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.

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