IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GMBH and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by Par Pharmaceutical, Inc. of Abbreviated New Drug Application ("ANDA") No. 204786 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of STAXYN® prior to the expiration of U.S. Patent Nos. 6,362,178 and 7,696,206.

THE PARTIES

2. Plaintiff Bayer Pharma AG, formerly known as Bayer Schering Pharma AG, is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

3. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim, Germany.

4. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 6 West Belt, Wayne, New Jersey.

5. On information and belief, defendant Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at One Ram Ridge Road, Spring Valley, NY 10977 and a place of business at 30 Dunnigan Drive, Suffern, NY 10901.

6. On information and belief, defendant Par Pharmaceutical Companies, Inc. ("Par Companies") is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 300 Tice Boulevard, Woodcliff Lake, NJ 07677.

7. On information and belief, Par Pharmaceutical, Inc. is a wholly-owned subsidiary of Par Companies and is controlled and dominated by Par Companies. Upon information and belief, Par Pharmaceutical, Inc. develops and manufactures numerous generic drugs for sale and use throughout the United States at the direction of, under the control of, and for the direct benefit of Par Companies.

8. On information and belief, Par Pharmaceutical, Inc.'s preparation and submission of ANDA No. 204786 for Par Pharmaceutical, Inc.'s Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg (Par's "ANDA Product") was done at the direction of, under the control of, and for the direct benefit of Par Companies.

9. On information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 204786, Par Pharmaceutical, Inc. and Par Companies will act in concert to distribute and sell Par's ANDA Product throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Par." Upon information and belief, following any FDA approval of ANDA No. 204786, Par knows and intends that its ANDA Product will be distributed and sold in the United States and within Delaware.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. Par Pharmaceutical, Inc. and Par Companies are subject to personal jurisdiction in Delaware because, among other things, they are incorporated in Delaware, they regularly transact and/or solicit business in Delaware, have consented to jurisdiction in Delaware in cases arising out of their filing of ANDAs, and have purposefully availed themselves of this forum such that they should reasonably anticipate being haled into court here.

12. On information and belief, Par Pharmaceutical, Inc. and Par Companies share common employees, officers and/or directors.

13. On information and belief, Par Pharmaceutical, Inc. and Par Companies are agents of each other, and/or operate in concert as integrated parts of Par's business.

14. On information and belief, various products for which Par Pharmaceutical, Inc. is the named applicant on approved ANDAs are available at retail pharmacies in Delaware, and are available for direct purchase by pharmacies in Delaware and elsewhere.

15. On information and belief, Par Pharmaceutical, Inc. and Par Companies participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 204786, the ANDA at issue in this litigation.

16. On information and belief, Par Pharmaceutical, Inc. and Par Companies will manufacture, market, and/or sell within the United States the generic product described in Par's ANDA No. 204786 if FDA approval is granted. If ANDA No. 204786 is approved, the generic product accused of infringing the '178 and '206 patents would, among other things, be marketed and distributed in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

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

BACKGROUND

18. STAXYN® (active ingredient vardenafil hydrochloride ("vardenafil HCl")) is a selective inhibitor of cyclic guanosine monophosphate-specific phosphodiesterase type 5. STAXYN® is indicated for the treatment of erectile dysfunction.

19. United States Patent No. 6,362,178 (herein, "the '178 patent"), entitled "2-Phenyl Substituted Imidazotriazinones As Phosphodiesterase Inhibitors", was duly and legally issued on March 26, 2002. The '178 patent is attached as Exhibit A hereto.

20. Bayer Intellectual Property GmbH is the assignee of the '178 patent.

21. Bayer Pharma AG holds an exclusive license under the '178 patent.

22. United States Patent No. 7,696,206 (herein, "the '206 patent"), entitled "2-Phenyl Substituted Imidazotriazinones As Phosphodiesterase Inhibitors," was duly and legally issued on April 13, 2010. The '206 patent is attached as Exhibit B hereto.

23. Bayer Intellectual Property GmbH is the assignee of the '206 patent.

24. Bayer Pharma AG holds an exclusive license under the '206 patent.

25. Bayer HealthCare Pharmaceuticals Inc. is the holder of New Drug Application No. 200179 for STAXYN®, which has been approved by the FDA. Pursuant to 21 U.S.C. § 355, both the '178 patent and the '206 patent are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with STAXYN®.

26. One or more claims of the '178 patent, incorporated by reference herein, cover STAXYN® and its active ingredient, the chemical compound vardenafil HCl. The claims of the '178 patent also cover a method of treating erectile dysfunction using vardenafil HCl.

27. One or more claims of the '206 patent, incorporated by reference herein, cover STAXYN® and its active ingredient, the chemical compound vardenafil HCl. The claims of the '206 patent also cover a method of treating erectile dysfunction using vardenafil HCl.

28. By letter dated April 2, 2013 (the "Notice Letter"), Par notified Plaintiffs Bayer Intellectual Property GmbH and Bayer HealthCare Pharmaceuticals Inc. that Par Pharmaceutical, Inc. had submitted to the FDA ANDA No. 204786 for Par's ANDA Product. This product is a generic version of STAXYN®.

29. The purpose of ANDA No. 204786 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, or sale of Par's ANDA Product prior to the expiration of the '178 and '206 patents.

30. In the Notice Letter, Par also notified Plaintiffs that, in connection with its ANDA No. 204786, Par Pharmaceutical, Inc. had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications"), with respect to the '178 and '206 patents. Upon information and belief, Par

Pharmaceutical, Inc. submitted Paragraph IV Certifications in connection with ANDA No. 204786 asserting that the '178 and '206 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Par's ANDA Product.

31. The Notice Letter provides no valid basis for concluding that the '178 patent or the '206 patent is invalid, unenforceable or not infringed.

32. In the Notice Letter, Par notified Plaintiffs Bayer Pharma AG and Bayer HealthCare Pharmaceuticals Inc. that Par's ANDA Product contains vardenafil HCl.

33. On information and belief, in ANDA No. 204786, Par seeks approval to market and sell Par's ANDA Product to treat erectile dysfunction.

34. Par had knowledge of the '178 patent and the '206 patent prior to its filing Paragraph IV Certifications for the '178 patent and the '206 patent in connection with ANDA No. 204786.

35. On information and belief, Par intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product immediately and imminently upon approval of ANDA No. 204786, *i.e.*, prior to the expiration date of the '178 patent and the '206 patent.

COUNT I
(Patent Infringement – '178 Patent)

36. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

37. Par's ANDA Product contains the chemical compound vardenafil HCl.

38. Par's submission of ANDA No. 204786 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Par's

ANDA Product before the expiration of the '178 patent infringed the '178 patent under 35 U.S.C. § 271(e)(2)(A).

39. Upon information and belief, Par will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product immediately and imminently upon approval of ANDA No. 204786.

40. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product would infringe one or more claims of the '178 patent.

41. Upon information and belief, Par will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 204786.

42. Upon information and belief, use of Par's ANDA Product in accordance with and as directed by Par's proposed labeling for that product would infringe one or more claims of the '178 patent.

43. Upon information and belief, Par plans and intends to, and will, actively induce infringement of the '178 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

44. Upon information and belief, Par knows that Par's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '178 patent, and that Par's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Par plans and intends to, and will, contribute to infringement of the '178 patent immediately and imminently upon approval of ANDA No. 204786.

45. The foregoing actions by Par constitute and/or will constitute infringement of the '178 patent, active inducement of infringement of the '178 patent, and contribution to the infringement by others of the '178 patent.

46. Upon information and belief, Par has acted with full knowledge of the '178 patent and without a reasonable basis for believing that it would not be liable for infringing the '178 patent, actively inducing infringement of the '178 patent, and contributing to the infringement by others of the '178 patent.

47. Unless Par is enjoined from infringing the '178 patent, actively inducing infringement of the '178 patent, and contributing to the infringement by others of the '178 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Patent Infringement – '206 Patent)

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

49. Par's ANDA Product contains the chemical compound vardenafil HCl.

50. Par's submission of ANDA No. 204786 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Par's ANDA Product before the expiration of the '206 patent infringed the '206 patent under 35 U.S.C. § 271(e)(2)(A).

51. Upon information and belief, Par will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product immediately and imminently upon approval of ANDA No. 204786.

52. The manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product would infringe one or more claims of the '206 patent.

53. Upon information and belief, Par will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Par's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 204786.

54. Upon information and belief, use of Par's ANDA Product in accordance with and as directed by Par's proposed labeling for that product would infringe one or more claims of the '206 patent.

55. Upon information and belief, Par plans and intends to, and will, actively induce infringement of the '206 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

56. Upon information and belief, Par knows that Par's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '206 patent, and that Par's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. Upon information and belief, Par plans and intends to, and will, contribute to infringement of the '206 patent immediately and imminently upon approval of ANDA No. 204786.

57. Tbe foregoing actions by Par constitute and/or will constitute infringement of the '206 patent, active inducement of infringement of the '206 patent, and contribution to the infringement by others of the '206 patent.

58. Upon information and belief, Par has acted with full knowledge of the '206 patent and without a reasonable basis for believing that it would not be liable for infringing the '206 patent, actively inducing infringement of the '206 patent, and contributing to the infringement by others of the '206 patent.

59. Unless Par is enjoined from infringing the '206 patent, actively inducing infringement of the '206 patent, and contributing to the infringement by others of the '206 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Par has infringed the '178 patent and the '206 patent;

(b) A judgment ordering that the effective date of any FDA approval for Par to make, use, offer for sale, sell, market, distribute, or import Par's ANDA Product, or any product or compound that infringes the '178 or '206 patent, be not earlier than the expiration date of the '178 or the '206 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(c) A preliminary and permanent injunction enjoining Par, and all persons acting in concert with Par, from making, using, selling, offering for sale, marketing, distributing, or importing Par's ANDA Product, or any product or compound that infringes the '178 patent or '206 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '178 patent or '206 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A judgment declaring that making, using, selling, offering for sale, marketing, distributing, or importing Par's ANDA Product, or any product or compound that infringes the '178 patent or '206 patent, prior to the expiration date of the '178 patent or '206 patent, will infringe, actively induce infringement of, and contribute to the infringement by others of the '178 patent or '206 patent;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 351-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH and Bayer HealthCare Pharmaceuticals Inc.

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
David I. Berl
Dov P. Grossman
Thomas S. Fletcher
Galina I. Fomenkova
WILLIAMS & CONNOLLY LLP
725 Twelfth St. NW
Washington, DC 20005
(202) 434-5000

May 14, 2013
7202785.1