IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

AJANTA PHARMA LIMITED, Plaintiff, v. PFIZER INC., PFIZER PRODUCTS INC., and, C.P. PHARMACEUTICALS INTERNATIONAL C.V. Defendants.	Civil Action No. 19-cv-6607

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Ajanta Pharma Limited ("Ajanta") alleges against Pfizer Inc., Pfizer Products Inc., and C.P. Pharmaceuticals International C.V. ("Pfizer") as follows:

NATURE OF THE ACTION

1. This action arises under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), which govern the U.S. Food and Drug Administration ("FDA") approval of both new and generic drugs. *See* 21 U.S.C. § 355 *et seq.*; 35 U.S.C. §§ 156, 217(e).

2. Ajanta submitted Abbreviated New Drug Application ("ANDA") No. 213019 to FDA seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of varenicline tablets, 0.5 mg and 1 mg ("Ajanta's proposed

ANDA product"). The Reference Listed Drug for ANDA No. 213019 is Chantix® (varenicline) tablets, 0.5 mg and 1 mg.

3. FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists U.S. Patent Nos. 6,890,927 ("the '927 patent") and 7,265,119 ("the '119 patent") for Chantix®. Ajanta's ANDA No. 213019 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that no valid claim of the '927 patent and the '119 patent would be infringed by the manufacture, use, sale or offer to sell within, and/or importation into, the United States of varenicline tablets, 0.5 mg and 1 mg.

4. In accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Ajanta transmitted a letter dated March 5, 2019 to Pfizer Inc. and Pfizer Prism CV notifying them that ANDA No. 213019 had been submitted to FDA under 21 U.S.C. § 355(j) and that ANDA No. 213019 included a Paragraph IV certification for the '927 and '119 patents ("Ajanta's March 5, 2019 Notice Letter"). In its March 5, 2019 Notice Letter, Ajanta included a detailed statement of the factual and legal bases upon which it based its Paragraph IV certification and extended to Pfizer an Offer of Confidential Access ("OCA") to Ajanta's ANDA No. 213019.

5. Pfizer Inc. and Pfizer Prism CV did not file suit against Ajanta within forty-five days after receiving Ajanta's March 5, 2019 Notice Letter.

6. The Hatch-Waxman Act provides for a "civil action to obtain patent certainty" when an ANDA applicant makes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV). *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc). This declaratory judgment provision in the Hatch-Waxman Act aims to encourage early resolution of patent disputes, and prevent brand-name drug companies from using tactics that forestall the competing generic drug makers from entering the

market. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

7. Ajanta's complaint seeks a judgment to obtain patent certainty that Ajanta's proposed ANDA product does not infringe any valid and enforceable claim of the '927 and '119 patents. Such judgment would enable Ajanta to bring Ajanta's proposed ANDA product to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

THE PARTIES

8. Ajanta is a corporation organized and existing under the laws of India, having its principal place of business at Ajanta House, Charkop, Kandivali (West) Mumbai, Maharashtra 400067 India.

9. On information and belief, Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 235 East 42nd Street, New York, New York 10017.

10. On information and belief, Pfizer Products Inc., is a corporation organized and existing under the laws of the State of Connecticut, having a place of business at Eastern Point Road, Groton, Connecticut 06340. On information and belief, Pfizer Products Inc. is a subsidiary of Pfizer Inc.

11. On information and belief, C.P. Pharmaceuticals International C.V. is a limited partnership organized and existing under the laws of the Netherlands, having a place of business at 235 East 42nd Street, New York, New York 10017. On information and belief, C.P. Pharmaceuticals International C.V. is a subsidiary of Pfizer Inc.

JURISDICTION AND VENUE

12. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 et seq.), the Declaratory Judgment Act (28 U.S.C. §§ 2201-02), 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

13. This Court has personal jurisdiction over Pfizer, at least because of Pfizer's continuous and systematic contacts with the state of New York, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in New York including, but not limited to, Chantix®.

14. This Court has personal jurisdiction over Pfizer at least because Pfizer, (1) upon information and belief, directly or indirectly markets and sells pharmaceutical products throughout the United States and in this judicial district and (2) have consented to personal jurisdiction in this judicial district by filing of suits in this judicial district, including, but not limited to *Pfizer Inc., et al. v. Mylan Inc. et al.*, 1:10-cv-06463-WHP (S.D.N.Y.); *Pfizer Inc. et al., v. Apotex Inc. et al.*, 1:10-cv-06464-WHP (S.D.N.Y.); and *Pfizer Inc., v. Intellipharmaceutics Int'l Inc.*, 1:14-cv-06373-GHW (S.D.N.Y.), thereby having availed themselves of the rights and benefits of New York law. Upon information and belief, Pfizer purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of Pfizer's pharmaceutical products.

15. Venue is proper in this District under 28 U.S.C. §§ 1391, 1400, and/or 21 U.S.C. § 355.

HATCH-WAXMAN OVERVIEW

16. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271(e). The Hatch-Waxman Act was intended to encourage drug competition while leaving intact incentives for research and development of new drugs by pioneering, i.e., "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

17. Under the Hatch-Waxman Act, a company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") to FDA, which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD. *See* 21 U.S.C. § 355. The NDA holder must also submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] … and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug." *See* 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), (c)(2). The FDA lists the patent number(s) and expiration date(s) in the Orange Book. *See* 21 U.S.C. § 355(b)(1).

18. The Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to FDA. *See* 21 U.S.C. § 355(j). An ANDA is "abbreviated" because ANDA applicants generally are not required to include the extensive pre-clinical and clinical data that must be included in an NDA for a brand-name drug. Instead, ANDA applicants can rely on the NDA's pre-clinical and clinical data if the proposed generic

product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

19. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "paragraph IV certification."

20. An applicant submitting an ANDA containing a paragraph IV certification must provide written notice (i.e., "a notice letter") informing both the patent holder and the NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

21. The Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if a paragraph IV certification has been made. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent holder or NDA holder brings suit within 45-days of receiving notice of the paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by FDA of the ANDA to allow parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

22. If neither the patent holder nor the NDA holder bring an action for infringement of a patent that is the subject of a paragraph IV certification within the 45-day period, the ANDA applicant may bring a declaratory judgment action against the patent holder and/or NDA holder,

provided that the ANDA applicant's notice letter included an offer of confidential access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

23. The Hatch-Waxman Act provides that the first generic applicant(s) to file a substantially complete ANDA that contains a lawfully maintained Paragraph IV certification is eligible to receive 180 days of marketing exclusivity. Until the 180 days of marketing exclusivity expires, FDA will not make another ANDA for the same product "effective." *See id.* at § 355(j)(5)(B)(iv). In other words, FDA will not grant final approval to another ANDA for the same product. *See id.* Therefore, the 180-day marketing exclusivity prevents subsequent filers from entering the marketplace for as long as the first filer holds the exclusivity. *See* § 355(a).

24. In an effort to prevent a first filer from indefinitely preventing subsequent filers from entering the market, the Hatch-Waxman act provides that a first filer may forfeit its 180-day marketing exclusivity under certain circumstances.

25. For example, a first filer will forfeit its exclusivity if it fails to market its product by the later of two events: (i) the earlier of either 75 days after the first filer's ANDA is approved or 30 months after the first filer submits its ANDA; and (ii) 75 days after a subsequent ANDA filer (who has tentative approval for its ANDA from FDA) obtains a final decision of noninfringement or invalidity for each patent for which the first filer submitted and lawfully maintained a Paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I). A "final decision" in this context is a decision from which no appeal has been or can be taken other than a petition to the Supreme Court for a writ of certiorari. *See id.*

26. A first filer will also forfeit its exclusivity if it fails to obtain tentative or final approval within 30 months after it files its ANDA unless the failure to obtain approval was

caused by a change in or a review of the requirements for approval of the application imposed after the date on which the application is filed. 21 U.S.C. § 355(j)(5)(D)(i)(IV).

PATENTS-IN-SUIT

27. Upon information and belief, Pfizer Prism CV is the holder of NDA No. 021928 on Chantix® (varenicline tartrate) tablets, 0.5 mg and 1 mg.

28. Upon information and belief, the '927 patent, titled "Tartrate Salts of 5,8, 14-Triazateracyclo[10.3.1.02,11 04.9]-Hexadeca-2(11),3,5,7,9-Pentaene And Pharmaceutical Compositions Thereof" was issued on May 10, 2005. A copy of the '927 patent is attached as Exhibit A.

29. Upon information and belief, Pfizer Inc. and Pfizer Products Inc. are the assignees of the '927 patent.

30. Upon information and belief, the '119 patent, titled "Tartrate Salts of 5,8,14-Triazatetracyclo[10.3.1.$0^{2,11}$.$0^{4,9}$]-Hexadeca-2(11),3,5,7,9-Pentaene and Pharmaceutical Compositions Thereof" was issued on September 4, 2007. A copy of the '119 patent is attached as Exhibit B.

31. Upon information and belief, Pfizer Inc. is the assignee of the '119 patent.

32. Upon information and belief, Pfizer Inc. has exclusively licensed the '927 and '119 patents to C.P. Pharmaceuticals International C.V.

APOTEX AND MYLAN'S FIRST FILED ANDAS

33. Upon information and belief, Apotex Inc. ("Apotex") and Mylan Pharmaceuticals Inc. ("Mylan") were the first to file substantially complete ANDAs that identify Chantix® as the Reference Listed Drug and submitted Paragraph IV certifications for the '927 and '119 patents.

34. As the generic companies that filed the first substantially complete ANDAs, Apotex and Mylan became eligible for the 180-day period of exclusivity.

35. Upon information and belief, Apotex received tentative approval for its ANDA on May 15, 2012.

36. Upon information and belief, Apotex has not received final approval for its ANDA, it has been more than thirty months since Apotex submitted its ANDA, and FDA has not made a formal determination of Apotex's eligibility for 180-day exclusivity.

37. Upon information and belief, Mylan received tentative approval for its ANDA on May 3, 2013.

38. Upon information and belief, Mylan has not received final approval for its ANDA, it has been more than thirty months since Mylan submitted its ANDA, and FDA has not made a formal determination of Mylan's eligibility for 180-day exclusivity.

ACTIONS GIVING RISE TO THIS SUIT

39. Ajanta submitted ANDA No. 213019 to FDA seeking approval to engage in the manufacture, use, sale or offer to sell within, and/or importation into, the United States of Ajanta's proposed ANDA product. Ajanta's ANDA No. 213019 contains a paragraph IV certification that the '927 and '119 patents are invalid and/or will not be infringed by the manufacture, use, or sale of Ajanta's ANDA Product.

40. In accordance with 21 U.S.C. § 355(j)(2)(B), Ajanta transmitted its March 5, 2019 Notice Letter to Pfizer Inc. and Pfizer Prism CV notifying them that ANDA No. 213019 had been submitted to FDA under 21 U.S.C. § 355(j) and included a Paragraph IV certification for the '927 and '119 patents. In its March 5, 2019 Notice Letter, Ajanta included a detailed statement of the

factual and legal bases upon which it based its Paragraph IV certification and extended to Pfizer an OCA to Ajanta's ANDA No. 213019.

41. Pfizer did not bring an action for infringement of the '927 and '119 patents within the 45-day period.

42. Accordingly, both requirements are met for the declaratory judgment action expressly authorized by the Hatch-Waxman Act: (1) the 45-day period has passed without Pfizer bringing an action for infringement, and (2) Ajanta made the statutory offer of confidential access in connection with the '927 and '119 patents. 21 U.S.C. § 355(j)(5)(C)(i).

43. Having met the statutory requirements, Ajanta possesses a statutory right to bring the present declaratory judgment action for patent certainty. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

44. Pfizer has demonstrated its intent to enforce the '927 and '119 patents. Pfizer has filed suit against other ANDA applicants alleging infringement of the '927 and '119 patents. *See Pfizer Inc. et al. v. Mylan Inc. et al.*, 1:10-cv-06463-WHP (S.D.N.Y.); *Pfizer Inc. et al. v. Apotex Inc. et al.*, 1:10-cv-06464-WHP (S.D.N.Y.).

45. Ajanta requested, but Pfizer did not provide, a covenant not to sue Ajanta on the '927 and '119 patents.

46. A judicial determination of invalidity of the '927 and '119 patents in Ajanta's favor could affect the timing of Ajanta's commercial manufacture, use, or sale of its proposed ANDA product, as such a decision could affect when Apotex and Mylan must market their products, or otherwise forfeit any 180-day marketing exclusivity that they may have. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I).

47. Pfizer's actions have resulted in a substantial controversy regarding the '927 and '119 patents between Ajanta and Pfizer of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the '927 and '119 patents are invalid.

COUNT ONE
(Declaratory Judgment Regarding Invalidity of U.S. Patent Nos. 6,890,927 and 7,265,119)

48. Ajanta repeats and reasserts the allegations in paragraphs 1 through 47 above as though fully set forth herein.

49. There is an actual, substantial, and continuing justiciable case or controversy between Ajanta and Pfizer regarding the invalidity of the '927 and '119 patents.

50. The claims of the '927 and '119 patents are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

51. Ajanta is entitled to a declaratory judgment that the claims of the '927 and '119 patents are invalid.

PRAYER FOR RELIEF

WHEREFORE, Ajanta respectfully requests this Court enter judgment as follows:

Declaring that the claims of the '927 and '119 patents are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103, and/or 112; and

Awarding Ajanta any other and further relief that this Court may deem just and proper.

Dated: July 16, 2019

Respectfully submitted,

By: */s/ Joseph N. Froehlich*

Joseph N. Froehlich
LOCKE LORD LLP
200 Vesey Street
New York, New York 10281
(212) 812-8345 Direct
(212) 812-8398 Fax
jfroehlich@lockelord.com

Of counsel
Michael J. Gaertner
David B. Abramowitz
Nina Vachhani
LOCKE LORD LLP
111 South Wacker Drive
Chicago, IL 60606
(312) 443-0700

Attorneys for Ajanta Pharma Limited