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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

SANTARUS, INC., and THE CURATORS OF THE UNIVERSITY OF MISSOURI, Plaintiffs, v. DR. REDDY'S LABORATORIES INC., and DR. REDDY'S LABORATORIES, LTD. Defendants.	Civil Action No.: _____ ***Document Electronically Filed***

COMPLAINT FOR PATENT INFRINGEMENT

Santarus, Inc. ("Santarus") and The Curators of the University of Missouri (the "University") (collectively "Plaintiffs") hereby assert the following claims for patent

infringement against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "DRL"), and allege as follows:

THE PARTIES

1. Santarus is a corporation organized and existing under the laws of Delaware, having a principal place of business at 3721 Valley Centre Drive, Suite 400, San Diego, California 92130.

2. The University is a public corporation and body politic, an arm or instrumentality of state government in the state of Missouri, having a place of business at 321 University Hall, Columbia, Missouri 65211.

3. On information and belief, Dr. Reddy's Laboratories, Inc. is a corporation organized and existing under the laws of New Jersey with a principal place of business at 200 Somerset Corporate Boulevard (Bldg. II), Bridgewater, New Jersey 08807. On information and belief, Dr. Reddy's Laboratories, Inc. is engaged in the manufacturing, marketing and sale of generic pharmaceutical products in the United States, including in the District of New Jersey, and conducts business throughout the United States.

4. On information and belief, Dr. Reddy's Laboratories, Ltd. is a corporation organized and existing under the laws of India with a principal place of business in Hyderabad, Andhra Pradesh, India. On information and belief, Dr. Reddy's Laboratories, Ltd. is engaged in the manufacturing, marketing and sale of generic pharmaceutical products in the United States, including in the District of New Jersey, and conducts business throughout the United States, including, without limitation, via its New Jersey subsidiary Dr. Reddy's Laboratories, Inc.

NATURE OF THE ACTION

5. This is a civil action for the infringement of United States Patent Nos. 6,699,885, 6,489,346, 6,645,988, and 7,399,772 (collectively "the Patents-in-Suit"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 et seq.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

7. DRL is subject to personal jurisdiction in this District because Dr. Reddy's Laboratories, Inc. is incorporated in New Jersey and has its principal place of business in Bridgewater, New Jersey, and because DRL conducts business in this District, purposefully avails itself of the rights and benefits of New Jersey law, and has substantial and continuing contacts with New Jersey.

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

THE PATENTS

9. On March 2, 2004, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,699,885 (the "'885 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since March 2, 2004, the University has been, and continues to be, the sole owner of the '885 Patent. A copy of the '885 Patent is attached hereto as Exhibit A.

10. On or about August 22, 2005, a third party requested reexamination of the '885 Patent by the PTO, which was granted by the PTO. On or about March 13, 2007, the reexamination proceedings concluded with the PTO issuing a Notice of Intent to Issue a

Reexamination Certificate confirming that all claims of the '885 Patent "are determined to be patentable as amended." On September 18, 2007, the PTO issued a Reexamination Certificate confirming that all claims as amended are "determined to be patentable." In the Reexamination Certificate, claims 1 and 26 were amended, and claims 52 and 53 were added. A copy of the Ex Parte Reexamination Certificate (5894th) for the '885 Patent is attached hereto as Exhibit B.

11. On December 3, 2002, the PTO issued U.S. Patent No. 6,489,346 (the "'346 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since December 3, 2002, the University has been, and continues to be, the sole owner of the '346 Patent. A copy of the '346 Patent is attached hereto as Exhibit C.

12. On November 11, 2003, the PTO issued U.S. Patent No. 6,645,988 (the "'988 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since November 11, 2003, the University has been, and continues to be, the sole owner of the '988 Patent. A copy of the '988 Patent is attached hereto as Exhibit D.

13. On July 15, 2008, the PTO issued U.S. Patent No. 7,399,772 (the "'772 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. Since July 15, 2008, the University has been, and continues to be, the sole owner of the '772 Patent. A copy of the '772 Patent is attached hereto as Exhibit E.

14. Santarus is the exclusive licensee under the Patents-in-Suit for Santarus' ZEGERID brand prescription pharmaceutical products (omeprazole 40 mg/sodium

bicarbonate 1100 mg and omeprazole 20 mg/sodium bicarbonate 1100 mg capsules) (collectively "ZEGERID Rx"). Plaintiffs have the right to sue to enforce the Patents-in-Suit.

15. The Patents-in-Suit are listed in the United States Food and Drug Administration's (the "FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the Orange Book, in support of ZEGERID Rx.

ACTS GIVING RISE TO THIS ACTION

16. On information and belief, on or before July 3, 2012, DRL submitted Abbreviated New Drug Application No. 204068 (the "DRL Rx ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The DRL Rx ANDA seeks approval to engage in the commercial manufacture, use, offer for sale, and/or sale of generic omeprazole and sodium bicarbonate capsules, 20 mg/1100 mg and 40 mg/100 mg (the "Proposed DRL Capsules"), a generic version of ZEGERID Rx. The DRL Rx ANDA specifically seeks FDA approval to market the Proposed DRL Capsules prior to the expiration of the Patents-in Suit.

17. Plaintiffs received a letter dated July 3, 2012, from DRL notifying them that the DRL Rx ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "DRL Paragraph IV Certification") that, in DRL's opinion, that the Patents-in-Suit are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the Proposed DRL Capsules.

18. Plaintiffs commenced this action within 45 days of receiving the DRL Paragraph IV Certification.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '885 PATENT

19. Plaintiffs incorporate by reference paragraphs 1 through 18.

20. The submission of the DRL Rx ANDA to the FDA, including the DRL Paragraph IV Certification, constitutes infringement of the '885 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed DRL Capsules, or any inducement of or contribution to such conduct during the term of the '885 Patent would further infringe the '885 Patent under 35 U.S.C. § 271(a)–(c).

21. DRL had actual and constructive notice of the '885 Patent prior to filing the DRL Rx ANDA.

22. DRL's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

SECOND CLAIM FOR RELIEF
INFRINGEMENT OF THE '346 PATENT

23. Plaintiffs incorporate by reference paragraphs 1 through 18.

24. The submission of the DRL Rx ANDA to the FDA, including the DRL Paragraph IV Certification, constitutes infringement of the '346 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed DRL Capsules, or any inducement of or contribution to such conduct during the term of the '346 Patent would further infringe the '346 Patent under 35 U.S.C. § 271(a)–(c).

25. DRL had actual and constructive notice of the '346 Patent prior to filing the DRL Rx ANDA.

26. DRL's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

THIRD CLAIM FOR RELIEF
INFRINGEMENT OF THE '988 PATENT

27. Plaintiffs incorporate by reference paragraphs 1 through 18.

28. The submission of the DRL Rx ANDA to the FDA, including the DRL Paragraph IV Certification, constitutes infringement of the '988 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed DRL Capsules, or any inducement of or contribution to such conduct during the term of the '988 Patent would further infringe the '988 Patent under 35 U.S.C. § 271(a)–(c).

29. DRL had actual and constructive notice of the '988 Patent prior to filing the DRL Rx ANDA.

30. DRL's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

FOURTH CLAIM FOR RELIEF
INFRINGEMENT OF THE '772 PATENT

31. Plaintiffs incorporate by reference paragraphs 1 through 18.

32. The submission of the DRL Rx ANDA to the FDA, including the DRL Paragraph IV Certification, constitutes infringement of the '772 Patent under 35 U.S.C. § 271(e)(2)(A). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed DRL Capsules, or any inducement of or contribution to such conduct during the term of the '772 Patent would further infringe the '772 Patent under 35 U.S.C. § 271(a)–(c).

33. DRL had actual and constructive notice of the '772 Patent prior to filing the DRL Rx ANDA.

34. DRL's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that:

1. Judgment be entered that DRL has infringed the Patents-in-Suit;

2. Judgment be entered that the commercial use, sale, offer for sale, manufacture, and/or importation by DRL of the Proposed DRL Capsules would infringe the Patents-in-Suit;

3. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of the DRL Rx ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be set (or if applicable reset) to a date that is not earlier than the expiration date of the Patents-in-Suit, including any extensions;

4. That DRL, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering to sell, or selling the Proposed DRL Capsules within the United States, or importing the Proposed DRL Capsules into the United States, prior to the expiration of the Patents-in-Suit, including any extensions; and

5. Such other and further relief as the Court may deem just and proper under the circumstances.

Respectfully submitted,

Dated: August 15, 2012
Newark, New Jersey

s/ Sheila F. McShane

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