IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Allergan Sales, LLC, Allergan USA, Inc., and Forest Laboratories Holdings, Ltd. (collectively, "Plaintiffs") allege for their complaint against defendants Aurobindo Pharma USA, Inc. and Aurobindo Pharma Ltd. (collectively, "Aurobindo" or "Defendants") 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. Effective January 1, 2018, pursuant to an internal corporate restructuring, Forest Laboratories, LLC (f/k/a Forest Laboratories, Inc.) merged with and into Allergan Sales, LLC, with Allergan Sales, LLC as the surviving entity.

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, Ltd. is an Irish corporation having a principal place of business at Canon's Court, 22 Victoria Street, Hamilton HM12, Bermuda.

4. On information and belief, defendant Aurobindo Pharma USA, Inc. is a Delaware corporation having a principal place of business at 279 Princeton-Hightstown Road, East Windsor, New Jersey 08520-1401.

5. On information and belief, defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

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 Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 211053 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. Aurobindo Pharma USA, Inc. is subject to personal jurisdiction in this District because it is a Delaware corporation. Moreover, Aurobindo Pharma USA, Inc. is in the business of, among other things, formulating, developing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market, including in this judicial district. On information and belief, upon receiving FDA approval, Aurobindo Pharma USA, Inc. intends to market and sell its proposed generic products at issue in this litigation in this judicial district. On information and belief, Aurobindo Pharma USA, Inc. holds a Pharmacy Wholesale License from

the State of Delaware under License No. A4-0001270. On information and belief, Aurobindo Pharma USA, Inc. has purposely availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court and asserting counterclaims in actions in this jurisdiction including, but not limited to, *Allergan, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 17-1290-GMS (D. Del.) (D.I. 9); *Shionogi Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 17-72-MSG (D. Del.) (D.I. 9); and *Allergan Sales, LLC v. Aurobindo Pharma Ltd. et al.*, C.A. No. 15-1032-LPS (D. Del.) (D.I. 8), and having engaged in systematic and continuous contacts with the State of Delaware.

9. Aurobindo Pharma Ltd. is subject to personal jurisdiction in this District. On information and belief, Aurobindo Pharma Ltd. develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district, through various directly or indirectly owned operating subsidiaries, including its wholly owned subsidiary Aurobindo Pharma USA, Inc. On information and belief, upon receiving FDA approval, Aurobindo Pharma Ltd. intends to market and sell the proposed generic products at issue in this litigation in this judicial district. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. work in concert for purposes of developing, formulating, manufacturing, marketing, and selling generic drug products throughout the United States, including in Delaware, and Delaware is a likely destination for Aurobindo's generic products. On information and belief, Aurobindo Pharma Ltd. has purposely availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court and asserting counterclaims in actions in this jurisdiction including, but not limited to, *Allergan, Inc. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 17-1290-GMS (D. Del.) (D.I. 9); *Shionogi Inc. et al. v. Aurobindo*

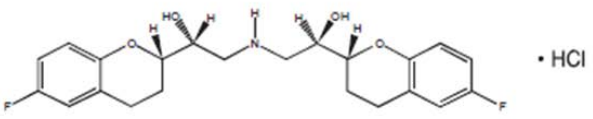
Pharma Ltd. et al., C.A. No. 17-72-MSG (D. Del.) (D.I. 9); and *Allergan Sales, LLC v. Aurobindo Pharma Ltd. et al.*, C.A. No. 15-1032-LPS (D. Del.) (D.I. 8), and having engaged in systematic and continuous contacts with the State of Delaware.

10. Alternatively, assuming that the above facts do not establish personal jurisdiction over Aurobindo Pharma Ltd., this Court may exercise jurisdiction over Aurobindo Pharma Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Aurobindo Pharma Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Aurobindo Pharma Ltd. has sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

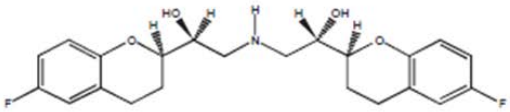
11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b). Specifically, venue is proper in Delaware because Aurobindo Pharma USA, Inc. is a Delaware corporation, and Aurobindo Pharma Ltd. is not incorporated anywhere in the United States and does not have a regular and established place of business in the United States and thus may be sued in any judicial district.

THE NDA AND THE '040 PATENT

12. 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:



SRRR - or d-nebivolol hydrochloride



RSSS - or l-nebivolol hydrochloride

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

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

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

16. 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.

17. 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."

18. 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.

19. 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").

20. 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.

21. 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.”

AUROBINDO’S ANDA AND NOTICE LETTER

22. On information and belief, Aurobindo submitted to the FDA ANDA No. 211053 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 (“Aurobindo’s ANDA Products”).

23. By letter (“Aurobindo Notice Letter”) dated December 7, 2017, and received by Forest Laboratories, LLC on December 8, 2017, Aurobindo informed Forest Laboratories, LLC that Aurobindo had submitted ANDA No. 211053 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.

24. The Aurobindo Notice Letter does not dispute that Aurobindo’s ANDA Products will infringe the ’040 Patent, except to the extent that it alleges that the ’040 Patent is invalid.

25. The Aurobindo Notice Letter's bases for purported invalidity of the '040 Patent rely on the same art and arguments that were rejected in the IPR by the PTAB as duplicative of arguments that the USPTO had already considered and rejected.

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

27. This action is being filed within 45 days of the receipt of Aurobindo's Notice Letter by Forest Laboratories, LLC.

CLAIM FOR RELIEF – INFRINGEMENT OF THE '040 PATENT

28. Plaintiffs incorporate by reference and reallege paragraphs 1 through 27 above as though fully restated herein.

29. On information and belief, Aurobindo submitted ANDA No. 211053 to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Aurobindo's ANDA Products prior to the expiration of the '040 Patent. By submitting this application, Aurobindo has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

30. On information and belief, the commercial manufacture, use, sale, offer to sell, or importation of Aurobindo'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, Aurobindo would infringe or aid another in the infringement of one or more of claims 2–6 of the '040 Patent.

31. On information and belief, Aurobindo's ANDA Products will have instructions for use that substantially copy the instructions for Bystolic®. On information and

belief, the proposed labeling for Aurobindo's ANDA Products directs the use of those products by physicians, health care providers, and/or patients for the treatment of hypertension.

32. On information and belief, Aurobindo 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, Aurobindo has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products upon approval of the Aurobindo ANDA. On information and belief, through such activities, Aurobindo specifically intends infringement of the '040 Patent.

33. On information and belief, if the FDA approves the Aurobindo ANDA, Aurobindo 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.

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

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

36. 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 Aurobindo's ANDA be a date that is not earlier than the expiration date of the '040 Patent, including any extensions.

37. On information and belief, Aurobindo was aware of the existence of the '040 Patent and was aware that the filing of ANDA No. 211053 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 Aurobindo and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more of claims 2–6 of the '040 Patent by submitting ANDA No. 211053 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo'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 Aurobindo'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. 211053 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 Aurobindo, 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 Aurobindo 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

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