IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN SALES, LLC, FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN USA, INC., and IRONWOOD PHARMACEUTICALS, INC., Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC., MYLAN PHARMACEUTICALS INC., and SANDOZ INC., Defendants.	C.A. No. 16-1114-RGA CONSOLIDATED
FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN USA, INC., ALLERGAN SALES, LLC and IRONWOOD PHARMACEUTICALS, INC., Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. 18-482-RGA

AMENDED COMPLAINT

Plaintiffs Forest Laboratories Holdings, Ltd., Allergan USA, Inc., Allergan Sales, LLC (collectively, "Forest"), and Ironwood Pharmaceuticals, Inc. (collectively with Forest, "Plaintiffs"), for their Complaint against Mylan Pharmaceuticals 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 Mylan Pharmaceuticals Inc. ("Mylan") is a West Virginia corporation having a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26506. Upon information and belief, Defendant Mylan 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 Mylan of 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"), 8,933,030 ("the '030 patent"), and 8,802,628 ("the '628 patent"). This action is based upon the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and arises from Mylan's filing of an Abbreviated New Drug Application ("ANDA") with the FDA seeking to commercialize a

generic version of Plaintiffs' Linzess® brand 72 microgram ("mcg") linaclotide capsules throughout the United States, including this judicial district, before the expiration of Plaintiffs' applicable patents.

JURISDICTION AND VENUE

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. This Court has personal jurisdiction over Mylan by virtue of the fact that, *inter alia*, Mylan 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. Mylan has participated in the preparation and/or filing of ANDA No. 211381 ("the Mylan ANDA") seeking FDA approval to market and sell generic capsule products containing 72 mcg of linaclotide as the active ingredient ("the Mylan Generic Product") – and has plans to manufacture, distribute, market, and/or sell the Mylan Generic Product throughout the United States, including in this judicial district – before the expiration of Plaintiffs' applicable patents. This Court has personal jurisdiction over Mylan 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 Mylan by virtue of, *inter alia*, (1) its presence in Delaware; (2) its consent to being sued in Delaware, including its registration to do business in Delaware and appointment of a registered agent for the receipt of service of process in Delaware; and (3) its systematic and continuous contacts with Delaware. Upon information and belief, Mylan is amenable to litigating in this forum based on Mylan's conduct in multiple prior litigations in this District. For example, Mylan did not contest personal jurisdiction in Civil Action No. 12-257 (D.I. 7), Civil Action No. 12-523 (D.I. 10), Civil Action No. 12-1065 (D.I. 7), Civil Action No. 13-1214 (D.I. 11), Civil Action No. 13-1605 (D.I. 10), or Civil Action No. 13-1781 (D.I.

10). Mylan has also filed actions in this District. Civil Actions No. 17-970 and 17-1653.

10. Upon information and belief, venue is proper in this judicial district as to Mylan pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

11. 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.

12. 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.

13. 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.

14. 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.

15. 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.

16. 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.

17. On January 13, 2015, the '030 patent, titled "Treatments For Gastrointestinal Disorders," was duly and lawfully issued by the USPTO. The USPTO issued a certificate of correction for the '030 patent on August 4, 2015. Ironwood is the sole owner of the '030 patent. Forest is the exclusive licensee of the '030 patent with respect to commercializing pharmaceutical products containing linaclotide in the United States. A copy of the '030 patent, including its certificate of correction, is attached hereto as Exhibit G.

18. On August 12, 2014, the '628 patent, titled "Stable Solid Formulation Of A GC-C Receptor Agonist Polypeptide Suitable For Oral Administration," was duly and lawfully issued

by the USPTO. Forest and Ironwood are the sole owners of the '628 patent. A copy of the '628 patent is attached hereto as Exhibit H.

19. As the successor in interest to Forest Laboratories, LLC, Allergan Sales, LLC holds New Drug Application ("NDA") 202-811, which covers, *inter alia*, Linzess® brand 72 mcg linaclotide capsules. Linzess® brand 72 mcg linaclotide capsules are approved for the treatment of chronic idiopathic constipation ("CIC"). The '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '030 patent are all listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for Linzess® brand 72 mcg linaclotide capsules.

20. Allergan USA, Inc. is the exclusive distributor of Linzess® brand 72 mcg linaclotide capsules in the United States.

ACTS GIVING RISE TO THIS ACTION

21. Upon information and belief, on or before February 12, 2018, Mylan submitted ANDA No. 211381 to the FDA under § 505 of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Mylan ANDA seeks FDA approval for the commercial manufacture, use, and sale of the Mylan Generic Product. The Mylan ANDA specifically seeks FDA approval to market the Mylan Generic Product prior to the expiration of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '030 patent, and the '628 patent.

22. Pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, the Mylan ANDA alleges that the claims of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '030 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the Mylan Generic Product. None of the Plaintiffs received written notification of the Mylan ANDA and its § 505(j)(2)(A)(vii)(IV)

allegations any earlier than February 14, 2018.

23. Mylan's submission of the Mylan ANDA to the FDA, including its § 505(j)(2)(A)(vii)(IV) allegations, constitutes infringement of one or more of Claims 1-2, 4-5, 7-9, 11-12, 18-20, 39, 41, and 43-44 of the '036 patent, Claims 1-3 and 6 of the '727 patent, Claims 1-4 and 13-14 of the '947 patent, Claims 1 and 3-4 of the '409 patent, Claims 1-2 of the '526 patent, Claims 3 and 5-8 of the '553 patent, and Claims 6, 18, and 19 of the '030 patent under 35 U.S.C. § 271(e)(2)(A). Moreover, if Mylan commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Mylan Generic Product, 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, the '553 patent, and the '030 patent under 35 U.S.C. § 271(a), (b), (c), and/or (g).

24. Mylan has infringed these claims under 35 U.S.C. § 271(e)(2)(A), and will further infringe these claims under 35 U.S.C. § 271(a), (b), (c), and/or (g), because, *inter alia*, the Mylan Generic Product and the methods of using the Mylan Generic Product – *e.g.*, by doctors, pharmacists, healthcare providers, and patients according to Mylan's proposed package insert – will meet each and every claim element of one or more of Claims 1-2, 4-5, 7-9, 11-12, 18-20, 39, 41, and 43-44 of the '036 patent, Claims 1-3 and 6 of the '727 patent, Claims 1-4 and 13-14 of the '947 patent, Claims 1 and 3-4 of the '409 patent, Claims 1-2 of the '526 patent, Claims 3 and 5-8 of the '553 patent, and Claims 6, 18, and 19 of the '030 patent either literally or under the doctrine of equivalents.

25. Upon information and belief, Mylan 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, the '553 patent, and the '030 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, the '553 patent, and the '030 patent once the Mylan Generic Product is commercially made, used, offered for sale, or sold in the United States, or imported into the United States.

26. Upon information and belief, Mylan has knowledge that if it were to receive approval from the FDA to market the Mylan Generic Product described in the Mylan ANDA and make the Mylan Generic Product available for sale and/or use by others – *e.g.*, by doctors, pharmacists, healthcare providers, and patients – during the proposed shelf life of the Mylan Generic Product before expiration of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '030 patent, such activities would result in the sale and/or use of a product especially made for an infringing use. Upon information and belief, Mylan has knowledge of such infringing use and also knows that the product described in the Mylan ANDA is not a staple article or commodity of commerce suitable for substantial noninfringing use, but rather is 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, the '553 patent, and the '030 patent.

27. Upon information and belief, Mylan was aware of the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, and the '030 patent prior to filing the Mylan ANDA, including its § 505(j)(2)(A)(vii)(IV) allegations with respect to those patents. Upon information and belief, the proposed label for the Mylan Generic Product 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, the '553 patent, and the

'030 patent, and Mylan possesses the specific intent to induce and encourage others to infringe those patents.

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

29. If Mylan commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States, the Mylan Generic Product, it would also infringe one of more of Claims 1-5 and 12-20 of the '628 patent under 35 U.S.C. § 271(a).

30. There is an actual and justiciable controversy between the parties as to the infringement of the '628 patent.

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

32. Plaintiffs will be irreparably harmed by Mylan'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 Mylan has infringed and/or will infringe the '036 patent, the '727 patent, the '947 patent, the '409 patent, the '526 patent, the '553 patent, the '030 patent, and the '628 patent;

B. That, pursuant to 35 U.S.C. § 271(e)(4)(A) and the Court's equitable powers, the effective date of any approval of Mylan'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, the '553 patent, the '030 patent, and the '628 patent, including any extensions or exclusivities;

C. That Mylan, 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 Mylan Generic Product, 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, the '553 patent, the '030 patent, and the '628 patent, prior to the expiration date of the last to expire of those patents, including any extensions or exclusivities;

D. That Plaintiffs be awarded monetary relief if Mylan commercially makes, uses, offers for sale, or sells in the United States, or imports into the United States, the Mylan Generic Product, 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, the '553 patent, the '030 patent, and the '628 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;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan
Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
jtigan@mnat.com

Attorneys for Plaintiffs

OF COUNSEL:

Peter J. Armenio, P.C.
Robert B. Wilson
Anne S. Toker
Krista M. Rycroft
QUINN EMANUEL
URQUHART & SULLIVAN, LLP
51 Madison Avenue
New York, NY 10010
(212) 849-7000

Gregory A. Morris
Vikram A. Mathrani
Simeon G. Papacostas
HONIGMAN MILLER
SCHWARTZ & COHN LLP
155 North Wacker Drive
Chicago, IL 60606
(312) 701-9300

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