IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANTARUS, INC., a Delaware corporation, and THE CURATORS OF THE UNIVERSITY OF MISSOURI, a public corporation and body politic of the State of Missouri,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendant.	)	

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 Par Pharmaceutical, Inc. ("Defendant"), 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 10590 West Ocean Air Drive, Suite 200, San Diego, California 92130. Santarus is a specialty pharmaceutical company focused on acquiring, developing and commercializing products for the prevention and treatment of gastrointestinal diseases and disorders.

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. Plaintiffs are informed and believe, and thereon allege, that Defendant is a corporation organized and existing under the laws of Delaware with a principal place of business

at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. Defendant is one of the largest manufacturers and distributors of generic pharmaceutical products. Defendant conducts business throughout the United States, including in this District.

JURISDICTION AND VENUE

4. This is an action for patent infringement arising under the patent laws of the United States of America, 35 U.S.C. § 1, et seq., including § 271. This Court has subject matter jurisdiction over the matters asserted herein under 28 U.S.C. §§ 1331 and 1338(a).

5. Defendant is subject to personal jurisdiction in this District because it is incorporated in Delaware, conducts business in this District, purposefully avails itself of the rights and benefits of Delaware law, and has substantial and continuing contacts with Delaware.

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

FACTS PERTINENT TO ALL CLAIMS FOR RELIEF

7. On March 2, 2004, the United States Patent and Trademark Office (the "PTO") issued U.S. Patent No. 6,699,885, entitled "Substituted Benzimidazole Dosage Forms and Methods of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips.

8. On or about August 22, 2005, reexamination of U.S. Patent No. 6,699,885 by the PTO was requested by a third party, 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 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 U.S.

Patent No. 6,669,885 and its Ex Parte Reexamination Certificate (5894th) are attached hereto as Exhibits A and B, respectively, and shall be hereafter referred to collectively as the "'885 Patent."

9. 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. A copy of the '346 Patent is attached hereto as Exhibit C.

10. 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. A copy of the '988 Patent is attached hereto as Exhibit D.

11. On August 24, 2004, the PTO issued U.S. Patent No. 6,780,882 (the "'882 Patent"), entitled "Substituted Benzimidazole Dosage Forms and Method of Using Same" to the University, the assignee of the named inventor Jeffrey O. Phillips. A copy of the '882 Patent is attached hereto as Exhibit E.

12. The University is the record owner of the '885, '346, '988, and '882 patents (collectively the "Patents-in-Suit"), and Santarus is the exclusive licensee. Plaintiffs have the right to sue to enforce the Patents-in-Suit.

13. 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 Santarus' Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg ("Zegerid®") products. Zegerid® is indicated for the treatment of heartburn and other symptoms of

gastroesophageal reflux disease, the treatment and maintenance of healing of erosive esophagitis, and the short-term treatment of active duodenal ulcers and active benign gastric ulcers. Zegerid® is the first and only immediate-release oral proton pump inhibitor approved by the FDA. Zegerid® is marketed by Santarus.

14. On information and belief, Defendant has submitted Abbreviated New Drug Application No. 79-182 (the "ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The ANDA seeks approval to market omeprazole and sodium bicarbonate powder for oral suspension, 20 mg/1680 mg (the "Proposed 20 mg Powder") and 40 mg/1680 mg (the "Proposed 40 mg Powder"), generic versions of Zegerid®, prior to the expiration of the Patents-in-Suit.

15. Plaintiffs received a letter dated November 13, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "First Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg Powder.

16. Plaintiffs received a letter dated December 6, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Second Paragraph IV Certification") that, in Defendant's opinion, the Patents-in-Suit are invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the Proposed 20 mg and 40 mg Powder.

17. Plaintiffs commenced this action within 45 days of receiving the First and Second Paragraph IV Certifications.

FIRST CLAIM FOR RELIEF

INFRINGEMENT OF THE '885 PATENT

18. Plaintiffs incorporate by reference paragraphs 1 through 17.

19. The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '885 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '885 Patent under 35 U.S.C. § 271(a)–(c).

20. Defendant has been aware of the existence of the '885 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '885 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

21. Defendant'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 17.

23. The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '346 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '346 Patent under 35 U.S.C. § 271(a)–(c).

24. Defendant has been aware of the existence of the '346 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '346 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

25. Defendant'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 17.

27. The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '988 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '988 Patent under 35 U.S.C. § 271(a)–(c).

28. Defendant has been aware of the existence of the '988 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder will not infringe the '988 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

29. Defendant'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 '882 PATENT

30. Plaintiffs incorporate by reference paragraphs 1 through 17.

31. The submission of the ANDA to the FDA, including the First and Second Paragraph IV Certifications, constitutes infringement of the '882 Patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, offer to sell, sale or import of the Proposed 20 mg or 40 mg Powder would infringe the '882 Patent under 35 U.S.C. § 271(a)–(c).

32. Defendant has been aware of the existence of the '882 Patent prior to filing the ANDA, and has no reasonable basis for believing that the Proposed 20 mg and 40 mg

Powder will not infringe the '882 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

33. Defendant'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 pray for judgment as follows:

1. For a determination that Defendant has infringed the Patents-in-Suit;

2. For a determination that the commercial use, sale, offer for sale, manufacture, and/or importation by Defendant of the Proposed 20 mg or 40 mg Powder would infringe the Patents-in-Suit;

3. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of the ANDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), be no earlier than the expiration date of Patents-in-Suit, including any extensions;

4. For an order preliminarily and permanently enjoining Defendant and its affiliates, subsidiaries, officers, directors, employees, agents, representatives, licensees, successors, assigns, and all those acting for them and on their behalf, or acting in concert with them directly or indirectly, from infringing the Patents-in-Suit;

5. For a declaration that this case is exceptional pursuant to 35 U.S.C. § 285 and an award of attorneys' fees and costs; and

6. For such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
James W. Parrett, Jr. (#4292)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
jblumenfeld@mnat.com
jparrett@mnat.com

Counsel for plaintiffs Santarus, Inc. and The Curators of the University of Missouri

Of Counsel:

For Plaintiff Santarus, Inc.:

Morgan Chu
Gary Frischling
Lisa N. Partain
Benjamin T. Wang
IRELL & MANELLA LLP
1800 Avenue of the Stars, Suite 900
Los Angeles, CA 90067-4276
(310) 277-1010

For Plaintiff The Curators of the University of Missouri:

James R. Ferguson
Jamison E. Lynch
MAYER BROWN LLP
71 S. Wacker Drive
Chicago, IL 60606
(312) 782-0600

December 20, 2007