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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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

COMPLAINT

Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") for their Complaint against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively, "Par") 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 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 No. 8,613,950 ("the '950 patent").

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 am Rhein, 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 100 Bayer Boulevard, Whippany, New Jersey 07981.

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

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

8. Upon information and belief, and consistent with their practice with respect to other generic products, following any FDA approval of ANDA No. 204786, Par Pharmaceutical and Par Companies will act in concert to distribute and sell Par's ANDA Product throughout the United States and within New Jersey. These two entities are herein 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 New Jersey.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

10. Par Pharmaceutical and Par Companies are subject to personal jurisdiction in New Jersey because, among other things, they regularly transact and/or solicit business in New Jersey, have consented to jurisdiction in New Jersey 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. In addition, both Par Companies and Par Pharmaceutical have their principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey.

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

12. On information and belief, Par Pharmaceutical and Par Companies are agents of each other, and/or operate in concert as integrated parts of Par's business. For example, in Par Companies' Form 10-K for the 2013 fiscal year, Par Companies stated that it is "a Delaware holding company that, principally through its wholly owned operating subsidiary,

Par Pharmaceutical, Inc., is in the business of developing, licensing, manufacturing, marketing and distributing generic and branded drugs in the United States." Par Companies further stated that it organizes its business into two business segments, one of which is Par Pharmaceutical, Par Companies' "generic products division."

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

14. On information and belief, Par Pharmaceutical 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. For example, although ANDA No. 204786 was filed by Par Pharmaceutical, Par Companies' 2013 Form 10-K states that "As of the fourth quarter of 2013, *we* or our strategic partners had approximately 73 ANDAs pending with the FDA, which included 27 first-to-file opportunities and four potential first-to-market product opportunities." (Emphasis added.)

15. On information and belief, Par Pharmaceutical 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 '950 patent would, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

16. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and (c), and 1400(b).

BACKGROUND

17. 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.

18. United States Patent No. 8,613,950, entitled "Pharmaceutical Forms with Improved Pharmacokinetic Properties," was duly and legally issued on December 24, 2013. The '950 patent is attached as Exhibit A to this complaint.

19. Bayer Intellectual Property GmbH is the assignee of the '950 patent.

20. Bayer Pharma AG holds an exclusive license under the '950 patent.

21. 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, the '950 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with STAXYN®.

22. One or more claims of the '950 patent, incorporated by reference herein, cover STAXYN®.

23. By letter dated March 17, 2014 (the "Notice Letter"), Par Pharmaceutical notified Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. that Par had submitted to the FDA ANDA No. 204786 for Par's ANDA Product. This product is a generic version of STAXYN®.

24. 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 '950 patent.

25. In the Notice Letter, Par also notified Plaintiffs that, in connection with its

ANDA No. 204786, Par had filed a certification 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 Certification"), with respect to the '950 patent. Upon information and belief, Par submitted a Paragraph IV Certification in connection with ANDA No. 204786 asserting that the '950 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of Par's ANDA Product.

26. The Notice Letter provides no valid basis for concluding that the '950 patent is invalid, unenforceable or not infringed. As to certain claims of the '950 patent, the Notice Letter also fails to identify any limitation of such claims that is not met literally by Par's ANDA Product.

27. In the Notice Letter, Par notified Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. that Par's ANDA Product contains vardenafil HCl in the form of an orally disintegrating tablet.

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

29. Par had knowledge of the '950 patent prior to its filing of a Paragraph IV Certification for the '950 patent in connection with ANDA No. 204786.

30. 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 '950 patent.

COUNT I – PATENT INFRINGEMENT – '950 PATENT

31. Bayer incorporates each of the preceding paragraphs 1-30 as if fully set

forth herein.

32. Par's ANDA Product contains the chemical compound vardenafil HCl in the form of an orally disintegrating tablet.

33. 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 '950 patent infringed the '950 patent under 35 U.S.C. § 271(e)(2)(A).

34. 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.

35. 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 '950 patent.

36. 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.

37. 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 '950 patent.

38. Upon information and belief, Par plans and intends to, and will, actively induce infringement of the '950 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. The foregoing actions by Par constitute and/or will constitute infringement of the '950 patent and active inducement of infringement of the '950 patent.

40. Upon information and belief, Par has acted with full knowledge of the '950 patent and without a reasonable basis for believing that it would not be liable for infringing the '950 patent or actively inducing infringement of the '950 patent.

41. Unless Par is enjoined from infringing the '950 patent and/or actively inducing infringement of the '950 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Bayer respectfully requests that judgment be entered in favor of Bayer and against Par and requests the following relief:

A. A judgment that Par has infringed the '950 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 that infringes the '950 patent, be not earlier than the expiration date of the '950 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 that infringes the '950 patent, or the inducement of any of the foregoing, prior to the expiration date of the '950 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 that infringes the '950 patent, prior to the expiration date of the '950 patent, will infringe and actively induce infringement by others of the '950 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 other and further relief as the Court may deem just and proper.

Respectfully submitted,

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Dated: April 2, 2014

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any pending arbitration or administrative proceeding. The patent asserted in this civil action is not the subject of any other action pending in any court. The ANDA filed by Par is the subject of an action pending in another court involving different, unrelated patents: *Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals, Inc. v. Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc.*, C.A. No. 13-845 (GMS) (D. Del.).

Pursuant to Local Civil Rule 40.1, I hereby certify that this civil action involves the validity or infringement of a patent which is involved in a case already pending in this Court, *Bayer Pharma AG et al. v. Watson Laboratories, Inc. et al.*, 2-14-cv-01084-JLL-JAD.

Respectfully submitted,

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Dated: April 2, 2014