IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

DR. REDDY'S LABORATORIES, INC., and DR. REDDY'S LABORATORIES, LTD., Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	:	Case No. _____

DR. REDDY'S LABORATORIES, LTD.'S AND
DR. REDDY'S LABORATORIES, INC.'S
COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") for their Complaint against Fresenius Kabi USA, LLC. ("Fresenius") allege as follows:

PARTIES

1. Plaintiff Dr. Reddy's Laboratories, Ltd. is an Indian corporation, with its principal place of business at Door No 8-2-337, Road No 3, Banjara Hills, Hyderabad - 500034, Andhra Pradesh, India.

2. Plaintiff Dr. Reddy's Laboratories, Inc. is a New Jersey corporation, with its principal place of business at 107 College Road East, Princeton, NJ 08540.

3. Upon information and belief, Defendant Fresenius Kabi USA, LLC. ("Fresenius") is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

JURISDICTION AND VENUE

4. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-3.

5. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA, 28 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5).

6. A substantial, present, genuine and justiciable controversy exists between DRL and Fresenius with respect to United States Patent No. 8,476,010 ("the '010 patent").

7. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the '010 patent.

8. This Court can and should declare the rights and legal relations of the parties regarding the '010 patent pursuant to, *inter alia*, the United States Patent Act, 35 U.S.C. §§ 1 *et seq*. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has personal jurisdiction over Fresenius, *inter alia*, because of Fresenius's continuous and systematic contacts with the State of Delaware, including its conducting of substantial and regular business therein through the marketing and sales of its pharmaceutical products in Delaware, and because Fresenius has availed itself of the jurisdiction of this Court by initiating litigation in this District. *See, e.g., Fresenius Kabi, USA, LLC v. Dr. Reddy's Laboratories, Ltd., et. al*, No. 1:13-cv-925-RGA, filed June 10, 2013; *Fresenius Kabi, USA, LLC v. Dr. Reddy's Laboratories, Ltd., et. al*, No. 1:14-cv-160-RGA, filed February 6, 2014.

10. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(b) and (c) and/or 1400(b).

BACKGROUND

11. Upon information and belief, Fresenius is the holder of approved New Drug Application ("NDA") No. 19627, and markets Diprivan®, known generically as propofol injectable emulsion product containing 10 mg propofol per 1 ml of emulsion, throughout the United States pursuant to NDA No. 19627.

12. Upon information and belief, Fresenius owns United States Patent No. 8,476,010 ("the '010 patent"). By virtue of patent information that Fresenius submitted to United States Food and Drug Administration ("FDA") in connection with NDA No. 19627, the '010 patent is listed in FDA's compilation of approved drugs and their respective patents entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

13. Upon information and belief, the '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures", issued on July 2, 2013 to Fresenius.

14. Upon information and belief, Fresenius also owns United States Patent Nos. 5,714,520 ("the '520 patent"), 5,731,355 ("the '355 patent"), 5,731,356 ("the '356 patent"), and 5,908,869 ("the '869 patent"), which are also listed in the Orange Book.

15. DRL filed an Abbreviated New Drug Application ("ANDA") with the FDA to sell a generic version of Fresenius's propofol injectable emulsion containing 10 mg propofol per 1 ml of the emulsion, marketed by Fresenius under the name Diprivan®. The ANDA number is 205067.

16. In conjunction with the filing of ANDA no. 205067, DRL filed "Paragraph IV certifications" with respect to each of the patents which were then listed in the "the "Orange Book," with respect to Fresenius's Diprivan®. Those patents are United States Patent Nos. 5,714,520 ("the '520 patent"), 5,731,355 ("the '355 patent"), 5,731,356 ("the '356 patent"), and 5,908,869 ("the '869 patent"). The '520, '355, '356, and '869 patents, each of which will expire on September 22, 2015, are still listed in the Orange Book.

17. DRL amended its ANDA No. 205067 to include a Paragraph IV certification for the '010 patent after the '010 patent issued on July 2, 2013 and was subsequently listed in the Orange Book for Diprivan®.

18. DRL filed ANDA No. 205067 to obtain FDA approval to engage in the commercial manufacture, use, and sale of DRL's propofol injectable emulsion product prior to expiration of the '520, '355, '356, '869, and '010 patents.

19. Fresenius brought a patent infringement action against DRL in this Court on May 23, 2013, asserting infringement of the '520, '355, '356, and '869 patents listed in the Orange Book under Fresenius' Diprivan® (Civil Action No. 1:13-cv-00925).

20. This Court issued a decision and final judgment dated September 8, 2014 after trial that DRL's proposed propofol injectable emulsion product according to ANDA No. 205067 does not infringe the '520, '355, '356, and '869 patents. Fresenius did not appeal that decision with the United States Court of Appeals for the Federal Circuit.

21. After the '010 patent issued and was subsequently listed in the Orange Book, Fresenius brought a separate patent infringement action against DRL in this Court asserting infringement of the '010 patent (Civil Action No. 1:14-cv-00160, "the DRL '010 Patent Case") on February 6, 2014.

22. DRL counterclaimed in the DRL '010 Patent Case for a declaratory judgment that the '010 patent is either invalid and/or DRL will not infringe the '010 patent. Fresenius admitted that this Court has subject matter jurisdiction over DRL's declaratory judgment action in the DRL '010 Patent Case.

23. On March 3, 2015, the DRL '010 Patent Case was dismissed without prejudice.

The Hatch-Waxman Regulatory Framework

24. The Hatch-Waxman Act provides that the first applicant to file a substantially complete ANDA containing a Paragraph IV certification to a listed patent will be eligible for a 180-day period of marketing exclusivity beginning on the earlier of the date it begins commercial marketing of its generic drug product, or from the date of a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken.

25. These two events - first commercial marketing and a court decision - are often called "triggering events" because they trigger the beginning of the 180-day exclusivity.

26. The 180-day exclusivity period will begin to run when any ANDA applicant obtains a court decision of invalidity, unenforceability or non-infringement, even if the first-filer has not yet received approval for its ANDA, or before the first-filer has begun commercial marketing of its ANDA product.

27. Conversely, if there is no court decision on an Orange Book-listed patent and the first-filer does not begin commercial marketing of the generic drug, there may be prolonged delays in the beginning of the first applicant's 180-day exclusivity period. Because the FDA cannot statutorily approve any subsequently-submitted ANDAs for the same drug until this 180-day exclusivity period has expired, subsequent ANDA-filers have a strong economic incentive to generate a triggering event allowing the FDA to approve their ANDAs immediately following

the expiration of the first-filer's exclusivity. Without a triggering event, no subsequent Paragraph IV filer's ANDA can be approved until the first-filer's exclusivity has expired.

28. On information and belief, another ANDA filer was the first ANDA filer that filed a Paragraph IV certification with respect to the '010 patent for a 10 mg/ml propofol injectable emulsion, and thus and is entitled to a 180-day period of marketing exclusivity with respect to the '010 patent. DRL was thus not the first generic drug manufacturer to file an ANDA containing a Paragraph IV certification to the '010 patent for the 10 mg/ml propofol injectable emulsion.

29. On information and belief, to date the FDA has not granted final approval to the ANDA filer who was the first to file a Paragraph IV certification with respect to the '010 patent.

30. To date the FDA has not approved DRL's ANDA No. 205067 for its generic propofol injectable emulsion product. Notwithstanding the prior dismissal of the DRL '010 Patent Case without prejudice, DRL's ANDA for its propofol injectable emulsion product is not eligible for final approval until the date that is 180 days after the earlier of 1) the start of commercial marketing of the blocking ANDA product or 2) a final decision of a court from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken holding that the '010 patent is invalid, unenforceable, or not infringed.

31. As a result of the non-launch of the blocking applicant's ANDA product, DRL cannot obtain final FDA approval and cannot market its ANDA product.

32. DRL is not only entitled to bring and maintain this lawsuit, but requires a Court decision to avoid a lengthy delay in the approval of its ANDA No. 205067 notwithstanding that its ANDA product does not infringe any claim of the '010 patent.

33. Moreover, unless DRL obtains a court order finding the '010 patent not infringed, invalid, or unenforceable, DRL will be harmed by the inability to market its generic product. A declaratory judgment from this Court as to the non-infringement of the '010 patent will alleviate DRL's harm by allowing DRL to obtain final approval of its ANDA product and compete in the market for propofol injectable emulsion product.

34. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between DRL and Fresenius regarding the infringement of the '010 patent over which this Court can and should exercise jurisdiction and declare the rights of the parties.

35. DRL is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of DRL's proposed propofol injectable emulsion product does not and will not infringe any claim of the '010 patent.

36. Absent the exercise of jurisdiction by this Court and such declaratory relief, DRL will be harmed by the substantial delay in its market entry for generic Diprivan®.

THE '010 PATENT

37. The '010 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") as covering propofol injectable emulsion, which is marketed by Fresenius under the brand name Diprivan®.

38. The '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures" issued on July 2, 2013. Upon information and belief, Fresenius is the owner of the '010 patent. The '010 patent is currently listed in the Orange Book for Diprivan®. The '010 patent is listed in the Orange Book as expiring on June 1, 2025 with pediatric exclusivity.

COUNT I
DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '010 PATENT

39. DRL realleges and incorporates by reference each of the allegations of paragraphs 1-38.

40. There is an actual and justiciable controversy between the parties concerning whether the manufacture, use, offering for sale, or importation of the propofol injectable emulsion product that is the subject of ANDA No. 205067 will infringe the '010 patent.

41. DRL's commercial manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 205067 will not infringe any of the claims of the '010 patent, either literally or under the doctrine of equivalents.

42. DRL is entitled to a judicial declaration that it has not infringed and does not infringe directly, by inducement, or by contribution of any claim of the '010 patent.

PRAYER FOR RELIEF

WHEREFORE, DRL respectfully requests the Court enter judgment and Order in its favor and against Fresenius a declaration that DRL's manufacture, use, offer for sale, sale or importation of the products covered by ANDA No. 205067 will not infringe the claims of U.S. Patent No. 8,476,010.

August 18, 2015

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