IN THE UNITED STATES DISTRICT COURT
FOR EASTERN DISTRICT OF NORTH CAROLINA

SEPRACOR INC., UCB S.A. and UCB, INC. Plaintiffs, vs. SYNTHON PHARMACEUTICALS, INC.; SYNTHON HOLDING B.V.; SYNTHON B.V.; and SYNTHON LABORATORIES, INC. Defendants.	Civil Action No. 5:09-cv-00264

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Sepracor Inc., UCB S.A. and UCB, Inc. (hereinafter "Plaintiffs") for their Complaint against Defendants Synthon Pharmaceuticals, Inc. ("Synthon Pharma"), Synthon Holding B.V. ("Synthon Holding"), Synthon B.V. ("Synthon B.V.") and Synthon Laboratories, Inc. ("Synthon Labs") (collectively, "Defendants") hereby allege as follows:

PARTIES

1. Plaintiff Sepracor Inc. ("Sepracor") is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

2. Plaintiff UCB S.A. is a Belgian corporation having a principal place of business at Allee de la Recherche 60, B-1070 Brussels, Belgium.

3. Plaintiff UCB, Inc. is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 1950 Lake Park Drive, Smyrna, GA 30080.

4. Upon information and belief, Defendant Synthon Pharma is a North Carolina corporation having a principal place of business at 9000 Development Drive, P.O. Box 110487, Research Triangle Park, North Carolina 27709.

5. Upon information and belief, Defendant Synthon Pharma, submitted Abbreviated New Drug Application ("ANDA") No. 91-263 to the United States Food and Drug Administration ("FDA") under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)).

6. Upon information and belief, Defendant Synthon Pharma, itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon B.V. and Synthon Labs, manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including this judicial district.

7. Upon information and belief, Defendant Synthon Holding is a Dutch entity having a principal place of business at Microweg 22, 6545 CM Nijmegen, Netherlands.

8. Upon information and belief, Defendant Synthon Holding is the ultimate parent of Defendants Synthon Pharma, Synthon B.V., and Synthon Labs.

9. Upon information and belief, Defendant Synthon Holding, itself and through its subsidiaries and agents Defendants Synthon B.V., Synthon Labs, and Synthon Pharma, manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including this judicial district.

10. Upon information and belief, Defendant Synthon B.V. is a Dutch entity having a principal place of business at Microweg 22, P.O. Box 7071, 6503 GN Nijmegen, Netherlands.

11. Upon information and belief, Defendant Synthon B.V., itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon Pharma and Synthon Labs, manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including this judicial district.

12. Upon information and belief, Defendant Synthon Labs is a Virginia corporation having a principal place of business at 7130 Heritage Village Plaza, Suite 201, Gainesville, Virginia 20155.

13. Upon information and belief, Defendant Synthon Labs, itself and on behalf of its parent Defendant Synthon Holding and its sister companies Defendants Synthon B.V. and Synthon Pharma, manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including this judicial district.

NATURE OF THE ACTION

14. This is a civil action for infringement of United States Patent No. 5,698,558 ("the '558 patent") (Exhibit A). This action is based upon the Patent laws of the United States, 35 U.S.C. § 100 *et seq.*

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States of America, Title 35, United States Code. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

16. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia,* each Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs.

17. This Court has personal jurisdiction over Defendant Synthon Pharma by virtue of, *inter alia:* (1) its presence in North Carolina at its principal place of business; and (2) the fact that it is a North Carolina corporation.

18. This Court has personal jurisdiction over Defendant Synthon Holding by virtue of, *inter alia:* (1) its presence in North Carolina through its subsidiary and agent Synthon Pharma; and (2) its systematic and continuous contacts with North Carolina, including through its subsidiaries and agents Synthon Pharma, Synthon, and Synthon Labs.

19. This Court has personal jurisdiction over Defendant Synthon B.V. by virtue of, *inter alia:* (1) its presence in North Carolina through its sister company and agent Synthon Pharma; and (2) its systematic and continuous contacts with North Carolina, including through its sister companies and agents Synthon Pharma and Synthon Labs.

20. This Court has personal jurisdiction over Defendant Synthon Labs by virtue of, *inter alia:* (1) the fact that it is an alter ego or agent of Synthon Pharma, a corporation present in North Carolina; (2) its systematic and continuous contacts with North Carolina, including through its alter ego or agent Synthon Pharma; and (3) its systematic and continuous contacts with North Carolina, including through its sister company Synthon.

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

22. Currently before this Court is another action for infringement of the ‘558 patent between these same Plaintiffs and Defendants. That action has been consolidated with three other actions under Civil Action No. 5:08-CV-362-H(3) using the caption Sepracor, Inc. et al. v. Barr Pharmaceuticals, Inc. et al. (the “Barr Consolidated Action”). In the Barr Consolidated

Action, Plaintiffs asserted *inter alia* that the instant Defendants infringe the '558 patent for a different levocetirizine product than is at issue in this Action.

23. In the Barr Consolidated Action, Defendants did not dispute venue or the jurisdiction of this Court.

THE PATENT-IN-SUIT

24. On December 16, 1997, the United States Patent and Trademark Office ("the PTO") issued the '558 patent, titled "Methods for Treating Allergic Disorders Using Optically Pure (-) Cetirizine," to Sepracor Inc., the assignee of the named inventor Nancy M. Gray.

25. Levocetirizine is another name for (-) cetirizine.

26. Plaintiff Sepracor is the record owner of the '558 patent.

27. Plaintiff UCB S.A. (and its subsidiary UCB Inc.) is the exclusive licensee of the '558 patent.

28. On February 19, 2008, the FDA approved New Drug Application ("NDA") No. 022157 for levocetirizine dihydrochloride oral solution.

29. UCB Inc. is the holder of NDA No. 022157 for levocetirizine dihydrochloride oral solution, which it sells under the registered name XYZAL® Oral Solution.

30. The '558 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") as covering XYZAL® Oral Solution.

ACTS GIVING RISE TO THIS ACTION

Count I – Infringement of The '558 Patent by Defendants Synthon Pharma, Synthon Labs, Synthon Holding, and Synthon B.V.

31. Upon information and belief, Defendant Synthon Pharma submitted ANDA No. 91-263 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §

355(j)). ANDA No. 91-263 seeks FDA approval for the commercial manufacture, use and sale of a generic oral solution product containing 0.5 mg/ml of levocetirizine dihydrochloride ("the Synthon Generic Product"). ANDA No. 91-263 specifically seeks FDA approval to market the Synthon Generic Product prior to the expiration of the '558 patent.

32. Upon information and belief, Defendant Synthon Pharma submitted ANDA No. 91-263 on behalf of its parent Synthon Holding and its sister companies Synthon Labs and Synthon.

33. In a letter dated May 5, 2009, Synthon Pharmaceuticals notified Plaintiffs them that ANDA No. 91-263 included a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification"), stating that Synthon believes that the '558 patent is invalid, unenforceable or will not be infringed by the commercial manufacture, use or sale of the levocetirizine products described in ANDA No. 91-263.

34. Plaintiffs commenced this action within 45 days of the date they received notice of ANDA No. 91-263 containing the Paragraph IV certification.

35. Synthon Pharma's submission of ANDA No. 91-263 to the FDA with a Paragraph IV Certification constitutes infringement of the '558 patent under 35 U.S.C. § 271 (e)(2). Moreover, if Synthon Pharma commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Products, or induces or contributes to any such conduct, it would further infringe the '558 patent under 35 U.S.C. § 27 1(a), (b) and/or (c).

36. Synthon Labs is jointly and severally liable for any infringement of the '558 patent. Upon information and belief, Synthon Labs participated in, contributed to, aided, abetted and/or induced Synthon Pharma's submission of ANDA No. 91-263 and its Paragraph IV Certification allegations to the FDA.

37. Synthon Labs' participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-263 and its Paragraph IV Certification allegations to the FDA constitutes infringement of the '558 patent under 35 U.S.C. § 271(e)(2). Moreover, if Synthon Labs commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Products, or induces or contributes to any such conduct, it would further infringe the '558 patent under 35 U.S.C. § 27 1(a), (b) and/or (c).

38. Synthon Holding is jointly and severally liable for any infringement of the '558 patent. Upon information and belief, Synthon Holding participated in, contributed to, aided, abetted and/or induced Synthon Pharma's submission of ANDA No. 91-263 and its Paragraph IV Certification allegations to the FDA.

39. Synthon Holding's participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-263 and its Paragraph IV Certification allegations to the FDA constitutes infringement of the '558 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Synthon Holding commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Products, or induces or contributes to any such conduct, it would further infringe the '558 patent under 35 U.S.C. § 271(a), (b), (c) and/or (f).

40. Synthon B.V. is jointly and severally liable for any infringement of the '558 patent. Upon information and belief, Synthon B.V. participated in, contributed to, aided, abetted and/or induced Synthon Pharma's submission of ANDA No. 91-263 and its Paragraph IV Certification allegations to the FDA.

41. Synthon B.V.'s participation in, contribution to, aiding, abetting and/or inducement of the submission of ANDA No. 91-263 and its Paragraph IV Certification allegations to the FDA constitutes infringement of the '558 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if

Synthon B.V. commercially manufactures, uses, offers to sell, sells, or imports any of the Synthon Generic Products, or induces or contributes to any such conduct, it would further infringe the '558 patent under 35 U.S.C. § 271(a), (b), (c) and/or (f).

42. Defendants were aware of the '558 patent prior to filing ANDA No. 91-263.

43. Defendants' actions render this an exceptional case under 35 U.S.C. § 285.

44. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That all Defendants have infringed the '558 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA identified in this Complaint shall not be earlier than the expiration date of the '558 patent, including any extensions;

C. That Defendants, their officers, agents, servants and employees, and those persons in active concert or participation with any of them, be preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing any of the proposed generic versions of Plaintiffs' XYZAL® Oral Solution product identified in this Complaint and any other product that infringes or induces or contributes to the infringement of the '558 patent, prior to the expiration of the '558 patent, including any extensions;

D. That this case is exceptional under 35 U.S.C. § 285;

E. That Plaintiffs be awarded the attorney fees, costs and expenses that they incur prosecuting this action; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

June 17, 2009

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