IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

COMPLAINT

Plaintiffs Forest Laboratories, LLC, Forest Laboratories Holdings, Ltd., Allergan USA, Inc., and Ironwood Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo" or "Defendants"), hereby allege as follows.

PARTIES

1. Plaintiff Forest Laboratories, LLC (successor-in-interest to Forest Laboratories, Inc.) is a Delaware limited liability company having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

2. 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.

3. Plaintiff Allergan USA, Inc. is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054 (referred to herein, together with Forest Laboratories, LLC and Forest Laboratories Holdings, Ltd., as "Forest").

4. Plaintiff Ironwood Pharmaceuticals, Inc. ("Ironwood") is a Delaware corporation having a principal place of business at 301 Binney Street, Cambridge, Massachusetts 02142.

5. Upon information and belief, Defendant Aurobindo Pharma Ltd. is an Indian corporation having a principal place of business at Plot No. 2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India. Upon information and belief, Defendant Aurobindo Pharma Ltd. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its subsidiary and agent Aurobindo Pharma USA, Inc.

6. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. is a Delaware corporation having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. is a wholly owned subsidiary of Aurobindo Pharma Ltd. Upon information and belief, Defendant Aurobindo Pharma USA, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as a subsidiary and agent of Aurobindo Pharma Ltd.

NATURE OF THE ACTION

7. This is a civil action for the infringement of one or more of the following patents by each of the Defendants: United States Patent Nos. 7,304,036 ("the '036 patent"), 7,371,727 ("the '727 patent"), 7,704,947 ("the '947 patent"), 7,745,409 ("the '409 patent"), 8,080,526 ("the '526 patent"), and 8,110,553 ("the '553 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and arises from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the FDA seeking to commercialize generic versions of Plaintiffs' Linzess® brand linaclotide capsules throughout the United States, including this

judicial district, before the expiration of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent.

JURISDICTION AND VENUE

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

9. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, induced, contributed to, and/or participated in the commission of, a tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiffs in Delaware. Each of the Defendants has participated in the preparation and/or filing of ANDA No. 209611 ("the Aurobindo ANDA") seeking FDA approval to market and sell generic versions of Plaintiffs' branded prescription drug product Linzess® ("the Aurobindo Generic Products") – and has plans to manufacture, distribute, market, and/or sell the Aurobindo Generic Products throughout the United States, including in this judicial district – before the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent expire. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

10. This Court has personal jurisdiction over Defendant Aurobindo Pharma Ltd. by virtue of, *inter alia*: (1) its presence in Delaware, including through its subsidiary and agent Defendant Aurobindo Pharma USA, Inc.; (2) its involvement in the manufacture, distribution, marketing, and/or sale of the Aurobindo Generic Products throughout the United States, including in this judicial district, upon FDA approval of the Aurobindo ANDA; and (3) its systematic and continuous contacts with Delaware, including through its subsidiary and agent

Defendant Aurobindo Pharma USA, Inc. Upon information and belief, Aurobindo Pharma Ltd. is amenable to litigating in this forum based on Aurobindo Pharma Ltd.'s conduct in multiple prior litigations in this District, including in Civil Action No. 16-1114 (D.I. 35), a related case involving the Aurobindo ANDA. For example, Aurobindo Pharma Ltd. did not contest jurisdiction in Civil Action No. 14-664 (D.I. 12), Civil Action No. 14-872 (D.I. 16), Civil Action No. 14-909 (D.I. 10), Civil Action No. 14-1203 (D.I. 9), Civil Action No. 14-1469 (D.I. 8), Civil Action No. 15-902 (D.I. 59), Civil Action No. 15-1032 (D.I. 8), Civil Action No. 16-451 (D.I. 8), or Civil Action No. 16-1114 (D.I. 35).

11. This Court has personal jurisdiction over Defendant Aurobindo Pharma USA, Inc. by virtue of, *inter alia*, the fact that Aurobindo Pharma USA, Inc. is a Delaware corporation.

12. Venue is proper in this judicial district as to Aurobindo Pharma Ltd. pursuant to 28 U.S.C. § 1391(c). Upon information and belief, Aurobindo Pharma Ltd. is amenable to litigating in this forum based on Aurobindo Pharma Ltd.'s conduct in multiple prior litigations in this District, including in related Civil Action No. 16-1114 (D.I. 35). For example, Aurobindo Pharma Ltd. admitted that venue was proper in this District in Civil Action No. 15-902 (D.I. 59). Aurobindo Pharma Ltd. did not contest venue in Civil Action No. 14-664 (D.I. 12), Civil Action No. 14-872 (D.I. 16), Civil Action No. 14-909 (D.I. 10), Civil Action No. 14-1203 (D.I. 9), Civil Action No. 14-1469 (D.I. 8), Civil Action No. 15-1032 (D.I. 8), Civil Action No. 16-451 (D.I. 8), or Civil Action No. 16-1114 (D.I. 35).

13. Venue is proper in this judicial district as to Aurobindo Pharma USA, Inc. pursuant to 28 U.S.C. § 1400(b).

THE PATENTS

14. On December 4, 2007, the '036 patent, titled "Methods And Compositions For The Treatment Of Gastrointestinal Disorders," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Ironwood is the sole owner of the '036 patent. Forest is the exclusive licensee of the '036 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '036 patent is attached hereto as Exhibit A.

15. On May 13, 2008, the '727 patent, titled "Methods And Compositions For The Treatment Of Gastrointestinal Disorders," was duly and lawfully issued by the USPTO. The USPTO issued a certificate of correction for the '727 patent on August 5, 2008. The USPTO issued a second certificate of correction for the '727 patent on December 28, 2010. Ironwood is the sole owner of the '727 patent. Forest is the exclusive licensee of the '727 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '727 patent, including its certificates of correction, is attached hereto as Exhibit B.

16. On April 27, 2010, the '947 patent, titled "Methods And Compositions For The Treatment Of Gastrointestinal Disorders," was duly and lawfully issued by the USPTO. The USPTO issued an *inter partes* reexamination certificate for the '947 patent on April 3, 2014. Ironwood is the sole owner of the '947 patent. Forest is the exclusive licensee of the '947 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '947 patent, including its reexamination certificate, is attached hereto as Exhibit C.

17. On June 29, 2010, the '409 patent, titled "Methods And Compositions For The Treatment Of Gastrointestinal Disorders," was duly and lawfully issued by the USPTO.

Ironwood is the sole owner of the '409 patent. Forest is the exclusive licensee of the '409 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '409 patent is attached hereto as Exhibit D.

18. On December 20, 2011, the '526 patent, titled "Methods And Compositions For The Treatment Of Gastrointestinal Disorders," was duly and lawfully issued by the USPTO. Ironwood is the sole owner of the '526 patent. Forest is the exclusive licensee of the '526 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '526 patent is attached hereto as Exhibit E.

19. On February 7, 2012, the '553 patent, titled "Methods And Compositions For The Treatment Of Gastrointestinal Disorders," was duly and lawfully issued by the USPTO. Ironwood is the sole owner of the '553 patent. Forest is the exclusive licensee of the '553 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '553 patent is attached hereto as Exhibit F.

20. Forest Laboratories, LLC holds New Drug Application ("NDA") 202-811 for Linzess® brand linaclotide capsules. Linzess® is approved for the treatment of irritable bowel syndrome with constipation ("IBS-C") and chronic idiopathic constipation ("CIC"). The '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent, as well as U.S. Patent Nos. 8,748,573 ("the '573 patent"), 8,802,628 ("the '628 patent"), and 8,933,030 ("the '030 patent"), are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Linzess®.

21. Allergan USA, Inc. is the exclusive distributor of Linzess® in the United States.

ACTS GIVING RISE TO THIS ACTION

22. Upon information and belief, on or before October 17, 2016, Aurobindo submitted the Aurobindo ANDA to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Aurobindo ANDA seeks FDA approval for the commercial manufacture, use, and sale of generic capsule products containing 145 μg and 290 μg of linaclotide as the active ingredient.

23. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, the Aurobindo ANDA previously included allegations that the claims of the '573 patent, the '628 patent, and the '030 patent are invalid and/or will not be infringed by the manufacture, use, or sale of the Aurobindo Generic Products. Plaintiffs received written notification of the Aurobindo ANDA and its previous § 505(j)(2)(A)(vii)(IV) allegations with respect to the '573 patent, the '628 patent, and the '030 patent no earlier than October 18, 2016, and timely brought suit against Aurobindo for infringement of the '030 patent on or about November 30, 2016 in *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 16-1114-RGA (D. Del.).

24. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Aurobindo recently amended the Aurobindo ANDA to include, for the first time, allegations that the claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent are invalid and/or will not be infringed by the manufacture, use, or sale of the Aurobindo Generic Products. None of the Plaintiffs received written notification of Aurobindo's amendment of the Aurobindo ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent any earlier than July 28, 2017.

25. Aurobindo's amendment of the Aurobindo ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent, constitutes infringement of one or more of Claims 1-70 of the '036 patent, Claims 1-6 of the '727 patent, Claims 1-16 of the '947 patent, Claims 1-7 of the '409 patent, Claims 1-2 of the '526 patent, and Claims 1-11 of the '553 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Aurobindo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any of the Aurobindo Generic Products, or induces or contributes to any such conduct, it would further infringe these claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

26. Aurobindo has infringed one or more of Claims 1-70 of the '036 patent, Claims 1-6 of the '727 patent, Claims 1-16 of the '947 patent, Claims 1-7 of the '409 patent, Claims 1-2 of the '526 patent, and Claims 1-11 of the '553 patent under 35 U.S.C. § 271(e)(2)(A), and will further infringe one or more of these claims under 35 U.S.C. § 271(a), (b), (c), and/or (g) if the Aurobindo Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States, because, *inter alia*, the Aurobindo Generic Products and the methods of using the Aurobindo Generic Products – *e.g.*, by doctors, pharmacists, healthcare providers, and patients according to Aurobindo's proposed package insert – will meet each and every claim element of one or more of Claims 1-70 of the '036 patent, Claims 1-6 of the '727 patent, Claims 1-16 of the '947 patent, Claims 1-7 of the '409 patent, Claims 1-2 of the '526 patent, and Claims 1-11 of the '553 patent either literally or under the doctrine of equivalents.

27. Upon information and belief, each of Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. has participated in, contributed to, aided, abetted, and/or induced infringement

of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent once the Aurobindo Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States. Each of Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. is jointly and severally liable for the infringement of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent.

28. Upon information and belief, Aurobindo has knowledge that if it were to receive approval from the FDA to market the Aurobindo Generic Products described in the Aurobindo ANDA and make the Aurobindo Generic Products available for sale and/or use by others – *e.g.*, by doctors, pharmacists, healthcare providers, and patients – during the proposed shelf life of the Aurobindo Generic Products before expiration of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Aurobindo has knowledge of such infringing use and also knows that the products described in the Aurobindo ANDA are not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather are especially made and/or adapted for use in the direct infringement of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent.

29. Upon information and belief, Aurobindo was aware of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent prior to filing the Aurobindo ANDA and prior to amending the Aurobindo ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label for the

Aurobindo Generic Products will induce others – *e.g.*, doctors, pharmacists, healthcare providers, and patients – to infringe the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent and Aurobindo possesses the specific intent to induce and encourage others to infringe those patents.

30. Upon information and belief, the Aurobindo Generic Products will be made in India using linaclotide active pharmaceutical ingredient ("linaclotide API") that will be made by a process patented in the United States, including under the '727 patent. Upon information and belief, the linaclotide API will be made in India, but will not be materially changed by subsequent processes and will not be rendered a trivial and nonessential component of the Aurobindo Generic Products that will be imported, marketed, and sold throughout the United States, including in this judicial district. Upon information and belief, if Aurobindo receives FDA approval for the Aurobindo ANDA and markets and sells the Aurobindo Generic Products, Aurobindo would, without authority, import into the United States, or offer to sell, sell, or use within the United States, linaclotide API and/or Aurobindo Generic Products containing linaclotide API. Such conduct would infringe at least the '727 patent under 35 U.S.C. § 271(g).

31. Aurobindo's actions render this an exceptional case under 35 U.S.C. § 285.

32. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. That Aurobindo has infringed the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Aurobindo's ANDA identified in this Complaint shall not be earlier than the expiration date of the last to expire of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent, including any extensions or exclusivities;

C. That Aurobindo, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, the Aurobindo Generic Products, and any other product that infringes or induces or contributes to the infringement of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities;

D. That Aurobindo, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, are preliminarily and permanently enjoined from commercially manufacturing, using, offering for sale, or selling in the United States, or importing into the United States, any linaclotide API manufactured under the Aurobindo DMF prior to the expiration of the last to expire of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and/or the '553 patent, including any extensions or exclusivities;

E. That all persons in active concert or participation with Aurobindo are preliminarily and permanently enjoined from commercially using, offering for sale, or selling in the United States, or importing into the United States, any product containing linaclotide API manufactured under the Aurobindo DMF that has not been materially changed by subsequent processes and/or rendered a trivial and nonessential component of such product prior to the

expiration of the last to expire of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and/or the '553 patent, including any extensions or exclusivities;

F. That Plaintiffs be awarded monetary relief if Aurobindo commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Aurobindo Generic Products, or any other product that infringes or induces or contributes to the infringement of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, and the '553 patent, prior to the expiration of the last to expire of those patents, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

G. That Plaintiffs be awarded the attorneys' fees, costs, and expenses that they incur prosecuting this action under 35 U.S.C. § 285;

H. That Plaintiffs be awarded all of the relief they seek in their related litigation against Aurobindo, *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al*., Civil Action No. 16-1114-RGA (D. Del.); and

I. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Maryellen Noreika

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