IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN SALES, LLC, ALLERGAN USA, INC. and FOREST LABORATORIES HOLDINGS LIMITED,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AJANTA PHARMA LTD. and AJANTA PHARMA USA INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Allergan Sales, LLC, Allergan USA, Inc., and Forest Laboratories Holdings Limited (collectively, "Plaintiffs") allege for their complaint against defendants Ajanta Pharma Ltd. and Ajanta Pharma USA Inc. (collectively, "Ajanta") as follows.

THE PARTIES

1. Plaintiff Allergan Sales, LLC is a Delaware limited liability company having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

2. Plaintiff Allergan USA, Inc. is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.

3. Plaintiff Forest Laboratories Holdings Limited is a corporation organized under the laws of the Republic of Ireland having offices at Canon's Court, 22 Victoria Street, Hamilton HM11, Bermuda.

4. On information and belief, Defendant Ajanta Pharma Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at No. 98, Ajanta House, Government Industrial Area, Charkop, Kandivali (West) Mumbai, Maharashtra 400067 India.

5. On information and belief, Defendant Ajanta Pharma USA Inc. is a corporation organized and existing under the laws of New Jersey, having its principal place of business at One Grande Commons, 440 U.S. Highway 22 East, Suite 150, Bridgewater, NJ 08807. On information and belief, Ajanta Pharma USA Inc. is a wholly-owned subsidiary of Ajanta Pharma Ltd. On information and belief, Ajanta Pharma USA Inc. is the U.S. agent for Ajanta Pharma Ltd.

NATURE OF THE ACTION

6. This is an action for infringement of U.S. Patent No. 6,545,040 ("the '040 Patent") under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, arising from Ajanta's submission of Abbreviated New Drug Application ("ANDA") No. 213349 to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of the pharmaceutical product Bystolic® before the expiration of the '040 Patent covering Bystolic® and its use. A copy of the '040 Patent is attached as Exhibit A.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

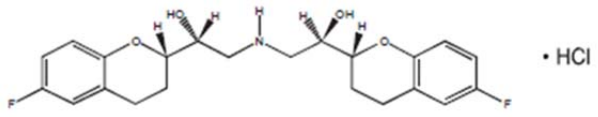
8. Defendants have consented to this Court's jurisdiction for the purposes of Plaintiffs' claims against Defendants in this case.

9. Defendants have consented to venue in this district.

THE NDA AND THE '040 PATENT

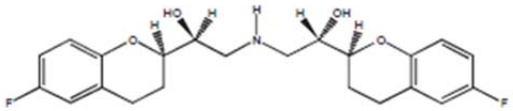
10. Plaintiff Allergan Sales, LLC currently holds New Drug Application ("NDA") No. 021742 for Bystolic® brand nebivolol hydrochloride (a beta-adrenergic blocking agent) 2.5 mg, 5 mg, 10 mg, and 20 mg tablets. Bystolic® is "indicated for the treatment of

hypertension, to lower blood pressure." According to its approved label, nebivolol is a racemic mixture of the SRRR- and RSSS-stereoisomers depicted below:



• HCl

SRRR - or d-nebivolol hydrochloride



• HCl

RSSS - or l-nebivolol hydrochloride

11. Plaintiff Allergan USA, Inc. is the exclusive distributor of Bystolic® in the United States.

12. On April 8, 2003, the United States Patent and Trademark Office ("USPTO") issued the '040 Patent to Janssen Pharmaceutica N.V.

13. On March 30, 2012, Janssen Pharmaceutica N.V. assigned all right, title, and interest in the '040 Patent to Plaintiff Forest Laboratories Holdings Limited.

14. The claims of the '040 Patent cover, *inter alia*, pharmaceutical compositions consisting of mixtures of SRRR- and RSSS-nebivolol and methods of treating hypertension by administration of the claimed compositions.

15. The '040 Patent was submitted to the USPTO for *ex parte* reexamination on January 26, 2007. On February 17, 2009, the USPTO issued an *Ex Parte* Reexamination Certificate for the '040 Patent, which is included in Exhibit A, stating that "no amendments have been made to the patent," and that the "patentability of claims 1–6 is confirmed."

16. The USPTO issued a Certificate Extending Patent Term Under 35 U.S.C. § 156. With the patent term extension, the '040 Patent will expire on December 17, 2021.

17. On December 22, 2015, Lower Drug Prices for Consumers, LLC filed a petition with the Patent Trial and Appeal Board ("PTAB") seeking *inter partes* review of all claims of the '040 Patent ("the IPR").

18. On July 1, 2016, the PTAB denied institution of the IPR under 35 U.S.C. § 325(d), finding that the USPTO had already considered (and rejected) the same prior art and substantially the same arguments submitted by the petitioner.

19. Bystolic® and its use in the treatment of hypertension are covered by one or more claims of the '040 Patent, and the '040 Patent has been listed in connection with Bystolic® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug."

AJANTA'S ANDA AND NOTICE LETTER

20. On information and belief, Ajanta submitted to the FDA ANDA No. 213349 under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic nebivolol tablets containing 2.5 mg, 5 mg, 10 mg, and 20 mg of nebivolol ("Ajanta's ANDA Products").

21. By letter ("Ajanta Notice Letter") dated May 21, 2019, and received on May 22, 2019, Ajanta informed Plaintiffs that Ajanta had submitted ANDA No. 213349 to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, or sell Nebivolol Tablets (2.5 mg, 5 mg, 10 mg, and 20 mg) before the expiration of the '040 Patent.

22. The Ajanta Notice Letter does not dispute that Ajanta's ANDA Products will infringe claims 2–6 of the '040 Patent, except to the extent that it alleges that those claims are invalid.

23. On information and belief, Ajanta intends to manufacture, import, use, sell, or offer to sell Ajanta's ANDA Products before the expiration of the '040 Patent, thus infringing the claims of the '040 Patent.

24. This action is being filed within 45 days of the receipt of Ajanta's Notice Letter.

CLAIM FOR RELIEF – INFRINGEMENT OF THE '040 PATENT

25. Plaintiffs incorporate by reference and reallege paragraphs 1 through 24 above as though fully restated herein.

26. On information and belief, Ajanta submitted ANDA No. 213349 to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Ajanta's ANDA Products prior to the expiration of the '040 Patent. By submitting this application, Ajanta has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. On information and belief, the commercial manufacture, use, sale, offer to sell, or importation of Ajanta's ANDA Products prior to the expiration of the '040 Patent would directly infringe the '040 Patent under 35 U.S.C. § 271(a), would actively induce infringement of the '040 Patent under 35 U.S.C. § 271(b), and would constitute contributory infringement of the '040 Patent under 35 U.S.C. § 271(c). Thus, Ajanta would infringe or aid another in the infringement of one or more of claims 2–6 of the '040 Patent.

28. On information and belief, Ajanta's ANDA Products will have instructions for use that substantially copy the instructions for Bystolic®. On information and belief, the proposed labeling for Ajanta's ANDA Products directs the use of those products by physicians, health care providers, and/or patients for the treatment of hypertension.

29. On information and belief, Ajanta has acted with full knowledge of the '040 Patent and without a reasonable basis for believing it would not be liable for infringement,

induced infringement, and contributory infringement of the ’040 Patent. Notwithstanding this knowledge, Ajanta has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Ajanta’s ANDA Products upon approval of the Ajanta ANDA. On information and belief, through such activities, Ajanta specifically intends infringement of the ’040 Patent.

30. On information and belief, if the FDA approves the Ajanta ANDA, Ajanta intends to, and will, infringe, actively induce infringement of, and contribute to the infringement of the ’040 Patent, and plans and intends to and will do so immediately and imminently upon approval.

31. On information and belief, Ajanta knows that Ajanta’s ANDA Products are especially made or adapted for use in infringing the ’040 Patent, and that Ajanta’s ANDA Products are not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Ajanta plans and intends to, and will, contribute to infringement of the ’040 Patent immediately and imminently upon approval of the Ajanta ANDA.

32. Plaintiffs will be substantially and irreparably harmed if Ajanta’s infringement of the ’040 Patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

33. Plaintiffs are 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 Ajanta’s ANDA be a date that is not earlier than the expiration date of the ’040 Patent, including any extensions.

34. On information and belief, Ajanta was aware of the existence of the ’040 Patent and was aware that the filing of ANDA No. 213349 and certification with respect to the ’040 Patent constituted infringement of that patent. This is an exceptional case.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for a judgment in their favor and against Ajanta and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Ajanta has infringed one or more of claims 2–6 of the '040 Patent by submitting ANDA No. 213349 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Ajanta's Proposed ANDA Products before the expiration of the '040 Patent;

B. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Ajanta's ANDA Products will infringe one or more of claims 2–6 of the '040 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 213349 for nebivolol tablets (2.5 mg, 5 mg, 10 mg, and 20 mg strengths) under § 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), shall not be earlier than the expiration of the '040 Patent, including any extensions;

D. A permanent injunction, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Ajanta, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from infringement of the '040 Patent for the full term thereof, including any extensions;

E. To the extent that Ajanta has committed any acts with respect to the subject matter claimed in the '040 Patent, other than those expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts;

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

G. Costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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July 2, 2019