

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, )

v. )

PAR PHARMACEUTICAL, INC., a Delaware )  
corporation, )

Defendant. )

C.A. No. \_\_\_\_\_

**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 (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. A copy of the ‘885 Patent is attached hereto as Exhibit A.

8. On or about August 22, 2005, reexamination of the ‘885 Patent by the PTO was requested by a third party. The PTO granted the request and commenced reexamination of the ‘885 Patent. 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.” Although the PTO’s electronic status system (PAIR) lists the status of the ‘885 Patent

reexamination as “Reexamination Certificate Issued,” as of the date hereof, a copy of the Reexamination Certificate has not been received by Plaintiffs and is not yet available on the PTO’s PAIR system. When a copy of the Reexamination Certificate is received, Plaintiffs will amend this complaint accordingly.

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 B.

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 C.

11. The University is the record owner of the ‘885, ‘346, and ‘988 patents (collectively the “Patents-in-Suit”), and Santarus is the exclusive licensee. Plaintiffs have the right to sue to enforce the Patents-in-Suit.

12. 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<sup>®</sup> (omeprazole/sodium bicarbonate) Capsules 20 mg and 40 mg (“Zegerid<sup>®</sup>”) products. Zegerid<sup>®</sup> 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<sup>®</sup> is the first and only immediate-release oral proton pump inhibitor approved by the FDA. Zegerid<sup>®</sup> is marketed by Santarus.

13. On information and belief, Defendant has submitted Abbreviated New Drug Application No. 78-966 (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 capsules, 20 mg/1100 mg and 40 mg/1100 mg (the “Proposed Capsules”), a generic version of Zegerid<sup>®</sup>, prior to the July 16, 2016, expiration of the Patents-in-Suit.

14. Plaintiffs received a letter dated August 2, 2007, from Defendant notifying them that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the “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 Capsules.

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

**FIRST CLAIM FOR RELIEF**

**INFRINGEMENT OF THE ‘885 PATENT**

16. Plaintiffs incorporate by reference paragraphs 1 through 15.

17. The submission of the ANDA to the FDA, including the Paragraph IV Certification, 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 Capsules would infringe the ‘885 Patent under 35 U.S.C. § 271(a)–(c).

18. 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 Capsules will not infringe the ‘885 Patent. This case is, therefore, “exceptional” within the meaning of 35 U.S.C. § 285.

19. 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**

20. Plaintiffs incorporate by reference paragraphs 1 through 15.

21. The submission of the ANDA to the FDA, including the Paragraph IV Certification, 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 Capsules would infringe the '346 Patent under 35 U.S.C. § 271(a)-(c).

22. 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 Capsules will not infringe the '346 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

23. 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**

24. Plaintiffs incorporate by reference paragraphs 1 through 15.

25. The submission of the ANDA to the FDA, including the Paragraph IV Certification, 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 Capsules would infringe the '988 Patent under 35 U.S.C. § 271(a)-(c).

26. 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 Capsules will not

infringe the '988 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

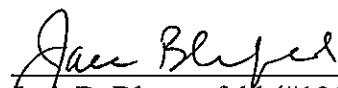
27. Defendant's infringing activities will irreparably harm Plaintiffs unless enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

**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 Capsules 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](mailto:jblumenfeld@mnat.com)  
[jparrett@mnat.com](mailto: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, California 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

September 13, 2007  
1232640