IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HORIZON PHARMA, INC. and HORIZON PHARMA USA, INC.,

Plaintiffs,

v.

PAR PHARMACEUTICAL COMPANIES, INC. and PAR PHARMACEUTICAL, INC.,

Defendants.

C.A. No. _____

COMPLAINT

Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc. (collectively, "Horizon") by their undersigned attorneys, bring this action against Defendants Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, "Par"), and hereby allege as follows:

THE PARTIES

1. Plaintiff Horizon Pharma, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 520 Lake Cook Road, Suite 520, Deerfield, Illinois.

2. Plaintiff Horizon Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1033 Skokie Boulevard, Suite 355, Northbrook, Illinois 60062.

3. Upon information and belief, Defendant Par Pharmaceutical Companies, Inc. is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677.

4. Upon information and belief, Defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at One Ram Ridge Road, Spring Valley, New York 10977, and is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc.

5. Upon information and belief, Par Pharmaceutical, Inc. is in the business of, among other activities, offering for sale, selling and/or importing copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

6. Upon information and belief, Par Pharmaceutical, Inc. makes regulatory submissions to the United States Food and Drug Administration ("FDA"), including submissions on behalf of Par Pharmaceutical Companies, Inc.

7. Upon information and belief, Par Pharmaceutical Companies, Inc. markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Par Pharmaceutical Companies, Inc. has engaged in systematic and continuous business within this judicial district. In addition, and upon information and belief, Par Pharmaceutical Companies, Inc. controls and dominates Par Pharmaceutical, Inc., and thus the activities of Par Pharmaceutical, Inc. in this judicial district are attributable to Par Pharmaceutical Companies, Inc.

8. On information and belief, Par Pharmaceutical, Inc. alone and through its parent Par Pharmaceutical Companies, Inc., markets and sells generic drugs throughout the United States, and in particular within this judicial district, and therefore Par Pharmaceutical, Inc. has engaged in systematic and continuous business within this judicial district.

9. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. collaborated in the research and development of Par's Abbreviated New Drug Application ("ANDA") No. 203658 for tablets that contain 800 mg of ibuprofen and 26.6 mg of famotidine as active ingredients ("the Par ANDA Product"), continue to collaborate in seeking approval of that application by the FDA, and intend to collaborate in the commercial manufacture, marketing, offer for sale and sale of the Par ANDA Product throughout the United States, including in the State of Delaware, in the event the FDA approves Par's ANDA.

JURISDICTION AND VENUE

10. This is a civil action arising under the patent laws of the United States, Title 35, United States Code, for infringement of U.S. Patent No. 8,309,127 ("the '127 patent") and U.S. Patent No. 8,318,202 ("the '202 patent"). This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Upon information and belief, Par Pharmaceutical Companies, Inc. is subject to personal jurisdiction in this judicial district because it is incorporated in this State and it has purposely availed itself of the benefits and protections of this State's laws such that it should reasonably anticipate being haled into court in this judicial district.

12. Upon information and belief, Par Pharmaceutical, Inc. is subject to personal jurisdiction in this judicial district because, inter alia, Par Pharmaceutical, Inc. is incorporated in this state, and Par Pharmaceutical, Inc., alone and through its parent Par Pharmaceutical Companies, Inc., has purposely availed itself of the benefits and protections of this State's laws such that it should reasonably anticipate being haled into court in this judicial district.

13. Upon information and belief, Par Pharmaceutical Companies, Inc. and/or Par Pharmaceutical, Inc. did not object to personal jurisdiction or venue in this judicial district in Civil Action Nos. 09-305-JJF, 09-481-LDD, 11-107-SLR, 11-705-LPS, and 12-393-LPS.

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

BACKGROUND

15. Horizon Pharma, Inc. is the holder of the approved New Drug Application ("NDA") No. 022519 for Duexis® tablets, which contains 26.6 mg of famotidine and 800 mg of ibuprofen as active ingredients. Duexis® was approved by the FDA on April 23, 2011, for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

16. On information and belief, Par Pharmaceutical, Inc. submitted ANDA No. 203658 to the FDA under the provisions of 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic copies of Duexis® tablets.

17. Upon information and belief, the Par ANDA Product that is the subject of Par's ANDA No. 203658 are tablets containing 800 mg of ibuprofen and 26.6 mg of famotidine as active ingredients, for the relief of signs and symptoms of rheumatoid arthritis and osteoarthritis and to decrease the risk of developing upper gastrointestinal ulcers.

THE PATENTS-IN-SUIT

18. On November 13, 2012, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '127 patent titled "Stable Compositions of Famotidine and Ibuprofen." A true and correct copy of the '127 patent is attached hereto as Exhibit A.

19. Horizon Pharma USA, Inc. is the sole owner of the '127 patent.

20. The '127 patent discloses and claims, inter alia, a pharmaceutical composition containing famotidine and ibuprofen.

21. The '127 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to Duexis®.

22. The '127 patent covers the Duexis® product.

23. On November 27, 2012, the U.S. Patent and Trademark Office ("PTO") duly and legally issued the '202 patent titled "Stable Compositions of Famotidine and Ibuprofen." A true and correct copy of the '202 patent is attached hereto as Exhibit B.

24. Horizon Pharma USA, Inc. is the sole owner of the '202 patent.

25. The '202 patent discloses and claims, inter alia, a pharmaceutical composition containing famotidine and ibuprofen.

26. The '202 patent is listed in the FDA publication entitled Approved Drug Products and Therapeutic Equivalence Evaluations ("the Orange Book") relative to Duexis®.

27. The '202 patent covers the Duexis® product.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '127 patent under 35 U.S.C. § 271(e)(2))

28. Horizon incorporates paragraphs 1-27 of this Complaint as if fully set forth herein.

29. Upon information and belief, Par Pharmaceutical, Inc. sent a letter dated December 4, 2012, to Horizon Pharma, Inc. and Horizon Pharma USA, Inc., which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter advised Horizon that Par's ANDA contains a Paragraph IV certification with respect to the '127 patent, and that no valid, enforceable claim of the '127 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Par ANDA Product.

30. Upon information and belief, Par Pharmaceutical, Inc. submitted Par's ANDA No. 203658 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the Duexis® product prior to the expiration of the '127 patent.

31. Upon information and belief, Par's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that, in its opinion, the '127 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Par ANDA Product.

32. By filing Par's ANDA No. 203658 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Par ANDA Product prior to the expiration of the '127 patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Par plans to commercially use, offer for sale, and/or sell the Par ANDA Product, and/or to induce or contribute to such activity, and by such actions Par would infringe one or more claims of the '127 patent under 35 U.S.C. § 271(a), (b) and/or (c).

33. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. participated in, contributed to, aided, and/or induced the submission of Par's ANDA No. 203658 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. will market and/or distribute the Par ANDA Product in the United States, and within this judicial district, if Par's ANDA No. 203658 is approved by the FDA. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. thus are jointly and severally liable for infringement of the '127 patent.

34. This action is being filed within 45 days of receipt by Horizon of the Par letter dated December 4, 2012, which purportedly advised Horizon of Par's Paragraph IV Certification with respect to the '127 patent.

35. Upon information and belief, Par had actual and constructive notice of the '127 patent prior to filing Par's ANDA No. 203658, and Par's infringement of the '127 patent has been, and continues to be, willful.

36. Horizon is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 203658 be a date that is not earlier than the expiration of the '127 patent, or any later expiration of exclusivity for the '127 patent to which it becomes entitled.

37. Horizon will be irreparably harmed if Par is not enjoined from infringing or actively inducing or contributing to infringement of the '127 patent, as Horizon has no adequate remedy at law.

38. This is an exceptional case, and Horizon is entitled to its costs and reasonable attorney fees.

COUNT II FOR PATENT INFRINGEMENT
(Infringement of the '202 patent under 35 U.S.C. § 271(e)(2))

39. Horizon incorporates paragraphs 1-27 of this Complaint as if fully set forth herein.

40. Upon information and belief, Par Pharmaceutical, Inc. sent a letter dated December 4, 2012, to Horizon Pharma, Inc. and Horizon Pharma USA, Inc., which purported to comply with the provisions of 21 U.S.C. § 355(j)(2)(B). This letter advised Horizon that Par's ANDA contains a Paragraph IV certification with respect to the '202 patent, and that no valid, enforceable claim of the '202 patent would be infringed by the manufacture, importation, use, sale or offer for sale of the Par ANDA Product.

41. Upon information and belief, Par Pharmaceutical, Inc. submitted Par's ANDA No. 203658 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of a generic copy of the Duexis® product prior to the expiration of the '202 patent.

42. Upon information and belief, Par's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") asserting that, in its opinion, the '202 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, offer for sale, sale and/or importation of the Par ANDA Product.

43. By filing Par's ANDA No. 203658 under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Par ANDA Product prior to the expiration of the '202 patent, Par has committed an act of infringement under 35 U.S.C. § 271(e)(2). Further, on information and belief, Par plans to commercially use, offer for sale, and/or sell the Par ANDA Product, and/or to induce or contribute to such activity, and by such actions Par would infringe one or more claims of the '202 patent under 35 U.S.C. § 271(a), (b) and/or (c).

44. Upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. participated in, contributed to, aided, and/or induced the submission of Par's ANDA No. 203658 and its Paragraph IV certification to the FDA. Additionally, upon information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. will market and/or distribute the Par ANDA Product in the United States, and within this judicial district, if Par's ANDA No. 203658 is approved by the FDA. Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. thus are jointly and severally liable for infringement of the '202 patent.

45. This action is being filed within 45 days of receipt by Horizon of the Par letter dated December 4, 2012, which purportedly advised Horizon of Par's Paragraph IV Certification with respect to the '202 patent.

46. Upon information and belief, Par had actual and constructive notice of the '202 patent prior to filing Par's ANDA No. 203658, and Par's infringement of the '202 patent has been, and continues to be, willful.

47. Horizon is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Par's ANDA No. 203658 be a date that is not earlier than the expiration of the '202 patent, or any later expiration of exclusivity for the '202 patent to which it becomes entitled.

48. Horizon will be irreparably harmed if Par is not enjoined from infringing or actively inducing or contributing to infringement of the '202 patent, as Horizon has no adequate remedy at law.

49. This is an exceptional case, and Horizon is entitled to its costs and reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Horizon Pharma, Inc. and Horizon Pharma USA, Inc. respectfully request the following relief:

A. A judgment that Par has infringed one or more claims of the '127 patent under 35 U.S.C. § 271(e)(2);

A. A judgment that Par has infringed one or more claims of the '202 patent under 35 U.S.C. § 271(e)(2);

B. An order pursuant to 35 U.S.C. § 271(e)(4) providing that the effective date of any FDA approval of Par's ANDA No. 203658 be not earlier than the latest of the

expiration dates of the '127 and '202 patents or any later expiration of exclusivity for these patents to which it may become entitled;

C. A permanent injunction restraining and enjoining Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. and each of their officers, agents, servants, employees and those persons acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale or sale within the United States or its territories, or importation into the United States or its territories, of the Par ANDA Product, or any product that infringes the '127 or '202 patents;

D. Declaring this to be an exceptional case and awarding Horizon its attorney fees under 35 U.S.C. § 285;

E. Damages and treble damages from Par from any commercial activity constituting infringement of the '127 or '202 patents;

F. Costs and expenses in this action; and

G. Such other and further relief as this Court determines to be just and proper.

Respectfully submitted,

Date: January 17, 2013

/s/ John C. Phillips, Jr.

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