UNITED STATES DISTRICT COURT
DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, *Plaintiff*, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., *Defendants*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius") brings this action for patent infringement against Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively and/or individually "DRL").

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 DRL'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 ("APP").

DRL

3. Upon information and belief, Defendant Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, 500034, India.

4. Upon information and belief, Defendant Dr. Reddy's Laboratories, Inc. ("DRL Inc.") is a New Jersey corporation with its principal place of business at 200 Somerset Corporate Boulevard, Building II, 7th Floor, Bridgewater, NJ 08807.

5. On information and belief, Defendant Dr. Reddy's Inc. is a wholly-owned subsidiary of Dr. Reddy's Ltd., and is controlled by Dr. Reddy's Ltd.

6. On information and belief, both DRL Inc. and DRL Ltd. submitted, collaborated and/or acted in concert in the preparation or submission of ANDA Number 205067 ("DRL 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 DRL

9. Upon information and belief, this Court has personal jurisdiction over DRL, at least because DRL has engaged in continuous and systematic contacts with Delaware and/or purposefully availed itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, DRL's pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

10. Further, DRL has previously admitted in *Merck & Co., Inc. v. Dr. Reddy's Labs, Ltd.*, Mo. 04-1313 (GMS) that due to their many contacts with Delaware they were "subject to personal jurisdiction in this judicial district."

Venue

11. 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

12. 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

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

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

15. 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 DRL ANDA

16. DRL 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 that DRL asserts is a generic copy of Diprivan® ("DRL's generic Diprivan® product") prior to the expiration of the '010 patent.

17. The FDA assigned the DRL ANDA number 205067.

18. By letter dated April 11, 2013, DRL notified Fresenius that it had filed an ANDA seeking approval to market DRL's generic Diprivan® product prior to the patents then listed in the Orange Book ("DRL Notice Letter").

19. The '010 patent had not issued at the time DRL submitted its certification under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act.

20. DRL is required to amend the patent certification in its ANDA to address the '010 patent prior to approval of its ANDA but, on information and belief, has yet to do so. Despite

repeated requests by Plaintiff's counsel, DRL has, to date, refused to disclose whether it will submit a Paragraph IV certification as to the ’010 patent.

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

21. The allegations of paragraphs 1-20 are realleged and incorporated herein by reference.

22. The use of DRL’s generic Diprivan® product is covered by one or more claims of the ’010 patent.

23. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL’s generic Diprivan® product would infringe one or more claims of the ’010 patent.

24. DRL has infringed the ’010 patent by submitting the DRL ANDA to the FDA seeking approval to market DRL’s generic Diprivan® product containing propofol before the expiration of the ’010 patent.

25. Upon information and belief, Defendants DRL Inc. and DRL Ltd. 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 of the DRL ANDA to the FDA.

26. Defendants DRL Inc. and DRL Ltd. induced the infringement of the ’010 patent by actively and knowingly aiding and abetting the preparation and submission of the DRL ANDA and in the preparation to sell DRL’s generic Diprivan® product in the United States.

27. Upon information and belief, DRL was aware of the ’010 patent when engaging in these knowing and purposeful activities and was aware that filing the DRL ANDA constituted an act of infringement of the ’010 patent.

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

29. Upon information and belief, DRL intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of DRL's generic Diprivan® product with its proposed labeling immediately and imminently upon approval of the DRL ANDA.

30. Upon information and belief, DRL plans and intends to, and will, actively induce infringement of the '010 patent when the DRL ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

31. Upon information and belief, DRL knows that DRL's generic Diprivan® product and the proposed labeling for DRL's generic Diprivan® product is especially made or adapted for use in infringing the '010 patent and that DRL's generic Diprivan® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, DRL plans and intends to, and will, contribute to the infringement of the '010 patent immediately and imminently upon approval of the DRL ANDA.

32. The foregoing actions by DRL 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.

33. Upon information and belief, DRL acted without a reasonable basis for believing that it 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.

34. Fresenius will be substantially and irreparably harmed by DRL's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at

law if DRL is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of DRL's generic Diprivan® product.

35. DRL's activities render this case an exceptional one, and Fresenius is entitled to an award of their reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that DRL's submission of the DRL ANDA No. 205067 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 DRL's generic Diprivan® product 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 DRL ANDA No. 205067 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 DRL's generic Diprivan® product, 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 patents 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 DRL ANDA No. 205067 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® product, 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: February 6, 2014

Respectfully submitted,

FARNAN LLP

/s/ Brian E. Farnan

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