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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.)
)
 ZYDUS PHARMACEUTICALS (USA) INC.,)
)
 Defendant.)
)
)
)

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 Defendant Zydus Pharmaceuticals (USA) Inc. (“Zydus”), 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, Zydus is a corporation organized and existing under the laws of New Jersey with a principal place of business at 73 Route 31 N., Pennington, New Jersey 08534. On information and belief, Zydus 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.

NATURE OF THE ACTION

4. 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

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

6. Zydus is subject to personal jurisdiction in this District because it is incorporated in New Jersey, has its principal place of business in Pennington, New Jersey, 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.

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

THE PATENTS

8. 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.

9. 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.

10. 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.

11. 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.

12. 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.

13. 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.

14. 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

15. On information and belief, on or before November 11, 2011, Zydus submitted Abbreviated New Drug Application No. 203290 (the “Zydus Rx ANDA”) to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The

Zydus 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 Zydus Capsules”), a generic version of ZEGERID Rx. The Zydus Rx ANDA specifically seeks FDA approval to market the Proposed Zydus Capsules prior to the expiration of the Patents-in Suit.

16. Plaintiffs received a letter dated November 11, 2011, from Zydus notifying them that the Zydus Rx ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “Zydus Paragraph IV Certification”) that, in Zydus’s opinion, no valid claim of the Patents-in-Suit will be infringed by the commercial manufacture, use or sale of the Proposed Zydus Capsules.

17. Plaintiffs commenced this action within 45 days of receiving the Zydus Paragraph IV Certification.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE ’885 PATENT

18. Plaintiffs incorporate by reference paragraphs 1 through 18.

19. The submission of the Zydus Rx ANDA to the FDA, including the Zydus 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 Zydus 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).

20. Zydus had actual and constructive notice of the ’885 Patent prior to filing the Zydus Rx ANDA.

21. Zydus’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

22. Plaintiffs incorporate by reference paragraphs 1 through 18.

23. The submission of the Zydus Rx ANDA to the FDA, including the Zydus 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 Zydus 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).

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

25. Zydus'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

26. Plaintiffs incorporate by reference paragraphs 1 through 18.

27. The submission of the Zydus Rx ANDA to the FDA, including the Zydus 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 Zydus 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).

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

29. Zydus'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

30. Plaintiffs incorporate by reference paragraphs 1 through 18.

31. The submission of the Zydus Rx ANDA to the FDA, including the Zydus 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 Zydus 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).

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

33. Zydus'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 Zydus has infringed the Patents-in-Suit;
2. Judgment be entered that the commercial use, sale, offer for sale, manufacture, and/or importation by Zydus of the Proposed Zydus 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 Zydus 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 Zydus, 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 Zydus Capsules within the United States, or importing the Proposed Zydus 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: December 21, 2011
Newark, New Jersey

s/ Sheila F. McShane

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