

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

MERIAL LIMITED and MERIAL SAS,

Plaintiffs,

v.

VELCERA, INC. and FIDOPHARM,
INC.,

Defendants.

Civil Case No. 3:12-cv-75

JURY TRIAL DEMANDED

**COMPLAINT FOR PATENT INFRINGEMENT
AND DEMAND FOR JURY TRIAL**

Plaintiffs Merial Limited and Merial SAS (collectively, “Merial”), for their Complaint for Patent Infringement against Defendants Velcera, Inc. (“Velcera”) and FidoPharm, Inc. (“FidoPharm”) (collectively, “Defendants”) allege as follows:

NATURE OF ACTION

1. This is an action in which Merial seeks damages and injunctive relief under the patent laws of the United States, 35 U.S.C. § 1 et seq., for Defendants’ 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* 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. Merial has a significant presence in Athens, Georgia, including a substantial Research and Development facility located here which employs approximately 400 people, conducts testing, research and development, and regulatory licensing-related activities with regard to, among other projects, companion animal flea and tick control products, including those at issue in this case.

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. Velcera is incorporated under the laws of the State of Delaware and has a principal place of business at 777 Township Line Road, Suite 170, Yardley, Pennsylvania 19067.

6. FidoPharm is incorporated under the laws of the State of Delaware and has a principal place of business at 777 Township Line Road, Suite 170, Yardley, Pennsylvania 19067.

7. Defendants Velcera and FidoPharm were founded by former executives of Merial.

JURISDICTION AND VENUE

8. This is an action arising under the patent laws of the United States, Title 35 of the United States Code. This Court has subject matter jurisdiction under Title 28, United States Code, §§ 1331 and 1338(a).

9. Defendants have, directly and/or through their distribution network, including sales to nationwide retailers, placed flea and tick products sold under the brand name PetArmor Plus (*i.e.*, LC-2010-4 (PetArmor Plus for Dogs) and LC-2010-3 (PetArmor Plus for Cats)) and PetArmor within a stream of commerce directed at this Judicial District with the knowledge and

understanding that such products would be sold in the state of Georgia, and the Athens Division of this Judicial District.

10. In particular, Defendants previously sold within the United States, including the State of Georgia, and the Athens Division of this Judicial District, flea and tick products under the brand name PetArmor Plus that infringed the '329 Patent. Defendants sold infringing PetArmor Plus products from approximately April, 2011 until August 20, 2011, when they were enjoined from doing so by this Court in the litigation captioned *BASF Agro B.V. et al. v. Cipla Limited et al.*, No. 3:07-cv-00125-CDL (M.D. Ga.) (the "Prior Infringement Suit"). This Court's Order, which enjoined Defendants from selling flea and tick products under the brand name PetArmor Plus was affirmed by the United States Court of Appeals for the Federal Circuit on May 31, 2012.

11. On information and belief, Defendants will, on or about July 1, 2012, begin selling within the United States, including the State of Georgia, and the Athens Division of this Judicial District, infringing flea and tick products under the brand name PetArmor Plus, which are the subject of this lawsuit.

12. Defendants have purposefully availed themselves of benefits and protections of this Judicial District, and in particular this Court, with regard to PetArmor Plus on several occasions. First, on April 8, 2011, Velcera moved the Court to intervene in the related case captioned *BASF Agro B.V. et al., v. Cipla, et al.*, No. 3:07-cv-00125-CDL (the "2007 Patent Litigation") in order to "protect its interest in the millions of dollars of [PetArmor Plus] product that Merial is seeking to have seized, impounded and destroyed" (D.I. 26; D.I. 26-1 at 17). This Court granted Defendants' Motion to Intervene on April 19, 2011 (*see* Docket Text Entry (April 19, 2011)).

13. Second, Defendants again sought the benefits and protections of this Judicial District, and in particular this Court, with regard to PetArmor Plus when they asked for clarification of the Court's June 21, 2011 Order in the 2007 Patent Litigation as to whether the PetArmor Plus products that they intend to begin selling on or about July 1, 2012 would fall within the scope of the Court's June 21, 2011 Order.

14. This Court has personal jurisdiction over Defendants.

15. Venue is proper in this Court pursuant to at least Local Rule 3.4 and 28 U.S.C. §§ 1391(b) and (c) because Defendants are corporations that are deemed to reside in any judicial district in which they are subject to personal jurisdiction at the time the action is commenced. Defendants have continuously and systematically advertised, offered for sale, and sold PetArmor Plus in the Athens Division of this District, and it is believed that conduct will resume when Velcera re-launches PetArmor Plus on or about July 1, 2012. Under the Patent Act, an infringement claim arises where the sale of the infringing product occurs. It is believed that Defendants' products will be offered for sale at retail outlets in Athens, Georgia. Defendants' actions in the Athens Division of this Judicial District will cause substantial injury to Merial in the Athens Division of this Judicial District. Moreover, Defendants have previously consented to the jurisdiction and venue of this Court by voluntarily intervening in the related 2007 Patent Litigation.

16. 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, including its Research and Development facility located in Athens, Georgia.

UNDERLYING FACTS

A. Merial and Its '329 Patent.

17. 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.

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

19. Merial's FRONTLINE PLUS® products are covered by claims of the '329 Patent including, but not limited to, Claim 4 of the '329 Patent.

20. 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 and present infringement thereof.

21. The '329 Patent relates to pesticidal combinations to control fleas on mammals, such as cats and dogs. The pesticidal combinations are in the form of "spot-on" compositions. A "spot-on" composition is one that is applied to an animal by being deposited on a small, localized area of the animal's skin.

22. The '329 Patent teaches particularly effective spot-on compositions comprising as active ingredients the pesticides known as fipronil and methoprene. An active ingredient in a pesticidal product is an ingredient that kills or otherwise prevents, destroys, repels or mitigates the target pests.

23. Fipronil and methoprene are effective at different stages of an insect's life cycle, but both cause an insect's death. Fipronil is a pesticide that targets, and kills, adult fleas and ticks by interrupting their central nervous system. Methoprene, which is a type of a pesticide known as a juvenile hormone mimic, kills fleas and ticks by interrupting their maturation cycle and preventing them from reaching maturity or reproducing.

24. The fipronil and methoprene spot-on compositions claimed in the '329 Patent have a synergistic effect resulting in a higher level of pesticidal activity over a longer period of time than what would be expected from simply combining the two active ingredients. Such better than expected efficacy is known as a "synergistic" effect.

25. In addition to active ingredients, pesticidal products may contain inert ingredients called adjuvants. An adjuvant is a substance in a composition that is not itself an active ingredient, but that aids or increases the action of the active ingredients in some way. Adjuvants can be, for example, solvents, cosolvents, crystallization inhibitors, wetting agents, spreaders, emulsifiers, dispersing agents, solubilizers, stickers, and surfactants that are not intended to act directly against the target pests.

26. The '329 Patent identifies a number of categories of customary spot-on formulation adjuvants for use in the compositions claimed in the '329 Patent, such as organic solvents, organic cosolvents, and/or crystallization inhibitors.

B. Factual and Procedural Background to This Action.

27. In 2007, Cipla Limited ("Cipla"), an Indian pharmaceutical manufacturer, sold flea and tick products under Protektor and Protektor Plus brand names into the United States through internet retailers who specifically targeted the United States market for the Protektor and Protektor Plus products they received from Cipla.

28. Cipla's Protektor and Protektor Plus brand name veterinary products contained either 9.7% fipronil or both 9.7% fipronil and 11.8% methoprene as their active ingredients.

29. On November 13, 2007, Merial filed a complaint against Cipla and others for, *inter alia*, making, offering to sell, selling, causing to be sold, or causing the use of infringing veterinary products containing fipronil or containing fipronil and methoprene in violation of the '329 patent. In its Complaint, Merial alleged that Cipla had infringed the '329 patent by selling and offering to sell fipronil and methoprene containing products under the brand names Protektor and Protektor Plus to various internet retailers that targeted the sale of those products to customers in the United States.

30. Merial served Cipla with its Complaint on November 20, 2007; Cipla chose not to answer. Merial then moved for a default judgment, which this Court granted on March 6, 2008 (the "2008 Injunction").

31. The Court's 2008 Injunction adjudged and decreed that the '329 patent is valid and enforceable.

32. With respect to the '329 patent, the Court in its 2008 Injunction found that:

making, having made, using, causing to be used, selling, causing to be sold, offering for sale, and causing to be offered for sale in the United States and importing and causing to be imported into the United States of veterinary products that contain fipronil and methoprene, including but not limited to the veterinary products that contain fipronil and methoprene denominated CIPLA PROTEKTOR PLUS, infringe at least one claim of the '329 patent.

33. The Court's 2008 Injunction found that the named defendants, including Cipla, infringed the '329 patent. The Court's 2008 Injunction permanently enjoined Cipla, as well as those persons and entities in active concert with Cipla who have notice of the 2008 Injunction, from, *inter alia*, committing any act that infringes or causes or induces infringement of any claim of the '329 patent.

34. On, April 15, 2008, this Court formally entered the Default Judgment against Cipla and the other named defendants.

35. The original PetArmor Plus products were approved by the EPA on January 10, 2011. In their applications to the EPA for regulatory approval, Defendants described the PetArmor Plus brand products as substantially similar or identical to Merial's FRONTLINE PLUS® products.

36. On February 11, 2011, Velcera, without any warning to Merial, filed a Declaratory Judgment Action against Merial in the U.S. District Court for the District of Delaware. In that action, Velcera sought, *inter alia*, a declaration that certain animal health products, which combined fipronil and methoprene—and for which Velcera had, in early January 2011, secured approval from the EPA to sell in the U.S.—did not infringe the '329 Patent.

37. Defendants were aware of the '329 Patent and Merial's rights to the '329 Patent before they began importing into, and offering to sell and selling throughout, the United States, including in the State of Georgia and in the Athens Division of this Judicial District, the infringing PetArmor Plus brand products.

38. On March 28, 2011, after learning that Cipla was producing the PetArmor Plus products which Defendants intended to begin selling in the United States, Merial brought a motion for contempt against Cipla for violation of the 2008 Injunction. The contempt motion explained that Cipla, acting through LoradoChem, had registered with the EPA two veterinary products containing fipronil and methoprene, one for dogs and one for cats.

39. In its motion, Merial requested that the Court find Cipla in contempt of the 2008 Injunction by having made, used, caused to be used, sold, caused to be sold, offered for sale, or

caused to be offered for sale in the United States or importing or causing to be imported into the United States veterinary products that contain fipronil and methoprene.

40. On April 8, 2011, Defendants voluntarily moved to intervene in this case.

41. At some time prior to the commercial launch of PetArmor Plus during the week of April 11, 2011, Defendants, in violation of the 2008 Injunction, began importing into, and offering to sell and selling throughout, the United States, including in the State of Georgia and in the Athens Division of this Judicial District, spot-on compositions for the protection against fleas and ticks under the brand name PetArmor Plus that infringe one or more claims of the '329 Patent.

42. On April 18, 2011, Merial consented to Defendants' motion to intervene and filed an emergency motion to show cause as to why Defendants should not also be held in contempt in light of their aiding and abetting Cipla's sale of PetArmor Plus products in the United States retail market.

43. On April 19, 2011, the Court granted Defendants' motion to intervene and scheduled a hearing on Merial's contempt and show cause motions.

44. On May 16-17, 2011, the Court conducted an evidentiary hearing on Merial's contempt and show cause motions.

45. On May 17, 2011, Velcera's CEO testified before this Court that Defendants chose to copy the active ingredient combinations in Merial's FRONTLINE PLUS® products so that Defendants could apply for accelerated regulatory approval of the PetArmor Plus brand products from the EPA.

46. On May 17, 2011, Velcera's CEO testified before this Court that, if the '329 Patent was valid, the original PetArmor Plus products infringe that patent.

47. In the Federal Circuit's May 31, 2012, affirmance of this Court's June 21, 2011 Order, the Federal Circuit stated, with regard to that testimony, "[o]ne would be hard-pressed to conceive of more compelling testimonial evidence on infringement, particularly when those statements come from the defendant's chief executive regarding his own products." *Merial Ltd., et al., v. Cipla Ltd., et al.*, Nos. 2011-1471, -1472, 2012 WL 1948879, at *14 (Fed. Cir. May 31, 2012).

48. The infringing original PetArmor Plus brand products contain the same combinations of active ingredients that are present in Merial's FRONTLINE PLUS® products. In particular both Merial's FRONTLINE PLUS® for dogs and the PetArmor Plus brand products for dogs contain 9.8% Fipronil and 8.8% (S)-Methoprene. Likewise, both Merial's FRONTLINE PLUS® for cats and the PetArmor Plus brand products for cats contain 9.8% Fipronil and 11.8% (S)-Methoprene.

49. Defendants' original PetArmor Plus brand products also contain at least one customary spot-on formulation adjuvant as that term is used in the claims of the '329 Patent, including diethylene glycol monoethyl ether and ethanol, both of which are also used in Merial's FRONTLINE PLUS® products.

50. On June 6, 2011, the Court heard argument with regard to Merial's contempt and show cause motions.

51. On June 21, 2011, after a two day evidentiary hearing and another day of additional argument, the Court granted Merial's contempt and emergency show cause motions (the "2011 Injunction"). The Court found that Cipla violated the Court's 2008 Injunction and that Defendants acted in concert with Cipla in violation of that injunction.

52. In the 2011 Injunction, this Court also found that the original PetArmor Plus brand products infringe one or more claims of the '329 Patent. The Federal Circuit later affirmed that decision on May 31, 2012, holding this Court considered “evidence that PetArmor Plus contains precisely the same concentrations of fipronil and methoprene as Frontline Plus, and that those concentrations constitute synergistically effective amounts as recited in the claim.”

53. In the 2011 Injunction, this Court enjoined Defendants from certain activities with regard to products that infringe the '329 Patent, including PetArmor Plus. Specifically, this Court found that “Velcera acknowledges that PetArmor Plus infringes at least one claim of Merial’s '329 Patent The evidence supports no other conclusion.” Thus, this Court concluded:

that the PetArmor Plus product infringes the '329 Patent. . . . Velcera’s chief executive officer readily admitted at the hearing that if the '329 Patent is valid, then PetArmor Plus violates that Patent. To corroborate that evidence, Merial’s expert presented credible testimony that PetArmor Plus infringes Merial’s 329 Patent. As explained above, PetArmor Plus for cats contains 9.8% fipronil and 11.8% methoprene, and PetArmor Plus for dogs contains 9.8% fipronil and 8.8% methoprene, which are the same as the percentages in Frontline Plus—Merial’s product using the '329 Patent formulation. PetArmor Plus contains at least one customary spot on adjuvant. Velcera submitted “me too” applications with the EPA claiming PetArmor Plus is essentially the same as Frontline Plus. The Court concludes that PetArmor Plus continues to infringe the relevant claims of Merial’s '329 Patent.

54. This Court ordered that “Velcera is herewith permanently enjoined from selling, causing to be sold, offering for sale, and causing to be offered for sale in the United States veterinary products for which Cipla participated in the development, manufacture, and/or packaging, which products contain fipronil and methoprene, regardless of brand name, including but not limited to the veterinary products Protektor Plus, PetArmor Plus, TrustGard Plus, and Velcera Fipronil Plus.”

55. On June 24, 2011, Merial and Velcera submitted a stipulated briefing schedule as to whether the United States District Court for the District of Delaware should dismiss Velcera's Declaratory Judgment Complaint in light of the 2011 Injunction. That issue was briefed and, on August 3, 2011, the Delaware Court concluded that subject matter jurisdiction did not exist for claims related to the '329 Patent and the PetArmor Plus product, and dismissed the related claims of Velcera's Declaratory Judgment Complaint.

56. On December 27, 2011, Defendants, seeking to re-introduce the PetArmor Plus products (*i.e.* LC-2010-3 Fipronil and S-Methoprene for Cats and LC-2010-4 Fipronil and S-Methoprene for Dogs) to the United States market, filed a Motion for Clarification of the 2011 Injunction. Defendants, however, did not disclose to the Court or Merial the planned composition of the products for which it sought clarification. On March 22, 2012, this Court issued an Order holding that the meaning of the Court's 2011 Injunction was clear and declined to issue an advisory opinion as to whether Defendants' re-introduction of PetArmor Plus products would violate the Court's 2011 Injunction.

57. On December 27, 2011, Velcera, without any warning to Merial, filed a second Declaratory Judgment Action against Merial in the U.S. District Court for the District of Delaware. In that action, Velcera sought, *inter alia*, a declaration that the PetArmor Plus products that it intended to re-launch during the 2012 flea and tick season did not infringe Merial's '329 Patent. Merial moved to dismiss (or in the alternative, transfer to this Court) that Declaratory Judgment Complaint on the grounds that, at the time it was filed, Merial did not know the PetArmor Plus product with the minor formulation amendment existed, thus no case or controversy existed and the Delaware Court lacked subject matter jurisdiction.

58. On April 20, 2012, upon learning further details of the planned re-introduction of PetArmor Plus to the market, Merial filed a motion for an order to require Defendants to show cause as to why this Court should not find Defendants in contempt for violating this Court's 2008 and 2011 Injunctions by virtue of the planned re-launch of PetArmor Plus. Merial also filed a motion for a temporary restraining order to preclude Defendants from making, using, offering for sale, selling, causing to be sold, and otherwise launching in, as well as importing into, the United States PetArmor Plus, pending a ruling on the motion to show cause.

59. On May 4, 2012, this Court heard argument on various issues related to the pending motions for an order to show cause and for a temporary restraining order. On May 21-23, 2012, this Court held an evidentiary hearing on Merial's motions.

60. On May 31, 2012, the Federal Circuit affirmed this Court's 2011 Injunction, holding that this Court properly found Cipla and Defendants in contempt for its actions related to PetArmor Plus.

61. On June 5, 2012, this Court held that there was not clear and convincing evidence that Defendants were in contempt of this Court's 2008 or 2011 Injunctions by virtue of their activities related to the re-launch of PetArmor Plus.

62. In that Order, this Court stated that the "preferred mechanism for resolving the important issue that is at the bottom of this controversy" is that Merial file "an infringement action against Velcera if it believes the new product violates its patent."

63. On information and belief, beginning on or about July 1, 2012, Defendants will begin selling within the United States, including the State of Georgia, and the Athens Division of this Judicial District, infringing flea and tick products under the brand name PetArmor Plus, which are the subject of this lawsuit.

64. Like Merial's FRONTLINE PLUS® products, and like Defendants' infringing original PetArmor Plus brand products, Defendants' PetArmor Plus products with a minor formulation amendment contain the same combinations of active ingredients that are present in Merial's FRONTLINE PLUS® products. In particular, Merial's FRONTLINE PLUS® for dogs, the infringing original PetArmor Plus brand products for dogs, and the minor amended PetArmor Plus brand products for dogs all contain 9.8% Fipronil and 8.8% (S)-Methoprene. Likewise, Merial's FRONTLINE PLUS® for cats, the infringing original PetArmor Plus brand products for cats, and the minor amended PetArmor Plus brand products for cats all contain 9.8% Fipronil and 11.8% (S)-Methoprene.

65. The minor amended PetArmor Plus brand products also contain a number of customary spot-on formulation adjuvants, including diethylene glycol monoethyl ether and ethanol, both of which are specifically identified in the '329 Patent and were found in the infringing original PetArmor Plus products.

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

66. The allegations in Paragraphs 1 through 65 of this Complaint are incorporated by reference as if set forth in their entirety.

67. Defendants have infringed, contributed to the infringement of, and/or actively induced the infringement of one or more claims of the '329 Patent by the making, using, selling, and/or offering for sale within, or importing into, the United States fipronil and methoprene-containing spot-on flea and tick products under the brand name PetArmor Plus.

68. Defendants have had notice of the '329 Patent since at least late 2007 and their infringement of the '329 Patent has been deliberate and willful.

69. Defendants' infringing acts have not been authorized by Merial and are in violation of Merial's rights in the '329 Patent.

70. As a direct result of Defendants' infringing acts, Merial has suffered damages and irreparable harm.

71. Merial has no adequate remedy at law for Defendants' infringing acts, and unless such infringing acts are enjoined by this Court, Merial will suffer further damage and irreparable harm.

PRAYER FOR RELIEF

WHEREFORE, Merial prays that the Court:

- (a) Enter a judgment that Defendants have infringed, either directly, by contribution and/or active inducement, one or more claims of the '329 Patent;
- (b) Preliminarily and permanently enjoin Defendants and those in privity with them from making, using, offering to sell, or selling within the United States, or importing into the United States, the PetArmor Plus brand products and all other products that are not more than colorably different therefrom;
- (c) Preliminary and permanently enjoin Defendants and those in privity with them from further acts of direct infringement, contributory infringement and active inducement of infringement of the '329 Patent;
- (d) Award Merial damages adequate to compensate it for Defendants' infringement of the '329 Patent;
- (e) Declare that Defendants' infringement of the '329 Patent has been knowing and willful;

- (f) Treble the award of any damages pursuant to 35 U.S.C. § 284 and in view of the willful nature of Defendants' infringement of the '329 Patent;
- (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 pre-judgment and post-judgment interest, and 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 Complaint.

Respectfully submitted this 5th day of June, 2012.

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