UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, *Plaintiff*, v. CLARIS LIFESCIENCES LTD. and CLARIS LIFESCIENCES INC., *Defendants*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius") brings this action for patent infringement against Defendants Claris Lifesciences Ltd. ("Claris Ltd.") and Claris Lifesciences Inc. ("Claris Inc.") (collectively, "Claris" or "Defendants").

1. This is an action by Fresenius against Defendants for infringement of United States Patent No. 8,476,010 ("the '010 patent"). This action arises out of Claris's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell generic versions of Diprivan®, an innovative intravenously administered sedative and anesthetic, prior to the expiration of the '010 patent.

THE PARTIES

Fresenius

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius Kabi USA, LLC was formerly known as APP Pharmaceuticals, LLC.

Defendants

3. Upon information and belief, Claris Ltd. is a corporation organized and existing under the laws of India, with its principal place of business at Nr. Parimal Crossing, Ellisbridge, Ahmedabad, 380006, India.

4. Upon information and belief, Claris Inc. is a corporation organized and existing under the laws of New Jersey with its principal place of business at 1445 US Highway 130, North Brunswick, NJ 08902.

5. Upon information and belief, Claris Inc. is a wholly-owned subsidiary of and is controlled by Claris Ltd.

6. Upon information and belief, both Claris Ltd. and Claris Inc. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 203421 (the "Claris ANDA").

JURISDICTION AND VENUE

Subject Matter Jurisdiction

7. This action for patent infringement arises under 35 U.S.C. § 271.

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction Over Defendants

9. Upon information and belief, this Court has personal jurisdiction over Claris Ltd.

10. Upon information and belief, Claris Ltd., through its wholly-owned subsidiary and agent Claris Inc., markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

11. Upon information and belief, Claris Ltd. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware, rendering it at home in Delaware.

12. Upon information and belief, Claris Ltd. routinely files ANDAs in the United States and markets a numerous generic injectable pharmaceutical products, including, *inter alia*, ciprofloxacin, fluconazole, furosemide, levofloxacin, metoprolol tartrate, metronidazole, norepinephrine bitartrate, and ondansetron hydrochloride.

13. Upon information and belief, Claris Ltd. has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of Delaware, including, *inter alia*, ciprofloxacin, fluconazole, furosemide, levofloxacin, metoprolol tartrate, metronidazole, norepinephrine bitartrate, and ondansetron hydrochloride.

14. Upon information and belief, Claris Ltd. has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Diprivan®, for sale and use throughout the United States, including the State of Delaware.

15. Upon information and belief, Claris Ltd. has applied for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including in Delaware.

16. On November 4, 2014, Claris Ltd. sent a letter to Fresenius, a Delaware Limited Liability Company, stating that it had filed ANDA No. 203421 seeking FDA approval to market a generic Diprivan® product prior to the expiration of the ’010 patent (the “Claris Notice Letter”).

17. Upon information and belief, Claris Ltd. will market, sell, and offer for sale its proposed generic version of Diprivan® in the State of Delaware following FDA approval of that product.

18. Upon information and belief, as a result of Claris Ltd.'s marketing, selling, or offering for sale of its generic version of Diprivan® in the State of Delaware, Fresenius will lose sales of Diprivan® and be injured in the State of Delaware.

19. Upon information and belief, Claris Ltd.'s systematic and continuous business contacts within Delaware render it at home in Delaware.

20. Upon information and belief, this Court has personal jurisdiction over Claris Ltd. for the reasons stated herein, including, *inter alia,* Claris Ltd.'s activities in the forum, activities directed at the forum, significant contacts with the forum, and consent, all of which render Claris Ltd. at home in the forum.

21. This Court also has personal jurisdiction over Claris Ltd. under Federal Rule of Civil Procedure 4(k)(2).

22. Upon information and belief, this Court has personal jurisdiction over Claris Inc.

23. Upon information and belief, Claris Inc., as an agent of Claris Ltd., markets, distributes and/or sells generic drugs throughout the United States and within the State of Delaware.

24. Upon information and belief, Claris Inc. has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of Delaware.

25. Upon information and belief, Claris Inc. collaborated and/or acted in concert with Claris Ltd. to apply for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including in Delaware.

26. Upon information and belief, Claris Inc. collaborated in the decision to send the Claris Notice Letter to Fresenius, a Delaware Limited Liability Company.

27. Upon information and belief, Claris Inc. will act as the agent of Claris Ltd. by marketing, selling, and/or offering for sale a generic version of Diprivan® in the State of Delaware on Claris Ltd.'s behalf following FDA approval of that product.

28. Upon information and belief, Claris Inc. has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Diprivan®, for sale and use throughout the United States, including the State of Delaware.

29. Upon information and belief, Claris Inc.'s systematic and continuous business contacts within Delaware render it at home in Delaware.

30. Upon information and belief, this Court has personal jurisdiction over Claris Inc. for the reasons stated herein, including by virtue of Claris Inc.'s activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Claris Inc. at home in the forum.

Venue

31. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and 1400(b).

BACKGROUND

The Patent-in-Suit: United States Patent No. 8,476,010

32. The ’010 patent, entitled “Propofol Formulations with Non-Reactive Container Closures,” was duly and lawfully issued on July 2, 2013 to inventors Neil P. Desai, Andrew Yang, and Sherry Xiaopei Ci. The named inventors assigned the ’010 patent to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC. Accordingly, Fresenius is the owner of all rights, title, and interest in the ’010 patent. The ’010 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “The Orange Book” (“Orange Book”) with respect to Diprivan®. The ’010 patent will expire on June 1, 2025. A true and accurate copy of the ’010 patent is attached hereto as Exhibit A.

The Diprivan® Drug Product

33. Fresenius currently sells, promotes, distributes, and markets Diprivan® (propofol) injectable emulsion in the United States.

34. Diprivan® is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

35. Fresenius holds an approved New Drug Application (“NDA”) No. 19627 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with the Diprivan® 1% (propofol) injectable emulsion product containing 10 mg propofol per 1 ml of emulsion.

The Claris ANDA

36. Claris filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation that Claris asserts is a generic copy of Diprivan® ("Claris's generic Diprivan® products") prior to the expiration of the '010 patent.

37. The FDA assigned the Claris ANDA the number 203421.

38. Claris filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '010 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Claris's generic Diprivan® products ("Claris's Paragraph IV Certification"). Claris notified Fresenius of this certification, in a letter dated November 4, 2014 sent by U.S. Mail.

39. In the Claris Notice Letter, Claris offered Fresenius confidential access to ANDA No. 203421 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The OCA provided by Claris contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order. For instance, the initial Claris OCA limited the number of Fresenius in-house counsel who could access the Claris ANDA and did not provide for access by in-house counsel's staff.

40. On November 10, 2014, Fresenius provided Claris with a revised draft of the OCA.

41. On November 21, 2014, Claris's counsel communicated to Teva that Claris would not consider Fresenius's proposed changes to the OCA.

42. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and Claris's refusal to negotiate regarding an OCA, Fresenius turns to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that Claris's generic Diprivan® products fall within the scope of one or more claims of the '010 patent.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY DEFENDANTS

43. The allegations of paragraphs 1-42 are realleged and incorporated herein by reference.

44. The use of Claris's generic Diprivan® products is covered by one or more claims of the '010 patent.

45. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Claris's generic Diprivan® products would infringe one or more claims of the '010 patent.

46. Defendants have infringed the '010 patent by submitting and maintaining the Claris ANDA before the FDA seeking approval to market Claris's generic Diprivan® products containing propofol before the expiration of the '010 patent.

47. Upon information and belief, Defendants acted in concert and actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of the Claris ANDA to the FDA.

48. Defendants induced the infringement of the ’010 patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of the Claris ANDA with the Paragraph IV Certification and in the preparation to sell Claris’s generic Diprivan® product in the United States.

49. Defendants were aware of the ’010 patent when engaging in these knowing and purposeful activities and were aware that filing the Claris ANDA with the Paragraph IV Certification with respect to the ’010 patent constituted an act of infringement of the ’010 patent.

50. Use of Claris’s generic Diprivan® products in accordance with and as directed by Claris’s proposed labeling for that product would infringe one or more claims of the ’010 patent.

51. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Claris’s generic Diprivan® products with its proposed labeling immediately and imminently upon approval of the Claris ANDA.

52. Upon information and belief, Defendants plan and intend to, and will, actively induce infringement of the ’010 patent when the Claris ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

53. Upon information and belief, Defendants know that Claris’s generic Diprivan® product and the proposed labeling for Claris’s generic Diprivan® product is especially made or adapted for use in infringing the ’010 patent and that Claris’s generic Diprivan® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the ’010 patent immediately and imminently upon approval of the Claris ANDA.

54. The foregoing actions by Defendants constitute and/or would constitute infringement of the ’010 patent, active inducement of infringement of the ’010 patent and/or contribution to the infringement by others of the ’010 patent.

55. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ’010 patent, actively inducing infringement of the ’010 patent, and/or contributing to the infringement by others of the ’010 patent.

56. Fresenius will be substantially and irreparably harmed by Defendants’ infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendants are not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Claris’s generic Diprivan® products.

57. Defendants’ activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that Defendants’ submission of Claris ANDA No. 203421 infringes one or more claims of the ’010 patent and that the making, using, offering to sell, or selling in the United States, or importing into the United States of Claris’s generic Diprivan® products prior to the expiration of the ’010 patent will infringe, actively induce infringement, and/or contribute to the infringement of one or more claims of the patent;

b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Claris ANDA No. 203421 seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10mg propofol per 1 ml of emulsion formulation, or any product or compound the use of which infringes the ’010 patent, shall be a date that is not earlier than the expiration of the patent;

c. An Order permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Claris’s generic Diprivan® products, or any other product or compound the use of which infringes the ’010 patent, or inducing or contributing to the infringement of the ’010 patent until after the expiration of the patent;

d. An Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of the Claris ANDA No. 203421 before the expiration of the ’010 patent;

e. An award of Plaintiff’s damages or other monetary relief to compensate Plaintiff if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ generic Diprivan® products, or any product or compound the use of which infringes the ’010 patent, or the inducement or contribution of the foregoing, prior to the expiration of the patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. A judgment that this is an exceptional case and awarding Plaintiff its attorneys’ fees under 35 U.S.C. § 285;

g. An award of Plaintiff’s reasonable costs and expenses in this action; and

h. An award of any further and additional relief to Plaintiff as this Court deems just and proper.

Dated: December 19, 2014

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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