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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD and NIPPON SHINYAKU CO., LTD.

Plaintiffs,

v.

MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, ALEMBIC PHARMACEUTICALS LIMITED, ALEMBIC PHARMACEUTICALS, INC., VGYAAN PHARMACEUTICALS LLC, AIZANT DRUG RESEARCH SOLUTIONS PRIVATE LIMITED, ZYDUS WORLDWIDE DMCC and ZYDUS PHARMACEUTICALS (USA) INC.,

Defendants.

Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

(Filed Electronically)

Plaintiffs Actelion Pharmaceuticals Ltd ("Actelion") and Nippon Shinyaku Co., Ltd. ("Nippon Shinyaku") (collectively, "Plaintiffs"), for their Complaint against Defendants Alembic Pharmaceuticals Limited ("Alembic Ltd.") and Alembic Pharmaceuticals, Inc. ("Alembic Inc.") (collectively, "Alembic"), MSN Laboratories Private Limited ("MSN Ltd.")

and MSN Pharmaceuticals Inc. ("MSN Inc.") (collectively, "MSN"), VGYAAN Pharmaceuticals LLC ("VGYAAN"), Aizant Drug Research Solutions Private Limited ("Aizant"), and Zydus Worldwide DMCC ("Zydus Worldwide") and Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") (collectively, "Zydus"), (all Defendants collectively, "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Actelion is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

2. Plaintiff Nippon Shinyaku is a Japanese corporation having a primary place of business at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan.

3. Upon information and belief, Defendant Alembic Ltd. is an entity organized and existing under the laws of India, with a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India.

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

5. Upon information and belief, Defendant Alembic Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 750 Route 202, Bridgewater, New Jersey 08807.

6. Upon information and belief, Alembic Inc. is a United States subsidiary of Alembic Ltd.

7. Upon information and belief, Alembic Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0101031141.

8. Upon information and belief, Alembic Inc. is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5004785.

9. Upon information and belief, Alembic Inc. develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

10. Upon information and belief, Defendant MSN Ltd. is an entity organized and existing under the laws of India, with a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 18, Telangana 500018, India.

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

12. Upon information and belief, Defendant MSN Inc. is an entity organized and existing under the laws of the State of Delaware, with a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

13. Upon information and belief, MSN Inc. is a wholly-owned subsidiary of MSN Ltd.

14. Upon information and belief, MSN Inc. is an authorized U.S. Agent for MSN Ltd.

15. Upon information and belief, MSN Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400627791.

16. Upon information and belief, MSN Inc. develops, manufactures, markets, sells, distributes, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

17. Upon information and belief, Defendant VGYAAN is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558.

18. Upon information and belief, VGYAAN is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0600406976.

19. Upon information and belief, VGYAAN is registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler under Registration No. 5005560.

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

21. Upon information and belief, Defendant Aizant is an entity organized and existing under the laws of India, with a principal place of business at Survey No. 172 & 173, Apparel Park Road, Dulapally, Quthbullapur Mandal, Hyderabad, Telangana 500100, India.

22. Upon information and belief, Aizant, either directly or through one or more of its agents, develops, manufactures, markets, distributes, sells, and/or imports generic

pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

23. Upon information and belief, Defendant Zydus Worldwide is an entity organized and existing under the laws of the United Arab Emirates, with a principal place of business at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

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

25. Upon information and belief, Defendant Zydus USA is an entity organized and existing under the laws of the State of New Jersey, with a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

26. Upon information and belief, Zydus USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100915422.

27. Upon information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003171.

28. Upon information and belief, Zydus USA develops, manufactures, markets, distributes, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

29. This is a civil action for infringement of United States Patent No. 7,205,302 ("the '302 patent"), United States Patent No. 8,791,122 ("the '122 patent"), and United States Patent No. 9,284,280 ("the '280 patent") (collectively, "the patents-in-suit"). 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. §§ 2201-02.

30. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, and 35 U.S.C. § 271. This Court may declare the rights and other legal relations of the parties under 28 U.S.C. §§ 2201-02 because this case is an actual controversy within the Court's jurisdiction.

31. Venue is proper in this Court as to Alembic Ltd. under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Alembic Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which Alembic Ltd. is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

32. This Court has personal jurisdiction over Alembic Ltd., and venue is proper as to Alembic Ltd., because, *inter alia*, Alembic Ltd.: (1) directs and/or controls Alembic Inc., which has a principal place of business in New Jersey; (2) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiary, agent, and/or alter ego; (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) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; (5) upon information and belief, intends to, directly or indirectly through

its subsidiary, agent, and/or alter ego, market, sell, or distribute Alembic's ANDA Products (as defined in paragraph 90 of this Complaint, *infra*); (6) sent a Notice Letter to Janssen Research & Development, LLC in Cherry Hill, New Jersey; and (7) sent a Notice Letter to Janssen Pharmaceuticals, Inc. in Raritan, New Jersey.

33. This Court also has personal jurisdiction over Alembic Ltd. because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction as well as asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Duke University et al., v. Alembic Pharm. Ltd. et al.*, No. 17-07453 (BRM) (TJB); *Otsuka Pharm. Co., Ltd. v. Alembic Pharm. Ltd. et al.*, No. 14-07405 (JBS) (KMW); *Otsuka Pharm. Co., Ltd. v. Alembic Pharm. Ltd. et al.*, No. 14-02982 (JBS) (KMW).

34. Alembic Ltd. has further availed itself of the jurisdiction of this Judicial District by initiating litigation in this Judicial District. *See Alembic Pharm. Ltd. v. Novartis Pharm. Corp.*, No. 19-20890 (SRC) (CLW).

35. Alternatively, this Court may exercise jurisdiction over Alembic Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Alembic Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Alembic Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, submitting various Abbreviated New Drug Applications ("ANDAs") to the United States Food and Drug Administration ("FDA") and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Ltd. satisfies due process.

36. Venue is proper in this Court as to Alembic Inc. under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Alembic Inc. has a regular and established place of

business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

37. This Court has personal jurisdiction over Alembic Inc., and venue is proper as to Alembic Inc., because, *inter alia*, Alembic Inc.: (1) has its principal place of business in New Jersey; (2) has employees in the place(s) of business it maintains in New Jersey; (3) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Services to do business in the State of New Jersey under Business ID No. 0101031141 and securing a New Jersey manufacturer's and wholesale drug distributor's license under Registration No. 5004785; (4) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey; (5) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of New Jersey; (6) directly or indirectly maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (7) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (8) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Alembic's ANDA Products (as defined in paragraph 90 of this Complaint, *infra*).

38. This Court also has personal jurisdiction over Alembic Inc. because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction in this Judicial District. *See, e.g.*, *Duke University et al., v.*

Alembic Pharm. Ltd. et al., No. 17-07453 (BRM) (TJB); *Otsuka Pharm. Co., Ltd. v. Alembic Pharm. Ltd. et al.*, No. 14-07405 (JBS) (KMW); *Otsuka Pharm. Co., Ltd. v. Alembic Pharm. Ltd. et al.*, No. 14-02982 (JBS) (KMW).

39. This Court has personal jurisdiction over Alembic because, *inter alia*, Alembic Ltd. and Alembic Inc. have each committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

40. Upon information and belief, Alembic Ltd. and Alembic Inc. 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 Alembic's proposed products that are the subject of ANDA No. 214414, for which Alembic has sought approval from the FDA.

41. Upon information and belief, Alembic Ltd. and Alembic Inc. 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 Alembic's proposed products that are the subject of ANDA No. 214414, for which Alembic has sought approval from the FDA.

42. Upon information and belief, Alembic Ltd., alone and/or together with its affiliate and agent Alembic Inc., filed or caused to be filed ANDA No. 214414 with the FDA.

43. Upon information and belief, the actions of Alembic of, *inter alia*, causing Alembic's ANDA No. 214414 to be filed and maintaining distribution channels, including in the State of New Jersey, establish that if granted approval, Alembic will commercially manufacture,

use, offer to sell, sell, and/or import Alembic's ANDA Products throughout the United States, including in New Jersey.

44. Alembic Ltd. sent Plaintiffs a Notice Letter dated February 28, 2020, stating that Alembic Ltd. filed ANDA No. 214414 seeking approval from the FDA to commercially manufacture, use, market, or sell generic selexipag tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1400 mcg, and 1600 mcg, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '122 and '280 patents.

45. Venue is proper in this Court as to MSN Ltd. under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because MSN Ltd. is a foreign corporation and may be sued in any judicial district in the United States in which MSN Ltd. is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

46. This Court has personal jurisdiction over MSN Ltd., and venue is proper as to MSN Ltd., because, *inter alia*, MSN Ltd.: (1) directs and/or controls MSN Inc., which has a principal place of business in New Jersey; (2) has purposely availed itself of the privilege of doing business in New Jersey, directly or indirectly through its subsidiary, agent, and/or alter ego; (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) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; (5) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute MSN's ANDA Products (as defined in paragraph 95 of this Complaint, *infra*); and (6) sent a Notice Letter to the firm Hoxie & Associates LLC in Millburn, New Jersey.

47. This Court also has personal jurisdiction over MSN Ltd. because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction as well as asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Mitsubishi Tanabe Pharma Corp. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 19-18958 (FLW) (DEA); *Mitsubishi Tanabe Pharma Corp. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 19-15616 (RMB) (JS); *Sumitomo Dainippon Pharma Co., Ltd. et al., v. Aurobindo Pharma Ltd. et al.*, No. 18-02620 (SRC) (CLW); *BTG Int'l Ltd. et al., v. MSN Pharm. Inc. et al.*, No. 18-02372 (KM) (JBC); *Merck Sharp & Dohme Corp. v. MSN Labs. Pvt. Ltd. et al.*, No. 18-00675 (PGS) (LHG); *Forest Labs., LLC et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-10140 (ES) (SCM); *Boehringer Ingelheim Pharm., Inc. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-08399 (MAS) (LHG); *Mitsubishi Tanabe Pharma Corp. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-05302 (RMB) (JS); *Sumitomo Dainippon Pharma Co., Ltd. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-01010 (SRC) (CLW).

48. Alternatively, this Court may exercise jurisdiction over MSN Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) MSN Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) MSN Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Ltd. satisfies due process.

49. Venue is proper in this Court as to MSN Inc. under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because MSN Inc. has a regular and established place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial

District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

50. This Court also has personal jurisdiction over MSN Inc., and venue is proper as to MSN Inc., because, *inter alia*, MSN Inc.: (1) has its principal place of business in New Jersey; (2) has employees in the place(s) of business it maintains in New Jersey; (3) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Services to do business in the State of New Jersey under Business ID No. 0400627791; (4) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey; (5) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of New Jersey; (6) directly or indirectly maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including through a network of wholesalers and distributors, for the purposes of marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey; (7) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (8) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute MSN's ANDA Products (as defined in paragraph 95 of this Complaint, *infra*).

51. This Court also has personal jurisdiction over MSN Inc. because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Mitsubishi Tanabe Pharma Corp. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 19-18958 (FLW) (DEA); *Mitsubishi Tanabe Pharma Corp. et al., v. MSN Labs. Pvt. Ltd. et al.*, No.

19-15616 (RMB) (JS); *BTG Int'l Ltd. et al., v. MSN Pharm. Inc. et al.*, No. 18-02372 (KM) (JBC); *Merck Sharp & Dohme Corp. v. MSN Labs. Pvt. Ltd. et al.*, No. 18-00675 (PGS) (LHG); *Forest Labs., LLC et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-10140 (ES) (SCM); *Boehringer Ingelheim Pharm., Inc. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-08399 (MAS) (LHG); *Mitsubishi Tanabe Pharma Corp. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-05302 (RMB) (JS); *Sumitomo Dainippon Pharma Co., Ltd. et al., v. MSN Labs. Pvt. Ltd. et al.*, No. 17-01010 (SRC) (CLW).

52. This Court has personal jurisdiction over MSN because, *inter alia*, MSN Ltd. and MSN Inc. have each committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

53. Upon information and belief, MSN Ltd. and MSN Inc. 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 MSN's proposed products that are the subject of ANDA No. 214367, for which MSN has sought approval from the FDA.

54. Upon information and belief, MSN Ltd. and MSN Inc. 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 MSN's proposed products that are the subject of ANDA No. 214367, for which MSN has sought approval from the FDA.

55. Upon information and belief, MSN Ltd., alone and/or together with its affiliate and agent MSN Inc., filed or caused to be filed ANDA No. 214367 with the FDA.

56. Upon information and belief, the actions of MSN of, *inter alia*, causing MSN's ANDA No. 214367 to be filed and maintaining distribution channels, including in the State of New Jersey, establish that if granted approval, MSN will commercially manufacture, use, offer to sell, sell, and/or import MSN's ANDA Products throughout the United States, including in New Jersey.

57. MSN Ltd. sent Plaintiffs a Notice Letter dated February 27, 2020, stating that MSN Ltd. filed ANDA No. 214367 seeking approval from the FDA to commercially manufacture, use, market, or sell generic selexipag tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '122 and '280 patents.

58. Venue is proper in this Court as to VGYAAN under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because VGYAAN is incorporated in New Jersey, has a regular and established place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

59. This Court also has personal jurisdiction over VGYAAN, and venue is proper as to VGYAAN, because, *inter alia*, VGYAAN: (1) is incorporated in New Jersey; (2) has its principal place of business in New Jersey; (3) has employees in the place(s) of business it maintains in New Jersey; (4) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Services to do business in the State of New Jersey under Business ID No. 0600406976 and securing a New Jersey manufacturer's and wholesale drug distributor's license

under Registration No. 5005560; (5) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey; (6) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of New Jersey; (7) directly or indirectly maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of New Jersey; (8) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; (9) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute VGYAAN's ANDA Products (as defined in paragraph 101 of this Complaint, *infra*); and (10) designated Andrew J. Miller of Windels Marx Lane & Mittendorf, LLP in Madison, New Jersey as its agent in the United States "authorized to accept service of process on behalf of VGYAAN."

60. This Court has personal jurisdiction over VGYAAN because, *inter alia*, VGYAAN has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

61. Venue is proper in this Court as to Aizant under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Aizant is a foreign corporation and may be sued in any judicial district in the United States in which Aizant is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

62. This Court has personal jurisdiction over Aizant, and venue is proper as to Aizant, because, *inter alia*, Aizant: (1) has purposely availed itself of the privilege of doing

business in New Jersey directly or indirectly through its subsidiary, agent, and/or alter ego; (2) 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; (3) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; (4) in its Notice Letter dated February 25, 2020, designated Andrew J. Miller of Windels Marx Lane & Mittendorf, LLP in Madison, New Jersey as its agent in the United States "authorized to accept service of process for Aizant;" and (5) sent a Notice Letter to the firm Hoxie & Associates LLC in Millburn, New Jersey.

63. This Court has personal jurisdiction over Aizant because, *inter alia*, Aizant has committed, aided, abetted, contributed to, and/or participated in the commission of, acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

64. Aizant sent Plaintiffs a Notice Letter dated February 25, 2020, stating that Aizant filed ANDA No. 214055 seeking approval from the FDA to commercially manufacture, use, market, or sell generic selexipag tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '122 and '280 patents.

65. Upon information and belief, Aizant filed or caused to be filed ANDA No. 214055 with the FDA. Upon information and belief, Aizant has transferred at least some ownership rights in ANDA No. 214055 to VGYAAN. Upon information and belief, Aizant retains certain rights in ANDA No. 214055, and intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute VGYAAN's ANDA Products (as defined in paragraph 101 of this Complaint, *infra*).

66. Alternatively, this Court may exercise jurisdiction over Aizant pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Aizant is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Aizant has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Aizant satisfies due process.

67. Venue is proper in this Court as to Zydus Worldwide under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Zydus Worldwide is a foreign corporation and may be sued in any judicial district in the United States in which Zydus Worldwide is subject to the court's personal jurisdiction. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

68. This Court has personal jurisdiction over Zydus Worldwide, and venue is proper as to Zydus Worldwide, because, *inter alia*, Zydus Worldwide: (1) has purposely availed itself of the privilege of doing business in New Jersey directly or indirectly through its subsidiary, agent, and/or alter ego; (2) 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; (3) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (4) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Zydus's ANDA Products (as defined in paragraph 109 of this Complaint, *infra*).

69. This Court has personal jurisdiction over Zydus Worldwide because, *inter alia*, Zydus Worldwide has committed, aided, abetted, contributed to, and/or participated in the

commission of, acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

70. This Court also has personal jurisdiction over Zydus Worldwide because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction as well as asserting counterclaims against plaintiffs in this Judicial District. *See Valeant Pharm. North Am. LLC et al., v. Zydus Pharm. (USA) Inc. et al.*, No. 18-13635 (BRM) (LHG).

71. Alternatively, this Court may exercise jurisdiction over Zydus Worldwide pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Plaintiffs' claims arise under federal law; (2) Zydus Worldwide is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Zydus Worldwide has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus satisfies due process.

72. Venue is proper in this Court as to Zydus USA under 28 U.S.C. §§ 1391(b), (c), and/or (d), and 1400(b) because Zydus USA is incorporated in New Jersey, has a regular and established place of business in New Jersey, and has committed and will commit further acts of infringement in this Judicial District. Venue is proper for the additional reasons set forth below, and for other reasons that will be presented to the Court if such venue is challenged.

73. This Court also has personal jurisdiction over Zydus USA because, *inter alia*, Zydus USA: (1) is incorporated in New Jersey; (2) has its principal place of business in

New Jersey; (3) has employees in the place(s) of business it maintains in New Jersey; (4) has purposely availed itself of the privilege of doing business in New Jersey, including, *inter alia*, registering with the State of New Jersey's Division of Revenue and Enterprise Services to do business in the State of New Jersey under Business ID No. 0100915422 and securing a New Jersey wholesale drug distributor's license under Registration No. 5003171; (5) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey; (6) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical drugs in the State of New Jersey; (7) directly or indirectly maintains pervasive, continuous, and systematic contacts with the State of New Jersey, including the marketing, distribution, and/or sale of generic pharmaceutical drugs in the State of New Jersey; (8) upon information and belief, derives substantial revenue from the sale of its products in New Jersey; and (9) upon information and belief, intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Zydus's ANDA Products (as defined in paragraph 109 of this Complaint, *infra*).

74. This Court also has personal jurisdiction over Zydus USA because, *inter alia*, it has availed itself of the legal protections of the State of New Jersey by previously consenting to personal jurisdiction and asserting counterclaims against plaintiffs in this Judicial District. *See, e.g.*, *Takeda Pharm. Co. Ltd. et al., v. Zydus Pharm. (USA) Inc. et al.*, No. 18-11792 (FLW) (TJB); *Sumitomo Dainippon Pharma Co., Ltd. et al., v. Aurobindo Pharma Ltd. et al.*, No. 18-02620 (SRC) (CLW); *Takeda Pharm. Co. Ltd. et al., v. Zydus Pharm. (USA) Inc. et al.*, No. 18-01994 (FLW) (TJB); *Impax Labs., Inc. v. Zydus Pharm. (USA) Inc. et al.*, No. 17-13476 (SRC) (CLW); *Forest Labs., LLC et al., v. Zydus Pharm. (USA) Inc.*, No. 17-10330 (ES) (SCM); *Otsuka Pharm. Co., Ltd. v. Zydus Pharm. (USA) Inc.*, No. 17-02754 (JBS) (KMW);

Celgene Corp. v. Zydus Pharm. (USA) Inc. et al., No. 17-02528 (SDW) (LDW); *Valeant Pharm. Luxembourg Sarl et al., v. Zydus Pharm. (USA) Inc. et al.*, No. 17-00449 (PGS) (LHG); *Mitsubishi Tanabe Pharma Corp. et al., v. Sandoz Inc. et al.*, No. 17-05319 (FLW) (DEA).

75. Zydus USA has further availed itself of the jurisdiction of this Judicial District by initiating litigation in this Judicial District. *See, e.g.*, *Zydus Pharm. (USA) Inc. v. Novartis Pharm. Corp. et al.*, No. 19-21259 (SRC) (CLW); *Zydus Pharm. (USA) Inc. v. Eli Lilly & Co.*, No. 10-05584 (DMC) (JAD).

76. This Court has personal jurisdiction over Zydus because, *inter alia*, Zydus Worldwide and Zydus USA have each committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement, including acts in the State of New Jersey, that have led to foreseeable harm and injury to Plaintiffs in the State of New Jersey.

77. Upon information and belief, Zydus Worldwide and Zydus USA 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 Zydus's proposed products that are the subject of ANDA No. 214302, for which Zydus has sought approval from the FDA.

78. Upon information and belief, Zydus Worldwide and Zydus USA 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 Zydus's proposed products that are the subject of ANDA No. 214302, for which Zydus has sought approval from the FDA.

79. Upon information and belief, Zydus Worldwide, alone and/or together with its affiliate and agent Zydus USA, filed or caused to be filed ANDA No. 214302 with the FDA.

80. Upon information and belief, the actions of Zydus of, *inter alia*, causing Zydus's ANDA No. 214302 to be filed and maintaining distribution channels, including in the State of New Jersey, establish that if granted approval, Zydus will commercially manufacture, use, offer to sell, sell, and/or import Zydus's ANDA Products throughout the United States, including in New Jersey.

81. Zydus USA, as agent for Zydus Worldwide, sent Plaintiffs a Notice Letter dated March 2, 2020, stating that Zydus Worldwide filed ANDA No. 214302 seeking approval from the FDA to commercially manufacture, use, market, or sell generic selexipag tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg, in the United States (including, upon information and belief, in the State of New Jersey), prior to the expiration of the '302, '122, and '280 patents.

THE PATENTS-IN-SUIT

82. Actelion holds approved New Drug Application ("NDA") No. 207947, under which the FDA granted approval on December 21, 2015 for oral tablets, marketed in the United States under the brand name UPTRAVI®. The UPTRAVI® labeling states that selexipag tablets are available in the following strengths: 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, 1600 mcg.

83. UPTRAVI® (selexipag), approved in NDA No. 207947, is indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for pulmonary arterial hypertension.

84. As part of the FDA approval for UPTRAVI®, Actelion received Orphan Drug exclusivity, which expires December 21, 2022.

85. Nippon Shinyaku is the assignee of the patents-in-suit. Actelion is an exclusive licensee of the patents-in-suit.

86. The '302 patent was duly and legally issued on April 17, 2007, and is titled "Heterocyclic Compound Derivatives and Medicines." A copy of the '302 patent is attached as Exhibit A.

87. The '122 patent was duly and legally issued on July 29, 2014 (reissued September 15, 2017), and is titled "Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-N-Isopropylamino]Butyloxy}-N-(Methylsulfonyl)Actemide." A copy of the '122 patent is attached as Exhibit B.

88. The '280 patent was duly and legally issued on March 15, 2016, and is titled "Use of Form-I Crystal of 2-{4-[N-(5,6-Diphenylpyrazin-2-yl)-N-Isopropyl-Amino]Butyloxy}-N-(Methyl-Sulfonyl)Acetamide." A copy of the '280 patent is attached as Exhibit C.

89. Pursuant to 21 U.S.C. § 355(b)(l), the patents-in-suit are listed in the FDA publication titled, *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book"), as covering Plaintiffs' UPTRAVI® brand selexipag tablets.

DEFENDANTS' ANDAS AND NOTICE LETTERS

90. Upon information and belief, Alembic Ltd. submitted ANDA No. 214414 to the FDA, including a certification with respect to the '122 and '280 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use,

offer for sale, or sale within the United States, and/or importation into the United States, of generic selexipag oral tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1400 mcg, and 1600 mcg ("Alembic's ANDA Products"), prior to expiration of the '122 and '280 patents.

91. Upon information and belief, Alembic Ltd. submitted a certification with respect to the '302 patent under § 505(j)(2)(A)(vii)(III) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph III Certification").

92. Upon information and belief, on or about February 28, 2020, Alembic Ltd. sent a Paragraph IV Certification Notice Letter to Actelion and Nippon Shinyaku. In its Notice Letter, Alembic Ltd. represented that ANDA No. 214414 included a Paragraph IV Certification with respect to the '122 and '280 patents and that Alembic Ltd. sought approval of ANDA No. 214414 prior to the expiration of the '122 and '280 patents.

93. On March 4, 2020, Plaintiffs requested that Alembic Ltd. produce its ANDA, Drug Master File(s) ("DMF"), representative samples of its Active Pharmaceutical Ingredient ("API") and tablets for the exhibit batches for certain dosage strengths of its ANDA products, among other information, in order to evaluate infringement of the '122 and '280 patents. Plaintiffs repeated this request on at least March 9, 2020, March 16, 2020, and March 18, 2020. To date, Alembic Ltd. has not provided Plaintiffs with any of the requested information or samples, which has impaired Plaintiffs' ability to evaluate infringement of the '122 and '280 patents.

94. Plaintiffs commenced this action within 45 days of the date of receipt of the Alembic Ltd. Paragraph IV Certification Notice Letter, which was dated February 28, 2020.

95. Upon information and belief, MSN Ltd. submitted ANDA No. 214367 to the FDA, including a Paragraph IV Certification with respect to the '122 and '280 patents under

§ 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of generic selexipag oral tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg ("MSN's ANDA Products"), prior to the expiration of the '122 and '280 patents.

96. Upon information and belief, MSN Ltd. submitted a Paragraph III Certification with respect to the '302 patent under § 505(j)(2)(A)(vii)(III) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355).

97. Upon information and belief, on or about February 27, 2020, MSN Ltd. sent a Paragraph IV Certification Notice Letter to Actelion and Nippon Shinyaku. In its Notice Letter, MSN Ltd. represented that ANDA No. 214367 included a Paragraph IV Certification with respect to the '122 and '280 patents and that MSN Ltd. sought approval of ANDA No. 214367 prior to the expiration of the '122 and '280 patents.

98. On March 4, 2020, Plaintiffs requested that MSN Ltd. produce its ANDA, DMF(s), representative samples of its API and tablets for the exhibit batches for certain dosage strengths of its ANDA products, among other information, in order to evaluate infringement of the '122 and '280 patents. Plaintiffs repeated this request on at least March 13, 2020 and March 22, 2020. To date, MSN Ltd. has not provided Plaintiffs with any of the requested information or samples, which has impaired Plaintiffs' ability to evaluate infringement of the '122 and '280 patents.

99. Separate and apart from certain contentions regarding patent noninfringement, MSN Ltd.'s Paragraph IV Notice Letter does not identify any factual bases for, or any opinion of, invalidity of the claims of the '122 and '280 patents.

100. Plaintiffs commenced this action within 45 days of the date of receipt of the MSN Ltd. Paragraph IV Certification Notice Letter, which was dated February 27, 2020.

101. Upon information and belief, Aizant submitted ANDA No. 214055 to the FDA, including a Paragraph IV Certification with respect to the '122 and '280 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of generic selexipag oral tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg ("VGYAAN's ANDA Products"), prior to the expiration of the '122 and '280 patents.

102. Upon information and belief, on or about February 25, 2020, Aizant sent a Paragraph IV Certification Notice Letter to Actelion and Nippon Shinyaku. In its Notice Letter, Aizant represented that ANDA No. 214055 included a Paragraph IV Certification with respect to the '122 and '280 patents and that Aizant sought approval of ANDA No. 214055 prior to the expiration of the '122 and '280 patents.

103. Upon information and belief, Aizant submitted a Paragraph III Certification with respect to the '302 patent under § 505(j)(2)(A)(vii)(III) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355).

104. On or about March 13, 2020, counsel for VGYAAN and Aizant stated to Plaintiffs that VGYAAN was the new owner of ANDA No. 214055 and provided a "Transfer of Ownership Acknowledgement" letter from the FDA reflecting the transfer. Upon this notification, on March 13, 2020 and March 22, 2020 Plaintiffs requested documents reflecting the change of ownership under the OCA so that Plaintiffs could "understand what, if any, rights Aizant holds, including with respect to the ANDA [No. 214055] or commercialization of the

ANDA products." To date, VGYAAN has not provided Plaintiffs with the requested documents reflecting the change of ownership with respect to ANDA No. 214055.

105. In reply to Plaintiffs' request for samples relating to ANDA No. 214055 under the OCA, VGYAAN stated to Plaintiffs that VGYAAN could not provide the requested materials as VGYAAN "d[id] not have the samples," despite its obligations to have samples available upon FDA request. Plaintiffs stated to VGYAAN that its lack of possession of samples and refusal to provide change of ownership documentation indicated that Aizant retained rights in connection with ANDA No. 214055 or the commercialization of the related ANDA products. To date, VGYAAN has not explained why it does not have access to samples relating to ANDA No. 214055. Upon information and belief, Aizant retains at least certain rights in ANDA No. 214055.

106. On March 5, 2020, Plaintiffs requested that Aizant produce its ANDA, DMF(s), representative samples of its API and tablets for the exhibit batches for certain dosage strengths of its ANDA products, among other information, in order to evaluate infringement of the '122 and '280 patents. Plaintiffs repeated this request to VGYAAN on at least March 13, 2020 and March 22, 2020. To date, VGYAAN has not provided Plaintiffs with any of the requested information or samples, which has impaired Plaintiffs' ability to evaluate infringement of the '122 and '280 patents.

107. Separate and apart from certain contentions regarding patent noninfringement, Aizant's Paragraph IV Notice Letter, adopted by VGYAAN, does not identify any factual bases for, or any opinion of, invalidity of the claims of the '122 and '280 patents.

108. Plaintiffs commenced this action within 45 days of the date of receipt of the Aizant Paragraph IV Certification Notice Letter, which was dated February 25, 2020.

109. Upon information and belief, Zydus Worldwide submitted ANDA No. 214302 to the FDA, including a Paragraph IV Certification with respect to the '302, '122, and '280 patents under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of generic selexipag oral tablets, 200 mcg, 400 mcg, 600 mcg, 800 mcg, 1000 mcg, 1200 mcg, 1400 mcg, and 1600 mcg ("Zydus's ANDA Products"), prior to the expiration of the '302, '122, and '280 patents.

110. Upon information and belief, on or about March 2, 2020, Zydus USA, as agent for Zydus Worldwide, sent a Paragraph IV Certification Notice Letter to Actelion and Nippon Shinyaku. In its Notice Letter, Zydus represented that ANDA No. 214302 included a Paragraph IV Certification with respect to the '302, '122, and '280 patents and that Zydus Worldwide sought approval of ANDA No. 214302 prior to the expiration of the '302, '122, and '280 patents.

111. On March 10, 2020, Plaintiffs requested that Zydus Worldwide produce its ANDA, DMF(s), representative samples of its API and tablets for the exhibit batches for certain dosage strengths of its ANDA products, among other information, in order to evaluate infringement of the '122 and '280 patents. Plaintiffs repeated this request on at least March 18, 2020, March 25, 2020, and April 2, 2020. To date, Zydus has not provided Plaintiffs any of the requested information or samples, which has impaired Plaintiffs' ability to evaluate infringement of the '122 and '280 patents.

112. Separate and apart from certain contentions regarding patent validity, Zydus's Paragraph IV Notice Letter does not identify any factual bases for, or any opinion of, noninfringement of the claims of the '302 patent.

113. Separate and apart from certain contentions regarding patent noninfringement, Zydus's Paragraph IV Notice Letter does not identify any factual bases for, or any opinion of, invalidity of the claims of the '122 and '280 patents.

114. Plaintiffs commenced this action within 45 days of the date of receipt of the Zydus Paragraph IV Certification Notice Letter, which was dated March 2, 2020.

ACTS GIVING RISE TO THIS ACTION

COUNT I – INFRINGEMENT OF THE '122 AND '280 PATENTS BY ALEMBIC

115. Plaintiffs re-allege paragraphs 1-114 as if fully set forth herein.

116. Alembic Ltd. and Alembic Inc. are jointly and severally liable for any infringement of the '122 and '280 patents because, upon information and belief, Alembic Ltd. and Alembic Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214414 and the Paragraph IV Certification to the FDA.

117. By seeking approval of ANDA No. 214414 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Alembic's ANDA Products prior to the expiration of the '122 and '280 patents, Alembic has infringed one or more claims of each of the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A).

118. Upon information and belief, including Alembic's failure to produce the requested samples and information, Alembic's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Alembic's ANDA Products meets or embodies all elements of one or more claims of each of the '122 and '280 patents.

119. Upon information and belief, Alembic intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Alembic's ANDA Products upon receipt of final FDA approval of ANDA No. 214414.

120. If Alembic manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Alembic's ANDA Products prior to the expiration of the '122 and '280 patents, Alembic will infringe one or more claims of each of the '122 and '280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

121. Alembic Ltd.'s Paragraph IV Notice Letter does not dispute that the '280 patent is valid.

122. Alembic had actual and constructive notice of the '122 and '280 patents prior to the filing of Alembic's ANDA No. 214414 seeking approval of the ANDA products.

123. Plaintiffs are 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 Alembic's ANDA No. 214414 be a date that is not earlier than the expiration date of the '122 and '280 patents, or any later expiration of any patent term extension or exclusivity for the '122 and '280 patents to which Plaintiffs are or become entitled.

124. Plaintiffs are entitled to a declaration that, if Alembic commercially manufactures, uses, offers for sale, or sells Alembic's ANDA Products within the United States, imports Alembic's ANDA Products into the United States, or induces or contributes to such conduct, Alembic will infringe one or more claims of each of the '122 and '280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g).

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

COUNT II – INFRINGEMENT OF THE '122 AND '280 PATENTS BY MSN

126. Plaintiffs re-allege paragraphs 1-114 as if fully set forth herein.

127. MSN Ltd. and MSN Inc. are jointly and severally liable for any infringement of the '122 and '280 patents because, upon information and belief, MSN Ltd. and MSN Inc. actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214367 and the Paragraph IV Certification to the FDA.

128. By seeking approval of ANDA No. 214367 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of MSN's ANDA Products prior to the expiration of the '122 and '280 patents, MSN has infringed one or more claims of each of the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A).

129. Upon information and belief, including MSN's failure to produce the requested samples and information, MSN's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of MSN's ANDA Products meets or embodies all elements of one or more claims of each of the '122 and '280 patents.

130. Upon information and belief, MSN intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of MSN's ANDA Products upon receipt of final FDA approval of ANDA No. 214367.

131. If MSN manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, MSN's ANDA Products prior to the expiration of the '122 and '280 patents, MSN will infringe one or more claims of each of the '122 and '280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

132. MSN Ltd.'s Paragraph IV Notice Letter does not dispute that the '122 or '280 patents are valid.

133. MSN had actual and constructive notice of the '122 and '280 patents prior to the filing of MSN's ANDA No. 214367 seeking approval of the ANDA products.

134. Plaintiffs are 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 MSN's ANDA No. 214367 be a date that is not earlier than the expiration date of the '122 and '280 patents, or any later expiration of any patent term extension or exclusivity for the '122 and '280 patents to which Plaintiffs are or become entitled.

135. Plaintiffs are entitled to a declaration that, if MSN commercially manufactures, uses, offers for sale, or sells MSN's ANDA Products within the United States, imports MSN's ANDA Products into the United States, or induces or contributes to such conduct, MSN will infringe one or more claims of each of the '122 and '280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g).

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

COUNT III – INFRINGEMENT OF THE '122 AND '280 PATENTS BY VGYAAN AND AIZANT

137. Plaintiffs re-allege paragraphs 1-114 as if fully set forth herein.

138. VGYAAN and Aizant are jointly and severally liable for any infringement of the ’122 and ’280 patents because, upon information and belief, VGYAAN and Aizant actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214055 and the Paragraph IV Certification to the FDA.

139. By seeking approval of ANDA No. 214055 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of VGYAAN’s ANDA Products prior to the expiration of the ’122 and ’280 patents, VGYAAN and Aizant have infringed one or more claims of each of the ’122 and ’280 patents under 35 U.S.C. § 271(e)(2)(A).

140. Upon information and belief, including VGYAAN’s and Aizant’s failure to produce the requested samples and information, the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of VGYAAN’s ANDA Products meets or embodies all elements of one or more claims of each of the ’122 and ’280 patents.

141. Upon information and belief, VGYAAN and Aizant intend to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of VGYAAN’s ANDA Products upon receipt of final FDA approval of ANDA No. 214055.

142. If Aizant and/or VGYAAN manufacture, use, offer to sell, or sell within the United States, or import into the United States, VGYAAN’s ANDA Products prior to the expiration of the ’122 and ’280 patents, VGYAAN and Aizant will infringe one or more claims

of each of the ’122 and ’280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

143. Aizant’s Paragraph IV Notice Letter, adopted by VGYAAN, does not dispute that the ’122 or ’280 patents are valid.

144. Aizant had actual and constructive notice of the ’122 and ’280 patents prior to the filing of ANDA No. 214055 seeking approval of the ANDA products.

145. Plaintiffs are 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. 214055 be a date that is not earlier than the expiration date of the ’122 and ’280 patents, or any later expiration of any patent term extension or exclusivity for the ’122 and ’280 patents to which Plaintiffs are or become entitled.

146. Plaintiffs are entitled to a declaration that, if VGYAAN and Aizant commercially manufacture, use, offer for sale, or sell VGYAAN’s ANDA Products within the United States, import VGYAAN’s ANDA Products into the United States, or induce or contribute to such conduct, VGYAAN and Aizant will infringe one or more claims of each of the ’122 and ’280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g).

147. Plaintiffs will be irreparably harmed by VGYAAN’s and Aizant’s infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT IV – INFRINGEMENT OF THE ’302 PATENT BY ZYDUS

148. Plaintiffs re-allege paragraphs 1-114 as if fully set forth herein.

149. Zydus Worldwide and Zydus USA are jointly and severally liable for any infringement of the ’302 patent because, upon information and belief, Zydus Worldwide and Zydus USA actively and knowingly caused to be submitted, assisted with, participated in,

contributed to, and/or directed the submission of ANDA No. 214302 and the Paragraph IV Certification to the FDA.

150. In its Paragraph IV Certification Notice Letter, Zydus represented that its "proposed ANDA products as described in ANDA No. 214302 are selexipag tablets." By seeking approval of ANDA No. 214302 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Zydus's ANDA Products prior to the expiration of the '302 patent, Zydus has infringed one or more claims of the '302 patent under 35 U.S.C. § 271(e)(2)(A).

151. Upon information and belief, Zydus's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Zydus's ANDA Products meets or embodies all elements of one or more claims of the '302 patent.

152. Upon information and belief, Zydus intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Zydus's ANDA Products upon receipt of final FDA approval of ANDA No. 214302.

153. If Zydus manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Zydus's ANDA Products prior to the expiration of the '302 patent, Zydus will infringe one or more claims of the '302 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

154. Zydus's Paragraph IV Notice Letter does not dispute that the '302 patent would be infringed by Zydus's proposed ANDA products.

155. Zydus had actual and constructive notice of the '302 patent prior to the filing of Zydus's ANDA No. 214302 seeking approval of the ANDA products.

156. Plaintiffs are 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 Zydus's ANDA No. 214302 be a date that is not earlier than the expiration date of the '302 patent, or any later expiration of any patent term extension or exclusivity for the '302 patent to which Plaintiffs are or become entitled.

157. Plaintiffs are entitled to a declaration that, if Zydus commercially manufactures, uses, offers for sale, or sells Zydus's ANDA Products within the United States, imports Zydus's ANDA Products into the United States, or induces or contributes to such conduct, Zydus will infringe one or more claims of the '302 patent under 35 U.S.C. §§ 271(a), (b), (c), or (g).

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

COUNT V – INFRINGEMENT OF THE '122 AND '280 PATENTS BY ZYDUS

159. Plaintiffs re-allege paragraphs 1-114 as if fully set forth herein.

160. Zydus Worldwide and Zydus USA are jointly and severally liable for any infringement of the '122 and '280 patents because, upon information and belief, Zydus Worldwide and Zydus USA actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of ANDA No. 214302 and the Paragraph IV Certification to the FDA.

161. By seeking approval of ANDA No. 214302 to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Zydus's ANDA Products prior to the expiration of the '122 and '280 patents,

Zydus has infringed one or more claims of each of the ’122 and ’280 patents under 35 U.S.C. § 271(e)(2)(A).

162. Upon information and belief, including Zydus’s failure to produce the requested samples and information, Zydus’s commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of Zydus’s ANDA Products meets or embodies all elements of one or more claims of each of the ’122 and ’280 patents.

163. Upon information and belief, Zydus intends to and will engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of Zydus’s ANDA Products upon receipt of final FDA approval of ANDA No. 214302.

164. If Zydus manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Zydus’s ANDA Products prior to the expiration of the ’122 and ’280 patents, Zydus will infringe one or more claims of each of the ’122 and ’280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g) either literally or under the doctrine of equivalents.

165. Zydus’s Paragraph IV Notice Letter does not dispute that the ’122 or ’280 patents are valid.

166. Zydus had actual and constructive notice of the ’122 and ’280 patents prior to the filing of Zydus’s ANDA No. 214302 seeking approval of the ANDA products.

167. Plaintiffs are 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 Zydus’s ANDA No. 214302 be a date that is not earlier than the expiration date of the ’122 and ’280 patents, or any

later expiration of any patent term extension or exclusivity for the ’122 and ’280 patents to which Plaintiffs are or become entitled.

168. Plaintiffs are entitled to a declaration that, if Zydus commercially manufactures, uses, offers for sale, or sells Zydus’s ANDA Products within the United States, imports Zydus’s ANDA Products into the United States, or induces or contributes to such conduct, Zydus will infringe one or more claims of each of the ’122 and ’280 patents under 35 U.S.C. §§ 271(a), (b), (c), or (g).

169. Plaintiffs will be irreparably harmed by Zydus’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 request that the Court grant the following relief:

A. A Judgment decreeing that Alembic has infringed the ’122 and ’280 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214414;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Alembic, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Alembic, from infringing the ’122 and ’280 patents by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Alembic’s ANDA Products;

C. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 214414 be a date that is not earlier than the expiration date of the latest to expire of the ’122 and ’280 patents, or any later expiration of any patent term

extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

D. An award of monetary relief to the extent Alembic commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the '122 and '280 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

E. A Judgment decreeing that MSN has infringed the '122 and '280 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214367;

F. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining MSN, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with MSN, from infringing the '122 and '280 patents by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of MSN's ANDA Products;

G. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 214367 be a date that is not earlier than the expiration date of the latest to expire of the '122 and '280 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

H. An award of monetary relief to the extent MSN commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United

States any product that infringes or induces or contributes to the infringement of the ’122 and ’280 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled;

I. A Judgment decreeing that Aizant and VGYAAN have infringed the ’122 and ’280 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214055;

J. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining VGYAAN and Aizant, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with VGYAAN and Aizant, from infringing the ’122 and ’280 patents by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of VGYAAN’s ANDA Products;

K. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 214055 be a date that is not earlier than the expiration date of the latest to expire of the ’122 and ’280 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

L. An award of monetary relief to the extent VGYAAN and Aizant commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the ’122 and ’280 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which

Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

M. A Judgment decreeing that Zydus has infringed the ’302, ’122, and ’280 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 214302;

N. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) or 35 U.S.C. § 283 restraining and enjoining Zydus, its directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with Zydus, from infringing the ’302, ’122, and ’280 patents by the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Zydus’s ANDA Products;

O. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any approval of ANDA No. 214302 be a date that is not earlier than the expiration date of the latest to expire of the ’302, ’122, and ’280 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents to which Plaintiffs are or become entitled;

P. An award of monetary relief to the extent Zydus commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the ’302, ’122, and ’280 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled;

Q. A declaration that this is an exceptional case and an award of reasonable attorney’s fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4)(A) and 285; and

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

Dated: April 9, 2020

By: *s/ Keith J. Miller*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, the undersigned, attorney of record for Plaintiffs, hereby certifies that to the best of my knowledge and based upon the information available to me, 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: April 9, 2020

By: *s/ Keith J. Miller*

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