

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FIDOPHARM, INC.,)	
)	
Plaintiffs,)	
)	
v.)	C.A. No. _____
)	
MERIAL LIMITED,)	
)	
Defendant.)	DEMAND FOR JURY TRIAL

COMPLAINT FOR DECLARATORY RELIEF

Plaintiff FidoPharm, Inc. (“FidoPharm”) files the following Complaint for Declaratory Relief against Merial Limited (“Merial”) to seek a declaration that its new product does not infringe any valid claims of U.S. Patent No. 6,096,329 (“the ‘329 patent”). In a prior case, this Court dismissed counts related to the ‘329 patent as moot in light of an injunction issued by the District Court for the Middle District of Georgia precluding FidoPharm from engaging in activities related to its then “current PetArmor Plus product.” (Civ. A. No. 11-134-GMS (D. Del.), D.I. 38 at 4 n.4.) Since the time of the dismissal in that case, FidoPharm has developed and obtained regulatory approval for a new fipronil and s-methoprene product to take the place of “PetArmor Plus,” the launch of which is imminent. In view of the parties’ history regarding the ‘329 patent and fipronil and s-methoprene products, and particularly Merial’s history of pursuing litigation to prevent competitors from reaching the market, FidoPharm seeks declaratory relief that its new product does not infringe any valid and enforceable claim of the ‘329 patent. In support thereof, FidoPharm alleges as follows:

THE PARTIES

1. Plaintiff FidoPharm is a Delaware corporation with its principal place of business in Yardley, Pennsylvania.

2. On information and belief, Defendant Merial is a company limited by shares registered in England and Wales with its registered office in England. Merial is domesticated in the State of Delaware as Merial LLC. Merial may be properly served through its domesticated agent, Merial, LLC. On information and belief, Merial's principal place of business is in Duluth, Georgia. Merial Limited and Merial LLC are referred to collectively as "Merial" herein.

JURISDICTION AND VENUE

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

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

5. 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 '329 patent.

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

GENERAL ALLEGATIONS

7. Plaintiff FidoPharm is a small, start-up company that seeks to provide high quality, affordable and more readily accessible pharmaceutical and parasiticide products for pets.

FidoPharm has developed several fipronil-based flea and tick control products for the retail over-the-counter and veterinary markets, including PetArmor® and PetArmor® Plus.

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

9. According to Merial, aspects of Merial's fipronil-containing animal health products are covered by a portfolio of patents, including the '329 patent.

10. 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 for the '329 patent 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

11. 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 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).

12. For example, on November 13, 2007, Merial, Merial S.A.S. and BASF Agro B.V. (“BASF Agro”) sued a number of entities, including an Indian company Cipla Limited (“Cipla”), in the Middle District of Georgia (No. 07-125) alleging infringement of its rights in two fipronil-related patents, including the ‘329 patent. In its complaint, Merial asserted that its FRONTLINE® PLUS products are 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 alleged “PROTEKTOR PLUS” animal-health products 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.

13. On March 18, 2010, Merial and BASF Agro filed a patent infringement action (No. 10-181) 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. On July 6, 2010, the court rejected Merial’s request for a preliminary injunction and Merial continued to pursue the litigation until after Virbac filed a motion for summary judgment when the parties reached a settlement

agreement. Soon thereafter on January 5, 2011, the Court dismissed the parties' claims and defenses with prejudice pursuant to a stipulation of dismissal.

14. On August 29, 2008, Merial, Merial S.A.S. and BASF Agro sued the Humane Society of Inverness, Florida (the "Humane Society") in the Middle District of Florida (No. 08-357). The Humane Society is known as 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 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 default judgment and permanent injunction against the Humane Society.

15. On April 8, 2010, Merial Limited's litigation partners, BASF Agro B.V., Arnhem (NL), Wadenswil Branch, and Bayer S.A.S (collectively, "BASF"), sued Cheminova, Inc. for patent infringement in the United States District Court for the Middle District of North Carolina (No. 10-274), alleging that Cheminova, Inc. infringes patents that purportedly cover methods and processes for using and manufacturing fipronil. On October 13, 2010, Merial Limited filed a motion to intervene and joined in the complaint as an exclusive licensee of patents allegedly infringed.

16. Most recently, on November 11, 2011, Merial commenced yet another litigation against Velcera, Inc. in the Middle District of Georgia alleging, among other things, trade dress infringement relating to its FRONTLINE® series of products. *See Merial Limited et al. v. Velcera, Inc. et al.*, 11-cv-157 (CDL).

17. Based on Merial's aggressive litigation history and on the events described below, Plaintiff has formed a reasonable belief that Merial will seek to utilize the same

aggressive litigation tactics against FidoPharm in an attempt to eliminate competition and prevent re-entry of FidoPharm's fipronil-based animal health products.

LITIGATION BETWEEN FIDOPHARM AND MERIAL REGARDING FIPRONIL-RELATED PATENTS INCLUDING THE '329 PATENT

18. Beginning in 2007, Velcera, Inc. ("Velcera"), recognized an opportunity to bring more affordable pet flea and tick treatments with greater consumer access to the market and began exploring possibilities for new fipronil-containing products.

19. Throughout 2007, Velcera developed a business plan to compete in the flea and tick control market. In the course of determining the regulatory pathway to market in the U.S., Velcera was introduced to OmniPharm Limited ("OmniPharm"), a British pharmaceutical company that was also exploring the market for fipronil-based animal health products.

20. In the course of developing its comprehensive business plan for selling fipronil-based animal health products to the U.S. market, Velcera established its wholly-owned subsidiary, FidoPharm, to carry out the business plan. Subsequently, FidoPharm entered into a license and development agreement with OmniPharm whereby OmniPharm and FidoPharm would develop and OmniPharm would exclusively license to FidoPharm proprietary formulations of fipronil and fipronil plus s-methoprene products for sale in the United States. FidoPharm then entered into a separate agreement with an Omnipharm affiliated entity, QEDetal Limited, to have FidoPharm's fipronil-containing products manufactured by Cipla to FidoPharm's specifications.

21. FidoPharm has developed several fipronil-based flea and tick control products for the retail over-the-counter and veterinary markets. For example, FidoPharm developed PetArmor®, a generic product to Merial's Frontline TopSpot®, and PetArmor® Plus, a generic combination product to Merial's Frontline® Plus.

22. Prior to launching PetArmor® Plus, on February 11, 2011, Velcera and FidoPharm filed a complaint for declaratory judgment against Merial in this Court (Civ. A. No. 11-134-GMS) (the “Delaware litigation”) seeking a declaration of non-infringement and invalidity as to the ‘329 Patent and two fipronil manufacturing patents. Merial answered the declaratory judgment action on March 7, 2011, and brought in an additional litigant, BASF Agro, the purported owner of the two process patents. Merial and BASF Agro asserted counterclaims of patent infringement of the same three patents, including the ‘329 Patent. In answering the complaint, Merial consented to the jurisdiction of this Court and admitted that Delaware was the appropriate venue for the parties to litigate their dispute over infringement of the ‘329 patent.

23. Shortly thereafter, on March 28, 2011, without notice to FidoPharm, Merial filed a motion in the Middle District of Georgia to show cause why Cipla should not be held in contempt of that Court’s March 6, 2008 Order granting a default judgment and permanent injunction against Cipla enjoining infringement of the ‘329 patent. Merial sought a permanent injunction against the making, using, selling, offering to sell, and importing into the United States of a variety of products, including FidoPharm’s PetArmor® Plus. *See BASF Agro B.V. et al. v. Cipla Limited et al.* (3:07-cv-125-CDL) (the “Georgia Action”). To protect its rights, FidoPharm filed a motion to intervene in the Georgia Action on April 8, 2011, which Merial did not oppose. Within days of FidoPharm intervening on April 18, 2011, Merial filed a motion to show cause against FidoPharm again seeking a permanent injunction against the making, using, selling, offering to sell, and importing into the United States a variety of products, including FidoPharm’s PetArmor® Plus.

24. FidoPharm launched PetArmor® Plus and PetArmor® in the United States in early April, 2011.

25. On June 21, 2011, the Georgia Court granted Merial's motions seeking contempt sanctions against Cipla, Velcera, and FidoPharm for violation of the Court's March 6, 2008 Order granting a default judgment and permanent injunction against Cipla. In doing so, the Georgia Court found that Velcera and FidoPharm had acted in concert with Cipla and that PetArmor® Plus was not more than colorably different than Cipla's product described in the Court's March 6, 2008 Order. The Georgia Court then entered a permanent injunction against Cipla prohibiting it, and those in active concert with it, from among other things, the making, using, selling, offering to sell, and importing into the United States a variety of fipronil and s-methoprene products, including FidoPharm's PetArmor® Plus. As to Velcera and FidoPharm, the Georgia Court specifically limited its order and injunction to specific fipronil and s-methoprene products "for which Cipla participated in the development, manufacture, and/or packaging." The Court stayed the order for 60 days.

26. Velcera and FidoPharm have complied with the Georgia Court's order and judgment, and as of August 19, 2011, stopped selling the enjoined PetArmor® Plus.

27. Shortly after entry of the Georgia Court's order and judgment on July 1, 2011, Merial filed a motion to dismiss the Delaware litigation (Civ. A. No. 11-134-GMS) involving the '329 Patent and the two fipronil manufacturing patents. Merial sought dismissal for lack of subject matter jurisdiction on the basis of the Georgia Court's permanent injunction imposed for violation of its 2008 order in relation to FidoPharm's PetArmor® Plus. On August 3, 2011, the Delaware Court granted Merial's motion as to the '329 Patent only, finding Velcera's and FidoPharm's allegations moot in light of the injunction by the Georgia Court that impacted FidoPharm's then current PetArmor® Plus. The Delaware Court specifically contemplated a case or controversy with respect to the '329 patent were Velcera and FidoPharm

to have a “new, non-enjoined product containing fipronil and methoprene.” The litigation involving the two fipronil patents is currently pending, but stayed.

FIDO PHARM DEVELOPED A NEW PET ARMOR® PLUS PRODUCT AND HAVE TAKEN CONCRETE STEPS TO RE-ENTER THE U.S. MARKET

28. Despite Merial’s aggressive efforts, FidoPharm remains committed to providing high quality, affordable and more readily accessible pharmaceutical and parasiticide products for pets. In furtherance of its objective, FidoPharm has recently completed numerous concrete steps completely independent of Cipla to introduce a new PetArmor® Plus formulation for cats and dogs containing fipronil and s-methoprene (hereinafter “New PetArmor® Plus”) into the U.S. market as a generic to Merial’s Frontline® Plus.

29. FidoPharm has taken substantial steps to modify their New PetArmor® Plus and have entirely removed Cipla from any involvement in the development, manufacture, packaging or sale of the new product. FidoPharm has developed “new, non-enjoined product[s] containing fipronil and [s-]methoprene” using a different manufacturing process. In the interests of ensuring absolute clarity, Plaintiff has filed on date even herewith, a Motion for Clarification with the Georgia Court to clarify that FidoPharm’s New PetArmor® Plus product falls outside the scope of the injunction.

30. FidoPharm received EPA approval for its New PetArmor® Plus formulation on September 20, 2011 and stands at the threshold of launching its new product into the market in the upcoming flea and tick season.

31. FidoPharm is poised to enter the U.S. market with its New PetArmor® Plus product.

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

33. Plaintiff's New PetArmor® Plus product does not infringe, either directly, by inducement, or contributorily, any valid and enforceable claim of the '329 patent.

34. 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 State Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and/or 112.

35. Given the above facts, including the contempt proceedings initiated by Merial against PetArmor® Plus, the counterclaim for infringement of the '329 patent asserted by Merial against FidoPharm in the Delaware litigation, Merial's demonstrated history of initiating infringement litigation against entities making preparations to enter the market for fipronil-based animal health products, including products combining fipronil and s-methoprene, and FidoPharm's imminent re-entry into the market with their New PetArmor® Plus approved by the EPA as a generic to Frontline® Plus, all of the circumstances 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 NON-INFRINGEMENT OF THE '329 PATENT

36. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 35 of this Complaint as though fully set forth herein.

37. Upon information and belief, Merial claims to be the owner by assignment of all right, title, and interest in and to the '329 Patent.

38. Plaintiff's New PetArmor® Plus product does not directly infringe any valid and enforceable claim of the '329 patent.

39. Plaintiff has not induced, and does not now induce, infringement of any valid and enforceable claim of the '329 patent.

40. Plaintiff has not contributorily infringed, and does not now contributorily infringe, any valid and enforceable claim of the '329 patent.

41. An actual and justiciable case or controversy exists between Plaintiff and Merial as to whether Plaintiff's New PetArmor® Plus product infringes the '329 patent, which requires a declaration of rights by this Court.

42. Plaintiff is entitled to a judicial determination and declaration that Plaintiff has not infringed and is not infringing, directly, indirectly, contributorily, by active inducement or otherwise, any valid and enforceable claim of the '329 Patent.

COUNT II
DECLARATORY JUDGMENT OF INVALIDITY OF THE '329 PATENT

43. Plaintiff incorporates by reference the allegations set forth in paragraphs 1 through 42 of this Complaint as though fully set forth herein.

44. Upon information and belief, Merial claims to be the owner by assignment of all right, title, and interest in and to the '329 Patent.

45. 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 State Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103 and/or 112.

46. An actual and justiciable case or controversy exists between Plaintiff and Merial concerning the invalidity of the '329 patent, which requires a declaration of rights by this Court.

47. Plaintiff is entitled to a judicial determination and declaration that one or more claims of the '329 patent is invalid.

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

- A. The Court enter judgment that Plaintiff's New PetArmor® Plus product does not infringe any valid and enforceable claim of the '329 patent under 35 U.S.C. § 271(a), nor has Plaintiff 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;
- B. The Court enter judgment that the claims of the '329 patent are invalid;
- C. 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 FidoPharm, or against its parent, subsidiaries or customers by reason of the sale or use of FidoPharm's New PetArmor® Plus product;
- D. Find this case to be an exceptional case pursuant to 35 U.S.C. § 285 and award Plaintiff its attorneys' fees and expenses;
- E. Award Plaintiff its costs; and
- F. Grant Plaintiff such other and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Plaintiff FidoPharm, Inc. hereby demands a trial by jury of all issues triable of right by a jury.

ASHBY & GEDDES

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