UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF WEST VIRGINIA

FRESENIUS KABI USA, LLC,

Plaintiff,

v.

AGILA SPECIALITIES PRIVATE LTD. and MYLAN INC.,

Defendants.

Civil Action No. 1:14-CV-205

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius") brings this action for patent infringement against Defendants Agila Specialties Private Ltd. ("Agila") and Mylan, Inc. ("Mylan") (collectively, "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 Defendants' 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, Defendant Agila is a corporation organized and existing under the laws of India, with its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

4. Upon information and belief, Mylan is a corporation organized and existing under the laws of Pennsylvania with its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317.

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

6. Upon information and belief, both Agila and Mylan submitted, collaborated and/or acted in concert in the preparation or submission of ANDA No. 206016 (the "Agila 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 Agila.

10. Upon information and belief, Agila maintains its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

11. Agila identified its location as 781 Chestnut Ridge Road, Morgantown, West Virginia 26505 in the letter and offer of confidential access it sent notifying Fresenius of Agila's certification regarding the '010 patent under 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

12. Upon information and belief, Agila and its agents market, distribute and/or sell generic drugs throughout the United States and within the State of West Virginia.

13. Upon information and belief, Agila and its agents have engaged in and maintained systematic and continuous business contacts within the State of West Virginia, and have purposefully availed themselves of the benefits and protections of the laws of West Virginia, rendering it at home in West Virginia.

14. Upon information and belief, Agila routinely files ANDAs in the United States and markets a numerous generic injectable pharmaceutical products, including, *inter alia*, adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid.

15. Upon information and belief, Agila has agreements with pharmaceutical retailers, wholesalers or distributors providing for the distribution of its products in the State of West Virginia, including, *inter alia*, adenosine, ampicillin sodium, dexamethasone sodium phosphate, doxycycline hyclate, etomidate, famotidine, flumazenil, haloperidol lactate, lidocaine hydrochloride, nafcillin sodium, rifampin, vancomycin hydrochloride, and zoledronic acid.

16. Upon information and belief, Agila 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 West Virginia.

17. Upon information and belief, Agila has applied for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including in West Virginia.

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

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

20. This Court also has personal jurisdiction over Agila under Federal Rule of Civil Procedure 4(k)(2).

21. Upon information and belief, this Court has personal jurisdiction over Mylan.

22. Upon information and belief, Mylan is registered with the West Virginia Secretary of State to do business as a foreign corporation in West Virginia and due to this registration, has authorized the West Virginia Secretary of State to accept service on its behalf.

23. Upon information and belief, Mylan has also authorized Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302 to accept service on its behalf.

24. Upon information and belief, Mylan maintains significant production and distribution sites in Morgantown, West Virginia and considers Morgantown, West Virginia the location of one of its global R&D centers of excellence.

25. Upon information and belief, Mylan's wholly-owned subsidiary, Mylan Pharmaceuticals Inc., is incorporated in and maintains its principal place of business in the State of West Virginia.

26. Upon information and belief, Mylan (through its wholly-owned subsidiaries including Mylan Pharmaceuticals Inc. and Agila Specialties Pharmaceuticals Ltd.) markets, distributes and/or sells generic drugs throughout the United States and within the State of West Virginia.

27. Upon information and belief, Mylan has engaged in and maintained systematic and continuous business contacts within the State of West Virginia, and has purposefully availed itself of the benefits and protections of the laws of West Virginia.

28. Upon information and belief, Mylan has collaborated and/or acted in concert with Agila to apply for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including in West Virginia.

29. Upon information and belief, as a result of Mylan's conduct, Agila will market, sell, and offer for sale its generic version of Diprivan® in the State of West Virginia following FDA approval of that product.

30. Upon information and belief, Mylan 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 West Virginia.

31. Upon information and belief, this Court also has personal jurisdiction over Mylan because it previously has been sued in this district without challenging this Court's assertion of personal jurisdiction over it, has admitted that Mylan has previously consented to personal

jurisdiction in this District, and has availed itself of this forum by asserting counterclaims for the purpose of litigating a patent infringement dispute. *See, e.g., Novartis Pharmaceuticals Corp. et al. v. Mylan Pharmaceuticals Inc. et al.*, 11-00015 (N.D.W.Va.); *Shire LLC et al v. Mylan Pharmaceuticals Inc. et al.*, 11-00201 (N.D.W.Va.).

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

Venue

33. 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

34. 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

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

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

37. 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 Agila ANDA

38. Defendants 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, in 20 mL, 50 mL and 100 mL vials, that Defendants assert is a generic copy of Diprivan® ("Agila's generic Diprivan® products") prior to the expiration of the '010 patent.

39. The FDA assigned the Agila ANDA the number 206016.

40. Defendants 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 Agila's generic Diprivan® products ("Agila's Paragraph IV Certification"). Agila notified Fresenius of this certification, in a letter dated October 14, 2014 sent by U.S. Mail ("Agila Notice Letter").

41. In the Agila Notice Letter, Agila offered Fresenius confidential access to ANDA No. 206016 on terms and conditions set forth in an attached "Offer of Confidential Access" ("OCA"). The OCA provided by Agila contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order. For instance, the initial Agila OCA barred Fresenius in-house counsel from access to the Agila ANDA.

42. On October 27, 2014, Fresenius provided Agila with a revised draft of the OCA but has yet to receive a response from Agila.

43. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and due to the lack of response from Agila to date, 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 Agila'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

44. The allegations of paragraphs 1-36 are realleged and incorporated herein by reference.

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

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

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

48. 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 Agila ANDA to the FDA.

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

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

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

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

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

54. Upon information and belief, Defendants know that Agila's generic Diprivan® product and the proposed labeling for Agila's generic Diprivan® product is especially made or adapted for use in infringing the '010 patent and that Agila'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 Agila ANDA.

55. 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.

56. 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.

57. 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 Agila's generic Diprivan® products.

58. 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 Agila ANDA No. 206016 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 Agila'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 Agila ANDA No. 206016 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, in 20 mL, 50 mL and 100 mL vials, 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 Agila'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 Agila ANDA No. 206016 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: November 26, 2014

Respectfully submitted,

SCHRADER BYRD & COMPANION, PLLC

/s/ James F. Companion

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