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. 07-551 (GMS) (Consolidated)
v.	)	**DEMAND FOR JURY TRIAL**
PAR PHARMACEUTICAL, INC., a Delaware corporation,	)	
Defendant.	)	

THIRD AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

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 13611 Valley Centre Drive, Suite 400, San Diego, California 92130. Santarus is a specialty pharmaceutical company focused on acquiring, developing, and commercializing products for, among other things, 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. The Curators of the University of Missouri is the governing body of the University of Missouri.

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 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 A.

8. 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. A copy of the '772 Patent is attached hereto as Exhibit B.

9. The University is the record owner of the '882 and '772 Patents, and Santarus is the exclusive licensee. Plaintiffs have the right to sue to enforce all of these patents.

10. The '772 Patent is 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) Capsules 20 mg and 40 mg ("Zegerid®") products. The '882 and '772 Patents are listed in the FDA's Orange Book in support of Santarus' Zegerid® (omeprazole/sodium bicarbonate) Powder for Oral Suspension 20 mg and 40 mg 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.

11. On information and belief, Defendant has submitted Abbreviated New Drug Application No. 78-966 (the "First 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®, prior to the July 2016 expiration of the '772 Patent.

12. 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 "First Paragraph IV Certification for Capsules") that, in Defendant's opinion, certain of Plaintiffs'

patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Proposed Capsules.

13. Plaintiffs commenced this action within 45 days of receiving the First Paragraph IV Certification for Capsules.

14. On information and belief, Defendant has submitted Abbreviated New Drug Application No. 79-182 (the "Second ANDA") to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Second 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") (collectively, the "Proposed Powder"), generic versions of Zegerid®, prior to the July 2016 expiration of the '882 and '772 Patents.

15. Plaintiffs received a letter dated November 13, 2007, from Defendant notifying them that the Second ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "First Paragraph IV Certification for Powder") that, in Defendant's opinion, the '882 Patent is 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 Second ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Second Paragraph IV Certification for Powder") that, in Defendant's opinion, the '882 Patent is 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 filed and served a Complaint, which became C.A. No. 07-827, within 45 days of receiving the First and Second Paragraph IV Certifications for Powder. The Court consolidated C.A. Nos. 07-551 and 07-827 on March 4, 2008.

18. Plaintiffs received a letter dated September 30, 2008, from Defendant notifying them that the First and Second ANDAs include a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "'772 Patent Paragraph IV Certification") that, in Defendant's opinion, the '772 Patent is invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of the Proposed 20 mg and 40 mg Powder and Capsule Products.

19. Plaintiffs filed their Second Amended Complaint in this action within 45 days of receiving the '772 Paragraph IV Certification.

20. This Court held an initial trial in this matter in July 2009. The Court ruled, *inter alia*, that "manufacture, use, or sale of Par's proposed generic 20-milligram and 40-milligram omeprazole/sodium bicarbonate capsules and powered products would infringe the asserted claims of the patents-in-suit," which included at least claims 4, 5, 8, 10, 12, 14, 15, 20, and 21 of the '772 Patent and claims 11 and 15 of the '882 Patent (with respect to powder only). Trial Tr. at 941; *see also id* at 234 (identifying asserted claims). The Court further ruled that Plaintiffs had proved that "Par's proposed generics infringed the method claims of the patents-in-suit," noting unchallenged evidence that "Par's ANDAs include the same method for administration as taught by the patents-in-suit and that other than the treatment of acid-caused gastrointestinal disorders, there were no other known uses for the drug at issue." Trial Tr. at 940-41. The Court also made subsequent rulings on validity and enforceability of the '772 and '882 Patents.

21. This Court's judgment based on the initial trial was entered April 21, 2010, and was appealed to the Court of Appeals for the Federal Circuit. Par did not challenge on appeal this Court's findings relating to infringement. On September 4, 2012, the Federal Circuit issued its ruling on appeal, holding that at least claims 4, 5, 8, 10, 12, 14, 15, 20, and 21 of the '772 Patent and claims 11 and 15 of the '882 Patent are not invalid and that neither the '772 Patent nor the '882 Patent is unenforceable. Par filed a petition for rehearing and/or rehearing *en banc* which was denied by the Federal Circuit. The Federal Circuit's September 4, 2012, decision became final, and its mandate issued December 17, 2012.

22. During the pendency of the Federal Circuit appeal, in or about mid-2010, Par commercially launched its Proposed 20 mg and 40 mg Capsule Products.

FIRST CLAIM FOR RELIEF
INFRINGEMENT OF THE '882 PATENT

23. Plaintiffs incorporate by reference paragraphs 1 through 22.

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

25. Defendant has been aware of the existence of the '882 Patent prior to filing the Second ANDA and has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder Products do not infringe the '882 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

26. 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 '772 PATENT

27. Plaintiffs incorporate by reference paragraphs 1 through 22.

28. The submission of the First and Second ANDAs to the FDA, including the '772 Patent Paragraph IV Certification, constitutes infringement of the '772 Patent under 35 U.S.C. § 271(e)(2).

29. Defendant further has infringed the '772 Patent under 35 U.S.C. § 271(a)–(c) by its commercial manufacture, use, offer to sell, sale, and/or import of the Proposed 20 mg and/or 40 mg Capsule Products. The Proposed 20 mg and 40 mg Capsule Products are especially made or adapted for use in the claimed methods of the '772 Patent and have no substantial non-infringing use. Defendant further has induced infringement of the '772 Patent by provision of materials, including package labeling, directing, and encouraging use of its Proposed 20 mg and 40 mg Capsule Products in an infringing manner. Defendant has been aware of the '772 Patent and the facts giving rise to its contributory and/or inducing infringement since before it sent the '772 Patent Paragraph IV Certification and, in any event, by the time it first commercially made, used, sold, or offered for sale the Proposed 20 mg and/or 40 mg Capsule Products.

30. Defendant has no reasonable basis for believing that the Proposed 20 mg and 40 mg Powder and Capsule products do not infringe the '772 Patent. This case is, therefore, "exceptional" within the meaning of 35 U.S.C. § 285.

31. 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 '882 and '772 Patents;

2. For an award to Plaintiffs of damages sufficient to compensate them for Defendant's infringement, together with interest;

3. For a determination, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date for approval of the First and Second ANDAs, 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 the '882 and '772 Patents , 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 '882 and '772 Patents;

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.

JURY TRIAL DEMAND

Plaintiffs demand a trial by jury on all issues so triable.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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February 1, 2013
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CERTIFICATE OF SERVICE

I hereby certify that on February 1, 2013, I electronically filed the foregoing with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused to be served copies of the foregoing document on February 1, 2013 upon the following in the manner indicated:

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