IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON VALLEY GENERICS, INC., and CEVA SANTE ANIMALE S.A.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	**JURY TRIAL DEMANDED**
MERIAL LIMITED, MERIAL, LLC, and MERIAL S.A.S.	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY RELIEF

Plaintiffs Horizon Valley Generics, Inc. ("HVG") and Ceva Santé Animale S.A.("Ceva") file the following Complaint for Declaratory Relief against Defendants Merial Limited, Merial LLC, and Merial S.A.S. (collectively, "Merial") to seek a declaration that its fipronil-related product does not infringe any valid and enforceable claims of U.S. Patent No. 6,096,329 (the "'329 patent"). In support thereof, Plaintiffs hereby allege as follows:

THE PARTIES

1. Plaintiff Horizon Valley Generics, Inc. is a Delaware corporation. Its registered office in the State of Delaware is Corporation Trust Center, 1209 Orange Street, Wilmington, County of New Castle, Delaware, 19801.

2. HVG is a wholly owned subsidiary of Plaintiff Ceva Santé Animale S.A. ("Ceva"), a French corporation, with its principal place of business in Libourne, France.

3. On information and belief, Defendant 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 Defendant Merial LLC. On information and belief, Merial Limited's principal place of business is in Duluth, Georgia. On information and belief,

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

JURISDICTION AND VENUE

4. This is a civil action for declaratory relief under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338, because Plaintiffs' claims for declaratory relief arise under the patent laws of the United States, 35 U.S.C. §§ 101, *et seq*.

6. This Court has personal jurisdiction over Merial because, on information and belief, Merial is domesticated in Delaware, has designated an agent for service of process in Delaware, and does and has done business in this judicial district, including regularly doing or soliciting business, engaging in other persistent courses of conduct, and/or deriving substantial revenue from products and services to individuals and entities in this District, including without limitation offering for sale and selling the Frontline® series of products, which are purportedly covered by the patent-in-suit.

7. Venue is proper in this District pursuant to 28 U.S.C. § 1391(b) and (c).

GENERAL ALLEGATIONS

8. Plaintiff HVG is an animal health company that has, in conjunction with its parent Ceva, developed several fipronil-based flea and tick control products for the United States market. In particular, HVG filed an application at the Environmental Protection Agency to register two products containing fipronil and S-methoprene. Plaintiff Ceva is a global veterinary health company focused on the research, development, production, and marketing of pharmaceutical products and vaccines for pets, livestock, swine, and poultry.

9. Defendant Merial is a multi-billion dollar company that produces and sells animal health products for pets, livestock, and other wildlife, including Frontline® and Frontline Plus® products for elimination of fleas and ticks in pets. The active ingredient in Frontline® and Frontline Plus® products is fipronil.

10. According to Merial, aspects of Merial's Frontline Plus® products are covered by a portfolio of patents, including the '329 patent.

11. The '329 patent, entitled "Insecticidal Combination to Control Mammal Fleas, In Particular Fleas on Cats and Dogs," was issued on August 1, 2000 and subject to an Ex Parte Reexamination Certificate issued by the United States Patent and Trademark Office on October 4, 2011. Merial S.A.S. is the named assignee on the face of the '329 patent. On information and belief, Merial S.A.S., through a grant of an irrevocable exclusive right and license under the '329 patent, has granted Merial all substantial rights to enforce the '329 patent. A true and correct copy of the '329 patent is attached hereto as Exhibit A.

MERIAL'S HISTORY OF LITIGATING ITS FIPRONIL-RELATED PATENT RIGHTS

12. Merial has consistently and aggressively litigated or threatened to litigate its fipronil-related patent rights to stop perceived competitors from bringing to market, or even attempting to develop, products that could potentially compete with its Frontline® series of products. In the last several years alone, Merial has initiated at least five separate lawsuits in four different jurisdictions in the U.S. alleging infringement of its fipronil-related patent rights. *See, e.g.*, *BASF Agro B.V. and Merial Ltd. et al. v. CIPLA Ltd., et al.*, No. 07-125 (M.D. Ga. filed Nov. 13, 2007) (closed); *BASF Agro, Merial Ltd. et al. v. Humane Society of Inverness, Inc.*, No. 08-357 (M.D. Fla. filed Aug. 29, 2008) (closed); *Merial Ltd., BASF Agro et al. v. Virbac S.A. et*

al., No. 10-181 (N.D. Tex. filed Mar. 18, 2010) (dismissed); *BASF Agro, Merial Ltd. et al. v. Cheminova, Inc.*, No. 10-274 (M.D.N.C. filed Apr. 8, 2010) (closed).

13. For example, in late 2007, Merial, Merial S.A.S and BASF Agro sued a number of entities, including an Indian company CIPLA, in the Middle District of Georgia for allegedly infringing its rights in two fipronil-related patents, including the '329 patent. In its complaint, Merial asserted that its Frontline® Plus product is covered by the '329 patent, which Merial asserted "generally relates to formulations containing a compound that is a derivative of an n-phenylpyrazole, e.g., fipronil, and an insect growth regulator, e.g., methoprene." Merial asserted that CIPLA's "PROTEKTOR PLUS" animal-health products included a combination of fipronil and methoprene and therefore infringed the '329 patent. On March 6, 2008, Merial obtained a default judgment against CIPLA and several other defendants, as well as a permanent injunction preventing CIPLA from making, using, selling or offering to sell in the United States infringing products, importing infringing products into the United States, or inducing others to infringe the asserted patents, including the '329 patent.

14. On March 18, 2010, Merial and BASF Agro filed a patent infringement action in the Northern District of Texas against Virbac S.A., a French company, and its U.S. affiliate, after learning that Virbac had commissioned studies of fipronil-containing animal health compositions. Based only on what future uses Merial speculated Virbac might make of these studies, Merial sought a preliminary injunction to enjoin Virbac from ever using the data, even after the expiration of the asserted patent. Although the court rejected Merial's request for a preliminary injunction, Merial continued to pursue the litigation until Virbac filed a motion for summary judgment. Soon thereafter, the Court dismissed the parties' claims and defenses with prejudice pursuant to a stipulation of dismissal.

15. In another display of its litigiousness, Merial S.A.S. and BASF Agro sued the Humane Society of Inverness, Florida (the "Humane Society"). The Humane Society is a small non-profit animal rescue and adoption organization with a stated mission "to aid in the reduction of the suffering of unwanted animals through education and promoting responsible pet ownership." That lawsuit, filed in the Middle District of Florida, claimed that a fipronil-based animal health product made, used, offered for sale or sold by the Humane Society of Inverness infringed Merial's fipronil-related patent rights and various trademarks. Merial sought and obtained a permanent injunction against the Humane Society.

16. Moreover, Merial has already asserted some of its foreign fipronil-related patent rights against Ceva and another of Ceva's wholly-owned subsidiaries, Sespo Indústria e Comércio Ltd. On June 2, 2008, Merial Limited, Merial SAS, and Merial Santé Animal filed suit against Ceva and Sespo in São Paulo, Brazil, alleging that Sespo and Ceva's "FIPROLEX" fipronil-based animal-health product infringed Merial's Brazilian fipronil-related patent rights. *See Merial Ltd. et al. v. Sespo et al.*, Process No. 2008.154051-3 (19th Civil Court of the Circuit Court of São Paulo-SP, filed June 2, 2008). Merial sought an injunction against the manufacture, use, and/or sale of Sespo and Ceva's FIPROLEX product. The Brazilian litigation, which is still pending, is a further example of Merial's litigiousness and demonstrates Merial's determination to defend its fipronil-related patent rights against Ceva and/or its subsidiaries as well.

17. Merial also has made a number of affirmative public statements, as recently as mid-2011, that it intends to continue to litigate its fipronil-related patent rights with respect to products that could potentially compete with Frontline® Plus. For example, a June 14, 2011 press release quotes Merial's head of intellectual property as stating: "We plan to continue to

vigorously defend our patent rights." And in a June 30, 2011 press release, Merial stated that it "will continue to vigorously enforce its patents covering the Frontline Plus® products."

18. As to the '329 patent, Merial sued Velcera and Fidopharm in the Middle District of Georgia, alleging that the defendants had infringed the '329 patent by making, using, selling, or offering for sale fipronil-based animal health products. After a preliminary injunction was granted and appealed, the parties settled. Velcera/Fidopharm are not currently marketing a product licensed under the '329 patent.

19. Based on Merial's aggressive litigation history, its affirmative public statements of its intentions to "continue to vigorously enforce its patents," and the events described below, HVG and Ceva formed a reasonable belief that Merial would utilize the same aggressive litigation tactics against HVG and Ceva to prevent its entry into the market for fipronil-based animal health products. HVG's and Ceva's belief was fully justified given that Merial filed in December, 2012, and served in January, 2013, a declaratory judgment infringement action in the Middle District of Georgia against the wrong party – Ceva Animal Health LLC. Ceva Animal Health has moved to dismiss that improperly filed action.

HVG HAS DEVELOPED A FIPRONIL-METHOPRENE PRODUCT AND TAKEN CONCRETE STEPS TO ENTER THE U.S. MARKET

20. HVG, in conjunction with Ceva, developed a formulation for cats and dogs containing fipronil and (s)-methoprene ("fipronil/methoprene product") and recently completed concrete steps to introduce its fipronil/methoprene product into the U.S. market as a generic alternative to Merial's Frontline® Plus product.

21. On September 25, 2012, HVG filed the requisite applications with the EPA for its planned fipronil/methoprene animal health product. In conjunction with that approval, HVG

made the requisite offer to pay compensation to the original data submitter, Merial, on September 25, 2012.

22. HVG anticipates that it will begin importing and selling its fipronil/methoprene animal health product into the United States in the near future.

23. HVG and Ceva seek declaratory judgment that their fipronil/methoprene product identified in its application to the EPA does not infringe, either directly or indirectly, any valid and enforceable claim of the '329 patent.

HVG CONTACTED MERIAL TO RESOLVE ANY PERCEIVED ISSUES RELATED TO MERIAL'S FIPRONIL-RELATED PATENTS

24. On Monday, November 5, 2012, a representative for Ceva contacted Merial to initiate discussions to resolve any perceived issues related to Merial's '329 patent without litigation. Merial responded by agreeing to meet on December 6, 2012 at the offices of its counsel.

25. On the evening before the meeting, Merial filed a premature declaratory judgment complaint in the Middle District of Georgia, against Ceva Animal Health LLC ("CAH LLC") a party that is not responsible for any of the efforts of HVG and Ceva relating to the fipronil/methoprene product identified in its application to EPA. The filing of this action against the wrong entity, not naming HVG or Ceva, is an admission that there is no jurisdiction in Georgia with respect to the controversy between Merial and HVG and Ceva.

26. The complaint was served on January 8, 2013. In that complaint, Merial stated that it "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."

27. Given its assertions and actions, declaratory judgment jurisdiction exists over the dispute between Merial and HVG and Ceva in this district, not Georgia. HVG and Ceva are not

subject to personal jurisdiction in Georgia, and subject matter jurisdiction does not exist for Merial's complaint against CAH LLC.

28. Upon information and belief, Merial contends that each and every claim of the '329 patent is valid.

29. Plaintiffs' fipronil/methoprene product does not infringe, either directly or indirectly, any valid and enforceable claim of the '329 patent.

30. The '329 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

31. All of the circumstances described above, including: (a) Merial's demonstrated history of initiating infringement litigation against entities making preparations to enter the market for fipronil-based animal health products (including litigation involving the '329 patent); (b) Merial's explicit statements that it will "continue to vigorously enforce its patents"; (c) its refusal to license the '329 patent to HVG and Ceva; (d) Plaintiffs imminent entry into the market with their EPA-approved fipronil/methoprene product as a generic alternative to Merial's Frontline® Plus product; and (e) the filing and service of a declaratory judgment complaint against CAH LLC in Georgia, demonstrate that there is a substantial controversy between parties having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

COUNT I

DECLARATORY JUDGMENT OF INVALIDITY OR NONINFRINGEMENT OF THE '329 PATENT

1. Plaintiffs incorporate by reference the allegations set forth in paragraphs 1 through 31 of this Complaint as though fully set forth herein.

2. Upon information and belief, Merial S.A.S. claims to be the owner by assignment of all right, title, and interest in and to the '329 patent and, through a grant of an irrevocable exclusive right and license under the '329 patent, has granted to Merial all substantial rights to enforce the '329 patent.

3. The '329 patent is invalid for failure to satisfy one or more of the conditions of patentability set forth in Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112.

4. Plaintiffs' fipronil/methoprene product does not directly infringe any valid and enforceable claim of the '329 patent.

5. Plaintiffs have not induced, and do not now induce, infringement of any valid and enforceable claim of the '329 patent.

6. Plaintiffs have not contributorily infringed, and do not now contributorily infringe, any valid and enforceable claim of the '329 patent.

7. On information and belief, Merial contends that each and every claim of the '329 patent is valid.

8. An actual and justiciable case or controversy exists between Ceva and HVG and Merial as to whether Plaintiffs' fipronil/methoprene product infringes, either directly or indirectly, any valid and enforceable claims of the '329 patent, which requires a declaration of rights by this Court.

9. Plaintiffs are entitled to a judicial determination and declaration that one or more claims of the '329 patent is invalid and that Plaintiffs have not infringed, and are not infringing—either directly, indirectly, contributorily, by active inducement or otherwise—any valid and enforceable claim of the '329 patent.

WHEREFORE, Plaintiffs request that the Court enter a judgment in its favor and against Merial as follows:

1. The Court enter judgment that Plaintiffs' fipronil/methoprene product does not infringe any valid and enforceable claim of the '329 patent under 35 U.S.C. § 271(a), nor have Plaintiffs induced infringement under 35 U.S.C. § 271(b), or contributorily infringed under 35 U.S.C. § 271(c), any valid and enforceable claim of the '329 patent;

2. The Court enter judgment that the claims of the '329 patent are invalid;

3. The Court enjoin Merial, and its affiliates, subsidiaries, officers, directors, agents, counsel, servants, employees, and all persons in active concert or participation with any of them, from attempting to enforce the '329 Patent against Plaintiffs, or against their parent, subsidiaries, or customers, by reason of the sale or use of Plaintiffs' product;

4. Find this case to be an exceptional case pursuant to 35 U.S.C. § 285 and award Plaintiffs their attorneys' fees and expenses;

5. Award Plaintiffs their costs; and

6. Grant Plaintiffs such other and further relief as the Court deems just and proper.

JURY DEMAND

HGV and Ceva demand a jury trial on all issues so triable.

Respectfully submitted,

POTTER ANDERSON & CORROON LLP

By: */s/ Richard L. Horwitz*

Richard L. Horwitz (#2246)
David E. Moore (#3983)
Bindu A. Palapura (#5370)
Hercules Plaza 6th Floor
1313 N. Market Street
Wilmington, DE 19899
Tel: (302) 984-6000
rhorwitz@potteranderson.com
dmoore@potteranderson.com
bpalapura@potteranderson.com

Attorneys for Plaintiffs Horizon Valley Generics, Inc. and Ceva Santé Animale S.A.

OF COUNSEL:

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

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