IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER PHARMA AG, BAYER INTELLECTUAL PROPERTY GMBH, and BAYER HEALTHCARE PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC GLOBAL HOLDING SA, AND ALEMBIC PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Pharma AG, Bayer Intellectual Property GmbH, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer" or "Plaintiffs"), for their Complaint against Alembic Pharmaceuticals Limited ("APL"), Alembic Global Holding SA ("Alembic Global"), and Alembic Pharmaceuticals, Inc. ("Alembic Pharma"), 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 APL of Abbreviated New Drug Application ("ANDA") No. 208324 with the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of STAXYN® prior to the expiration of U.S. Patent No. 8,613,950 ("the '950 patent").

THE PARTIES

2. Plaintiff Bayer 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 APL is a company organized and existing under the laws of India having a principal place of business at Alembic Road, Vadodara, 390 003, Gujarat, India.

6. Upon information and belief, defendant Alembic Global is a corporation organized and existing under the laws of Switzerland, having a place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland.

7. Upon information and belief, defendant Alembic Pharma is a Delaware corporation, having a place of business at 116 Village Boulevard, Suite 200, Princeton, New Jersey, 08650.

8. Upon information and belief, Alembic Global is a wholly-owned subsidiary of APL and is controlled and dominated by APL.

9. Upon information and belief, Alembic Pharma is a wholly-owned subsidiary of Alembic Global, and is controlled and dominated by Alembic Global and APL.

10. Upon information and belief, APL is in the business of manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, upon information and belief, APL, acting in concert with Alembic Global and Alembic Pharma, files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, as a part of these ANDAs, APL, acting in concert with Alembic Global and Alembic Pharma, files certifications of the type described in Sections 505(b)(2)(A)(iv) and 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

11. Upon information and belief, Alembic Pharma markets, distributes, sells and/or offers for sale generic drugs throughout the United States and in Delaware at the direction of, under the control of, and for the direct benefit of APL and Alembic Global.

12. Upon information and belief, Alembic Global and Alembic Pharma assisted in the preparation and submission of ANDA No. 208324 for APL's 10 mg vardenafil hydrochloride orally disintegrating tablets ("Alembic's ANDA Product"), which was done at the direction of, under the control of, and for the direct benefit of APL.

13. Upon information and belief, APL, Alembic Global, and Alembic Pharma are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution

of pharmaceutical products throughout the United States, including in Delaware, of generic pharmaceuticals, including the infringing Alembic's ANDA Product at issue.

14. Upon information and belief, following any FDA approval of ANDA No. 208324, APL, Alembic Global, and Alembic Pharma will act in concert to market, distribute, offer for sale, and sell Alembic's ANDA Product throughout the United States and within Delaware. These three entities are hereafter collectively referred to as "Alembic" or "Defendants." Upon information and belief, following any FDA approval of ANDA No. 208324, Alembic knows and intends that its ANDA Product will be marketed, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION AND VENUE

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

16. This Court has personal jurisdiction over Alembic Pharma because, *inter alia*, Alembic Pharma is a corporation formed under the laws of the State of Delaware.

17. In addition, this Court has personal jurisdiction over Alembic Pharma because, upon information and belief, Alembic Pharma has registered to do business in the State of Delaware and has appointed a registered agent in Delaware, (National Registered Agents, Inc., 160 Greentree Drive, Suite 101, Dover, Delaware 19904) to accept service of process. Alembic Pharma has thus consented to jurisdiction in Delaware.

18. APL and Alembic Global are subject to personal jurisdiction in Delaware because, among other things, upon information and belief, (1) APL and Alembic Global are in the business of manufacturing drug products which they market, distribute, offer for sale and sell, either themselves or through one or more of their agents (including Alembic Pharma),

throughout the United States, including in Delaware, derive substantial revenue from services or things used or consumed in the State of Delaware, and transact business with companies located and/or headquartered in Delaware; (2) APL, acting in concert with Alembic Global and Alembic Pharma, has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Alembic's ANDA Product in the United States, including in Delaware; and (3) Alembic Pharma, acting as APL's and Alembic Global's agent and/or alter ego, will market, distribute, offer for sale, and/or sell Alembic's ANDA Product in the United States, including in Delaware, upon approval of ANDA No. 208324, and will derive substantial revenue from the use or consumption of Alembic's ANDA Product in the State of Delaware.

19. Upon information and belief, Alembic Pharma is responsible for marketing, distributing, offering for sale, and/or selling generic copies of branded pharmaceutical products for the U.S. market, including in Delaware, and relies on contributions from APL and Alembic Global.

20. On information and belief, Alembic Pharma, acting as the agent of APL and Alembic Global, markets, distributes, offers for sale, and/or sells in Delaware and elsewhere in the United States generic pharmaceutical products that are manufactured by APL or for which APL is the named applicant on approved ANDAs. Upon information and belief, Alembic Pharma, Alembic Global and/or APL are parties to one or more contractual agreements regarding the distribution of such generic pharmaceutical products. Upon information and belief, such agreements are nearer than arm's length.

21. On information and belief, APL and Alembic Global earn revenue from the marketing, distribution, offer for sale, and/or sale in Delaware by Alembic Pharma of generic

pharmaceutical products that are manufactured by APL or for which APL is the named applicant on approved ANDAs. On information and belief, various products for which APL is the named applicant on approved ANDAs are available at retail pharmacies in Delaware. On information and belief, APL, Alembic Global, and Alembic Pharma will market, distribute, offer for sale, and/or sell within the United States, including in Delaware, Alembic's ANDA Product if FDA approval is granted. On information and belief, if ANDA No. 208324 is approved, the generic product charged with infringing the '950 patent would, among other things, be marketed, distributed, offered for sale, and/or sold 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.

22. On information and belief, APL, Alembic Global, and Alembic Pharma participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 208324 (the ANDA at issue in this litigation) for Alembic's ANDA Product.

23. In addition, upon information and belief, this Court has personal jurisdiction over Defendants because the Notice Letter (defined below) was sent to Plaintiff Bayer HealthCare Pharmaceuticals Inc. and Bayer HealthCare LLC. That has led and/or will lead to foreseeable harm and injury to one or more Plaintiffs in Delaware. APL, Alembic Global, and Alembic Pharma have been litigants in connection with other infringement actions under the Hatch-Waxman Act, and reasonably should have anticipated that by sending the Notice Letter to Bayer HealthCare Pharmaceuticals Inc., a Delaware corporation, and Bayer HealthCare LLC, a Delaware limited liability company, that Alembic would be sued in Delaware for patent infringement.

24. Alternatively, if APL's connections with Delaware, including its connections with Alembic Pharma, are found to be insufficient to confer personal jurisdiction, then, upon information and belief, APL is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over APL in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

25. Alternatively, if Alembic Global's connections with Delaware, including its connections with Alembic Pharma, are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Alembic Global is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Alembic Global in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

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

BACKGROUND

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

28. 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.

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

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

31. 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®.

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

33. By letter dated August 6, 2015 (the "Notice Letter"), APL notified Bayer Intellectual Property GmbH, Bayer HealthCare Pharmaceuticals Inc., and Bayer HealthCare LLC that APL had submitted to the FDA ANDA No. 208324 for Alembic's ANDA Product. This product is a generic version of STAXYN®.

34. In the Notice Letter, APL stated that ANDA No. 208324 was submitted to obtain approval under the FDCA to engage in the commercial manufacture, use, or sale of Alembic's ANDA Product prior to the expiration of the '950 patent.

35. In the Notice Letter, APL stated that, in connection with its ANDA No. 208324, APL 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. APL also asserted in the Notice Letter that it has certified to the FDA that, in its opinion, the '950 patent is invalid, unenforceable, and/or will not be infringed by the manufacture, importation, use, or sale of Alembic's ANDA Product.

36. In the Notice Letter, APL described Alembic's ANDA Product as vardenafil hydrochloride orally disintegrating tablets.

37. APL had knowledge of the '950 patent prior to its filing of a Paragraph IV Certification for the '950 patent in connection with ANDA No. 208324.

38. On information and belief, Alembic intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product

immediately and imminently upon approval of ANDA No. 208324, *i.e.*, prior to the expiration date of the '950 patent.

39. In the Notice Letter, APL included an Offer of Confidential Access to portions of its ANDA. The offer, however, was subject to various unreasonably restrictive conditions.

40. Plaintiffs attempted to negotiate access to Alembic confidential information, proposing that the parties use the protective order that had been entered in another action involving the '950 patent, and seeking access to documents and samples beyond Alembic's ANDA that are relevant to infringement of the '950 patent. Although Alembic ultimately agreed to provide Plaintiffs with a copy of ANDA 208324 pursuant to the aforementioned protective order, Alembic refused to provide Plaintiffs with other materials Plaintiffs requested.

41. This action is being commenced before the expiration of forty-five days from the date of the receipt of the Notice Letter.

CLAIM FOR PATENT INFRINGEMENT – '950 PATENT

42. Plaintiffs incorporate each of the preceding paragraphs 1-41 as if fully set forth herein.

43. Alembic's submission of ANDA No. 208324 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Alembic's ANDA Product prior to the expiration of the '950 patent infringed the '950 patent under 35 U.S.C. § 271(e)(2)(A).

44. Upon information and belief, Alembic's ANDA Product is covered by one or more claims of the '950 patent.

45. Upon information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product immediately and imminently upon approval of ANDA No. 208324.

46. Upon information and belief, the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product prior to the expiration of the '950 patent would infringe one or more claims of the '950 patent.

47. Upon information and belief, Alembic will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Alembic's ANDA Product with its proposed labeling immediately and imminently upon approval of ANDA No. 208324.

48. Upon information and belief, use of Alembic's ANDA Product in accordance with and as directed by Alembic's proposed labeling for that product would infringe one or more claims of the '950 patent.

49. Upon information and belief, Alembic 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.

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

51. Unless Alembic 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, Plaintiffs respectfully request that judgment be entered in favor of Plaintiffs and against Alembic and requests the following relief:

A. A judgment that Alembic has infringed the '950 patent;

B. A judgment ordering that the effective date of any FDA approval for Alembic to make, use, offer for sale, sell, market, distribute, or import Alembic'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 Alembic, and all persons acting in concert with Alembic, from making, using, selling, offering for sale, marketing, distributing, or importing Alembic'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 Alembic'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.

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
(302) 658-9200
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
Dov P. Grossman
Thomas S. Fletcher
Galina I. Fomenkova
Christopher T. Berg
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
(202) 434-5000

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