribution and/or active inducement, one or more claims of the '329 Patent;
- (b) Preliminarily and permanently enjoin HVG and Ceva France—and those in privity or acting in concert with them—from making, using, offering to sell, or selling within, or importing into, the United States, the generic FRONTLINE PLUS products and all other products that are not more than colorably different therefrom;
- (c) Preliminary and permanently enjoin HVG and Ceva France and those in privity, or acting in concert, with them from further acts of direct infringement, contributory infringement and active inducement of infringement of the '329 Patent;
- (d) If necessary at some future date, award Merial damages in an amount adequate to compensate it for harm caused by HVG's and Ceva France's infringement of the '329 Patent, but in no event less than a reasonable royalty;
- (e) If necessary at some future date, award Merial pre-judgment and post judgment interest on the damages caused to it by reason of HVG's and Ceva France's infringement of the '329 Patent;
- (f) Declare that any infringement of the '329 Patent by HVG and Ceva France has been and is willful, and enter an Order trebling any damages awarded for that infringement;

- (g) Declare this to be an exceptional case pursuant to 35 U.S.C. § 285;
- (h) Award Merial its attorneys' fees, costs and expenses in this action; and
- (i) Award Merial such further relief as the Court deems just and proper.

JURY TRIAL DEMAND

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

Respectfully submitted, this 12th day of November, 2013.

Judy Jarecki-Black, Ph.D.
(judy.jarecki@merial.com)
Georgia Bar No. 801698
MERIAL LIMITED
3239 Satellite Blvd.
Duluth, Georgia 30096-4640
Tel.: (678) 638-3805
Fax: (678) 638-3350

J. Patrick Elsevier, Ph. D.
(jpelsevier@jonesday.com)
Georgia Bar No. 246694
JONES DAY
12265 El Camino Real
Suite 200
San Diego, California 92130-4096
Tel.: (858) 314-1200
Fax.: (858) 314-1150

s/ Matthew W. Howell
Edward D. Tolley
(etolley@mindspring.com)
Georgia Bar No. 714300
COOK, NOELL, TOLLEY & BATES, LLP
304 East Washington Street
P.O. Box 1927
Athens, GA 30603-1927
Tel.: (706) 549-6111
Fax: (706) 548-0956

Frank G. Smith, III
(frank.smith@alston.com)
Georgia Bar No. 657550
John W. Cox, Ph.D.
(john.cox@alston.com)
Georgia Bar No. 134059
Matthew W. Howell
(matthew.howell@alston.com)
Georgia Bar No. 607080
Pamela H. Councill
(pamela.councill@alston.com)
Georgia Bar No. 740490
ALSTON & BIRD LLP
One Atlantic Center
1201 West Peachtree Street
Atlanta, Georgia 30309-3424
Tel.: (404) 881-7000
Fax: (404) 881-7777

Counsel for Plaintiffs Merial Limited and Merial SAS

CERTIFICATE OF SERVICE

I hereby certify that on November 12, 2013, I electronically filed the foregoing pleading with the Clerk of Court using the CM/ECF system which will provide notification of this filing to all attorneys of record.

Joseph L. Waldrep
Neal J. Callahan
WALDREP, MULLIN & CALLAHAN LLC
P.O. Box 351
105 13th Street
Suite B
Columbus, GA 31902-0351
Tel: 706-320-0600
Email: jlw@waldrepmullin.com
Email: njc@waldrepmullin.com

Eric H. Weisblatt
Robert J. Scheffel
Matthew J. Dowd
WILEY REIN LLP
1776 K Street NW
Washington, DC 20006
Tel: (202) 719-7000
Email: eweisblatt@wileyrein.com
Email: rscheffel@wileyrein.com
Email: mdowd@wileyrein.com

This 12th day of November, 2013.

s/ Matthew W. Howell
Matthew W. Howell