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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

MERCK SHARP & DOHME CORP.,

Plaintiff,

v.

TEVA PHARMACEUTICALS USA, INC., ACTAVIS ELIZABETH LLC, and WATSON LABORATORIES, INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiff Merck Sharp & Dohme Corp. ("Merck") for its Complaint against Defendants Teva Pharmaceuticals USA, Inc. ("Teva"), Actavis Elizabeth LLC ("Actavis"), and Watson Laboratories, Inc. ("Watson") (collectively, "Defendants") hereby alleges as follows:

THE PARTIES

1. Merck is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Upon information and belief, Teva is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. Teva is registered with the State of New Jersey as a drug wholesaler under Registration Nos. 5000583 and 5003436. Teva is registered to do business in New Jersey under Business Registration No. 0100250184.

3. Upon information and belief, Teva, either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, Teva, either directly or through one or more of its wholly-owned subsidiaries and/or agents, markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

4. Upon information and belief, Actavis is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey 07207. Actavis is registered with the State of New

Jersey as a drug wholesaler under Registration No. 5003329. Actavis is registered to do business in New Jersey under Business Registration No. 0600272818.

5. Upon information and belief, Actavis is a wholly-owned subsidiary of Teva.

6. Upon information and belief, Actavis develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District. Upon information and belief, Actavis markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

7. Upon information and belief, Watson is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054. Watson has also provided an address of 200 Elmora Avenue, Elizabeth, New Jersey 07207 in its "Notice of ANDA No. 208295 Alvimopan Capsules, 12 mg With Paragraph IV Certification Concerning U.S. Patent Nos. 6,469,030, 8,112,290, 8,645,160 and 8,946,262 Pursuant to 21 USC § 355(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act" ("Paragraph IV notice letter"), dated July 26, 2017, as the primary point of contact for requesting access to Watson's confidential information in its Abbreviated New Drug Application ("ANDA") No. 208295.

8. Upon information and belief, Watson is a wholly-owned subsidiary of Teva.

9. Upon information and belief, Watson, either directly or through one or more of its agents, develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in this Judicial District.

Upon information and belief, Watson, either directly or through one or more of its agents, markets, distributes, and/or sells generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

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

12. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201-2202 because this case is an actual controversy within the Court's jurisdiction.

13. Venue is proper in this Court under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b).

14. Teva did not contest venue in at least nine actions brought in this Judicial District in the last five years. *See, e.g*., Civ. Action Nos. 15-5982, 15-8663, 15-7889, 15-5909, 14-6398, 14-5878, 14-7811, 14-6341, and 14-5498.

15. Actavis did not contest venue in at least five actions brought in this Judicial District in the last five years. *See, e.g*., Civ. Action Nos. 16-1668, 16-2667, 15-0776, 15-3107, and 14-7106.

16. Watson did not contest venue in at least twelve actions brought in this Judicial District in the last five years. *See, e.g*., Civ. Action Nos. 16-1522, 16-1505, 15-5723, 15-5591, 15-4532, 15-2499, 15-2499, 15-2350, 14-6102, 14-4617, 14-3126, and 13-4542.

17. This Court has personal jurisdiction over, and venue is proper as to, each of the Defendants because, *inter alia*, each Defendant has committed, aided, abetted, contributed

to, and/or participated in the commission of an act of patent infringement that has led to foreseeable harm and injury to Merck in this Judicial District. Merck, which will be harmed by Defendants' actions, is a New Jersey corporation and is headquartered in this Judicial District. This Court has personal jurisdiction over, and venue is proper as to, each of the Defendants for the additional reasons set forth below, and for other reasons that will be presented to the Court if such jurisdiction or venue is challenged.

18. Upon information and belief, Teva, Actavis, and Watson are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to the proposed generic alvimopan product that is the subject of ANDA No. 208295 ("Defendants' ANDA product"), for which they have sought approval from the United States Food and Drug Administration ("FDA").

19. Upon information and belief, Teva, Actavis, and Watson are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to Defendants' ANDA product.

20. Upon information and belief, Actavis acts at the direction, and for the benefit, of Teva, and is controlled and/or dominated by Teva.

21. Upon information and belief, Watson, alone and/or together with its affiliates, Teva and Actavis, filed ANDA No. 208295 with the FDA.

22. Upon information and belief, Watson acts at the direction, and for the benefit, of Teva, and is controlled and/or dominated by Teva.

23. This Court has personal jurisdiction over, and venue is proper as to, Teva because, *inter alia*, it: (1) has purposely availed itself of the privilege of doing business in New Jersey, including securing a New Jersey wholesale drug distributor's license (Registration Nos. 5003436 and 5000583) and a New Jersey Business Entity identification number (Registration No. 0100250184); (2) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiary, agent, and/or alter ego, Actavis, a company with a principal place of business in New Jersey; (3) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (4) has employees located at 8 Gloria Lane, Fairfield, New Jersey and 400 Chestnut Ridge Road, Woodcliff Lake, New Jersey; (5) sent Defendants' Paragraph IV notice letter, addressed to Merck in this Judicial District, where Defendants state that they intend to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA product, including in this Judicial District; and (6) indicated the "Offer of Confidential Access" in Defendants' Paragraph IV notice letter should be governed by the laws of the State of New Jersey. Upon information and belief, Teva purposefully has conducted and continues to conduct business in this Judicial District. Upon information and belief, Teva works in concert with its agents with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of its generic pharmaceutical products throughout the United States, including in this Judicial District.

24. Additionally, Teva has routinely consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting Counterclaims in this Court. *See, e.g., Celgene Corp. v. Par Pharmaceutical, Inc. et al.*, No. 17-3159 (ES)(JAD) (D.N.J.); *AstraZeneca Pharmaceuticals LP et al. v. Teva Pharmaceuticals USA,*

Inc. et al., No. 15-7889 (RMB)(KMW) (D.N.J.); *BTG International Limited et al. v. Actavis Laboratories FL, Inc. et al.*, No. 15-5909 (KM)(JBC) (D.N.J.). Teva has further availed itself of the jurisdiction of this Court by previously initiating litigation in this Court. *See, e.g.*, *Teva Pharmaceuticals USA, Inc. et al. v. Sandoz Inc. et al.*, No. 17-0275 (FLW)(DEA) (D.N.J.); *Teva Pharmaceuticals USA, Inc. et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, No. 17-0517 (FLW)(DEA) (D.N.J.).

25. This Court has personal jurisdiction over, and venue is proper as to, Actavis because, *inter alia*, it: (1) maintains a principal place of business in this Judicial District; (2) has purposely availed itself of the privilege of doing business in New Jersey, including securing a New Jersey wholesale drug distributor's license (Registration No. 5003329) and a New Jersey Business Entity identification number (Registration No. 0600272818); (3) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (4) identified an individual located in Elizabeth, New Jersey with an email address ending in "@actavis.com" to contact for purposes of access to Defendants' ANDA in connection with the "Offer of Confidential Access" made in Defendants' Paragraph IV notice letter; and (5) indicated the "Offer of Confidential Access" in Defendants' Paragraph IV notice letter should be governed by the laws of the State of New Jersey. Upon information and belief, Actavis purposefully has conducted and continues to conduct business in this Judicial District. Upon information and belief, Actavis works in concert with its agents with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of its generic pharmaceutical products throughout the United States, including in this Judicial District.

26. Additionally, Actavis has routinely consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting Counterclaims in this Court. *See, e.g., Rhodes Pharmaceuticals L.P. v. Actavis, Inc. et al.*, No. 16-1668 (WHW)(CLW) (D.N.J.); *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, No. 15-3107 (MAS)(LHG) (D.N.J.); *Sanofi-Aventis U.S. LLC et al. v. Actavis LLC et al.*, No. 15-0776 (MAS)(LHG) (D.N.J.).

27. This Court has personal jurisdiction over, and venue is proper as to, Watson because, *inter alia*, it: (1) maintains a principal place of business in this Judicial District located at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey; (2) identifies a second regular and established place of business of "Watson Laboratories, Inc." in this Judicial District located at 200 Elmora Avenue, Elizabeth, New Jersey as its primary correspondence address for purposes of the "Offer of Confidential Access" made in the Paragraph IV notice letter; (3) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its affiliate, agent, and/or alter ego, Actavis, a company registered with the State of New Jersey as a drug wholesaler under Registration No. 5003329 and registered as a New Jersey Business Entity under Registration No. 0600272818; (4) has purposely availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its parent, agent, and/or alter ego, Teva, a company registered with the State of New Jersey as a drug wholesaler under Registration Nos. 5003436 and 5000583 and registered as a New Jersey Business Entity under Registration No. 0100250184; (5) maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (6) sent Defendants' Paragraph IV notice letter, addressed to Merck in this Judicial District, where

Defendants state that they intend to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Defendants' ANDA product, including in this Judicial District; and (7) indicated the "Offer of Confidential Access" in Defendants' Paragraph IV notice letter should be governed by the laws of the State of New Jersey. Upon information and belief, Watson purposefully has conducted and continues to conduct business in this Judicial District. Upon information and belief, Watson works in concert with its agents with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of its generic pharmaceutical products throughout the United States, including in this Judicial District.

28. Additionally, Watson has routinely consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting Counterclaims in this Court. *See, e.g., Senju Pharmaceutical Co., Ltd. et al. v. Watson Laboratories, Inc. et al.*, No. 16-1522 (JBS)(KMW) (D.N.J.); *Jazz Pharmaceuticals, Inc. et al. v. Watson Laboratories, Inc.*, No. 16-1505 (ES)(JAD) (D.N.J.); *Supernus Pharmaceuticals, Inc. v. Actavis Inc. et al.*, No. 15-2499 (RMB)(JS) (D.N.J.); *Gilead Sciences, Inc. et al. v. Watson Laboratories, Inc. et al.*, No. 15-2350 (RMB)(JS) (D.N.J.).

29. Upon information and belief, Watson is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. Upon information and belief, this Judicial District will be a destination for Defendants' ANDA product. Upon information and belief, Watson also prepares and/or aids in the preparation and submission of ANDAs to the FDA.

CLAIM FOR RELIEF

30. Merck is the holder of New Drug Application ("NDA") No. 21-775, under which the FDA granted approval for capsules containing alvimopan (12 mg) for oral

administration. Merck markets the capsules in the United States under the trade name "Entereg® (alvimopan) capsules." Entereg® is indicated, *inter alia*, for use to accelerate the time to upper and lower gastrointestinal recovery following partial large or small bowel resection surgery with primary anastomosis.

31. Merck owns all right, title, and interest in U.S. Patent No. 6,469,030 ("the '030 patent"), which was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on October 22, 2002, and is titled "Methods for the Treatment and Prevention of Ileus." A copy the '030 patent is attached as Exhibit A.

32. Merck owns all right, title, and interest in U.S. Patent No. 8,946,262 ("the '262 patent"), which was duly and legally issued by the USPTO on February 3, 2015, and is titled "Methods of Preventing and Treating Gastrointestinal Dysfunction." A copy the '262 patent is attached as Exhibit B.

33. Pursuant to 21 U.S.C. § 355(b)(1), the '030 and '262 patents are listed in the FDA's publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Entereg® or its use.

34. Upon information and belief, Defendants submitted ANDA No. 208295 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Defendants' ANDA No. 208295 seeks FDA approval to manufacture, use, and sell Defendants' ANDA product prior to the expiration of the '030 and '262 patents. Upon information and belief, Defendants' ANDA No. 208295 contains a certification with respect to the '030 and '262 patents under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification").

35. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Defendants certified in ANDA No. 208295 that the claims of the '030 and '262 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, or offer for sale of Defendants' ANDA product.

36. Upon information and belief, by filing ANDA No. 208295, Defendants have represented to the FDA that Defendants' ANDA product has the same active ingredient as Entereg®, and has the same or substantially the same proposed labeling as Entereg®.

37. Defendants sent their Paragraph IV notice letter, dated July 26, 2017, to Merck, via Federal Express, in which Defendants represented that they had filed an ANDA for Defendants' ANDA product containing a Paragraph IV certification with respect to the '030 and '262 patents, and that they sought approval of their ANDA prior to the expiration of the '030 and '262 patents.

38. This action was commenced within 45 days of the date of receipt of the Paragraph IV notice letter by Merck.

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 6,469,030

39. Merck re-alleges paragraphs 1-38 as if fully set forth herein.

40. In their Paragraph IV notice letter, Defendants did not set forth an opinion of noninfringement of Claims 1-6, 11-12, and 15-25 of the '030 patent separate and apart from any assertions of invalidity of those claims. In their Paragraph IV notice letter, Defendants did not set forth an opinion that Claims 1-6, 11-12, and 15-25 of the '030 patent are invalid based on a ground other than obviousness.

41. By seeking approval of Defendants' ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '030 patent before its expiration,

including any patent term extension, Defendants have infringed the '030 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

42. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA product described in ANDA No. 208295, if approved by the FDA prior to the expiration of the '030 patent, including its patent term extension, would infringe the '030 patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

43. Upon information and belief, Defendants were aware of the existence of the '030 patent before filing their ANDA, and that the filing of their ANDA and Paragraph IV certification with respect to the '030 patent constituted an act of infringement of that patent.

44. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA product immediately and imminently upon approval of their ANDA.

45. Upon information and belief, upon FDA approval of their ANDA, Defendants will infringe the '030 patent by making, using, offering to sell, and selling their generic ANDA product in the United States and/or importing such a product into the United States.

46. Merck is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 208295 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '030 patent to which Merck is or becomes entitled.

47. Merck is entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell Defendants' ANDA product within the United States, import Defendants' ANDA product into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '030 patent under 35 U.S.C. § 271(a), (b), and/or (c).

48. Merck will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Merck does not have an adequate remedy at law.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 8,946,262

49. Merck re-alleges paragraphs 1-48 as if fully set forth herein.

50. In their Paragraph IV notice letter, Defendants did not set forth an opinion of noninfringement of Claims 1-6 of the '262 patent separate and apart from any assertions of invalidity of those claims. In their Paragraph IV notice letter, Defendants did not set forth an opinion that Claims 1-6 of the '262 patent are invalid based on a ground other than obviousness.

51. By seeking approval of Defendants' ANDA to engage in the commercial manufacture, use, or sale of a drug product claimed in the '262 patent before its expiration, including any patent term extension, Defendants have infringed the '262 patent pursuant to 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, the commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA product described in ANDA No. 208295, if approved by the FDA prior to the expiration of the '262 patent, including its patent term extension, would infringe the '262 patent under 35 U.S.C. § 271, either literally or under the doctrine of equivalents.

53. Upon information and belief, Defendants were aware of the existence of the '262 patent before filing their ANDA, and that the filing of their ANDA and Paragraph IV certification with respect to the '262 patent constituted an act of infringement of that patent.

54. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of Defendants' ANDA product immediately and imminently upon approval of their ANDA.

55. Upon information and belief, upon FDA approval of their ANDA, Defendants will infringe the '262 patent by making, using, offering to sell, and selling their generic ANDA product in the United States and/or importing such a product into the United States.

56. Merck is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of ANDA No. 208295 be a date that is not earlier than the expiration of the patent term extension granted by the USPTO pursuant to 35 U.S.C. § 156, or any later expiration of exclusivity for the '262 patent to which Merck is or becomes entitled.

57. Merck is entitled to a declaration that, if Defendants commercially manufacture, use, offer for sale, or sell Defendants' ANDA product within the United States, import Defendants' ANDA product into the United States, and/or induce or contribute to such conduct, Defendants will infringe the '262 patent under 35 U.S.C. § 271(a), (b), and/or (c).

58. Merck will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Merck does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Merck respectfully requests the following relief:

A. That a Judgment be entered that Defendants have infringed the '030 and '262 patents by submitting Defendants' ANDA No. 208295 to the FDA;

B. That preliminary and permanent injunctions be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Defendants, their officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of Defendants' ANDA product, or from inducing and/or encouraging the infringing use of methods claimed in the '030 and '262 patents;

C. That an Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 208295 be a date that is not earlier than the expiration of the '030 and '262 patents, including any extensions thereof and any later expiration of exclusivity for those patents to which Merck is or becomes entitled;

D. That an Order be entered that Merck be awarded the attorney fees, costs and expenses that they incur in prosecuting this action; and

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

Dated: September 8, 2017

By: s/ John E. Flaherty

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, Plaintiff Merck Sharp & Dohme Corp., by its undersigned attorneys, hereby certifies that the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 8, 2017

By: s/ John E. Flaherty

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