IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN USA, INC., ALLERGAN SALES, LLC and IRONWOOD PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SANDOZ INC.,	)	
Defendant.	)	

COMPLAINT

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

PARTIES

1. 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.

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

3. Plaintiff Allergan Sales, LLC (successor-in-interest to Forest Laboratories, LLC) is a Delaware corporation having a principal place of business at 5 Giralda Farms, Madison, New Jersey 07940 (referred to herein, together with Forest Laboratories Holdings, Ltd. and Allergan USA, Inc. 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 Sandoz Inc. ("Sandoz") is a Colorado corporation having a principal place of business at 100 College Road West, Princeton, New Jersey 08540. Upon information and belief, Defendant Sandoz manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district.

NATURE OF THE ACTION

6. This is a civil action for the infringement by Sandoz of United States Patent No. 9,708,371 ("the '371 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and arises from Sandoz's filing of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("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 '371 patent.

JURISDICTION AND VENUE

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

8. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, Sandoz 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. Sandoz has participated in the preparation and/or filing of ANDA No. 209630 ("the Sandoz ANDA") seeking FDA approval to market and sell generic versions of Plaintiffs' branded prescription drug product Linzess® ("the Sandoz Generic Products") – and has plans to manufacture, distribute, market, and/or sell the Sandoz Generic Products throughout the United States, including in this judicial district – before the '371 patent expires. Sandoz

consented to personal jurisdiction and has asserted counterclaims in related case *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 16-1114-RGA (D. Del.) (D.I. 1 at ¶ 15; D.I. 24). This Court has personal jurisdiction over Sandoz for the additional reasons set forth below and for other reasons that will be presented to the Court if such personal jurisdiction is challenged.

9. This Court has personal jurisdiction over Sandoz by virtue of, *inter alia*, (1) its presence in Delaware; (2) its registration to do business in Delaware, including its Pharmacy - Wholesale license number A4-0000260; and (3) its systematic and continuous contacts with Delaware. Upon information and belief, Sandoz Inc. is amenable to litigating in this forum based on Sandoz Inc.'s conduct in multiple prior litigations in this District. For example, Sandoz Inc. did not contest personal jurisdiction in Civil Action No. 17-407-LPS (D.I. 9 at ¶¶ 9-10, 12), Civil Action No. 16-1267-GMS (D.I. 20 at ¶¶ 94-97), Civil Action No. 16-952-JFB (D.I. 12 at ¶ 8), Civil Action No. 16-354-GMS (D.I. 12 at ¶ 9), Civil Action No. 15-1207-RGA (D.I. 12 at ¶¶ 5-15), and Civil Action No. 15-1161-GMS (D.I. 12 at ¶¶ 7-10).

10. Venue is proper in this judicial district as to Sandoz pursuant to 28 U.S.C. § 1400(b). Sandoz has consented to venue in related case *Forest Laboratories, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 16-1114-RGA (D. Del.) (D.I. 24 at ¶ 18).

THE PATENTS

11. On July 18, 2017, the '371 patent, titled "Treatments for Gastrointestinal Disorders," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO"). Ironwood is the sole owner of the '371 patent. Forest is the exclusive licensee of

the '371 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '371 patent is attached hereto as Exhibit A.

12. As the successor-in-interest to Forest Laboratories, LLC, Allergan Sales, 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"). 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"), 8,110,553 ("the '553 patent"), 8,748,573 ("the '573 patent"), 8,802,628 ("the '628 patent"), 8,933,030 ("the '030 patent"), and the '371 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Linzess®.

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

ACTS GIVING RISE TO THIS ACTION

14. Upon information and belief, on or before November 1, 2016, Sandoz submitted the Sandoz ANDA to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Sandoz 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.

15. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, the Sandoz ANDA previously included allegations that the claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '573 patent, the '628 patent, and the '030 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Generic Products. Plaintiffs received written notification

of the Sandoz ANDA and its previous § 505(j)(2)(A)(vii)(IV) allegations with respect to '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '573 patent, the '628 patent, and the '030 patent no earlier than November 3, 2016, and timely brought suit against Sandoz for infringement of those patents 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.).

16. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, Sandoz recently amended the Sandoz ANDA to include, for the first time, allegations that the claims of the '371 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Sandoz Generic Products. None of the Plaintiffs received written notification of Sandoz's amendment of the Sandoz ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '371 patent any earlier than January 10, 2018.

17. Sandoz's amendment of the Sandoz ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to the '371 patent constitutes infringement of one or more of Claims 1-28 of the '371 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Sandoz commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, any of the Sandoz Generic Products, or induces or contributes to any such conduct, it would further infringe these claims of the '371 patent under 35 U.S.C. § 271(a), (b), and/or (c).

18. Sandoz has infringed one or more of Claims 1-28 of the '371 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), and/or (c) if the Sandoz 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

Sandoz Generic Products and the methods of using the Sandoz Generic Products – *e.g.*, by doctors, pharmacists, healthcare providers, and patients according to Sandoz's proposed package insert – will meet each and every claim element of one or more of Claims 1-28 of the '371 patent either literally or under the doctrine of equivalents.

19. Upon information and belief, Sandoz has participated in, contributed to, aided, abetted, and/or induced infringement of the '371 patent and/or will participate in, contribute to, aid, abet, and/or induce infringement of the '371 patent once the Sandoz Generic Products are commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

20. Upon information and belief, Sandoz has knowledge that if it were to receive approval from the FDA to market the Sandoz Generic Products described in the Sandoz ANDA and make the Sandoz 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 Sandoz Generic Products before expiration of the '371 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Sandoz has knowledge of such infringing use and also knows that the products described in the Sandoz 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 '371 patent.

21. Upon information and belief, Sandoz was aware of the '371 patent prior to amending the Sandoz ANDA to add § 505(j)(2)(A)(vii)(IV) allegations with respect to that patent. Upon information and belief, the proposed label for the Sandoz Generic Products will induce others – *e.g.*, doctors, pharmacists, healthcare providers, and patients – to infringe the

'371 patent and Sandoz possesses the specific intent to induce and encourage others to infringe those patents.

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

23. Plaintiffs will be irreparably harmed by Sandoz'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 Sandoz has infringed the '371 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sandoz's ANDA identified in this Complaint shall not be earlier than the expiration date of the '371 patent, including any extensions or exclusivities;

C. That Sandoz, 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 Sandoz Generic Products, and any other product that infringes or induces or contributes to the infringement of the '371 patent, prior to the expiration date of the '371 patent, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Sandoz commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Sandoz Generic Products, or any other product that infringes or induces or contributes to the infringement of the '371 patent prior to the expiration of the '371 patent, including any extensions or exclusivities, and that such monetary relief be awarded to Plaintiffs with prejudgment interest;

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

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

G. 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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January 30, 2018