Charles M. Lizza
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520,
Newark, NJ 07102-5426
(973) 286-6715
clizza@saul.com

Attorneys for Plaintiffs

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS IRELAND LIMITED and PHARMA MAR, S.A., Plaintiffs, v. SANDOZ, INC., INVAGEN PHARMACEUTICALS, INC., CIPLA USA, INC., CIPLA (EU) LIMITED, CIPLA LIMITED, ZYDUS LIFESCIENCES GLOBAL FZE, ZYDUS PHARMACEUTICALS (USA) INC., ZYDUS LIFESCIENCES LIMITED, RK PHARMA, INC., APICORE US LLC, ARCHIS PHARMA LLC, VGYAAN PHARMACEUTICALS LLC, MSN PHARMACEUTICALS INC., and MSN LABORATORIES PVT. LTD., Defendants.	Civil Action No. _____ (Filed Electronically)

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Jazz Pharmaceuticals Ireland Limited ("Jazz") and Pharma Mar, S.A. ("Pharma Mar") (collectively, "Plaintiffs"), for their Complaint against Defendants Sandoz, Inc. ("Sandoz"); InvaGen Pharmaceuticals, Inc. ("InvaGen"), Cipla USA, Inc. ("Cipla USA"), Cipla (EU) Limited

("Cipla EU"), and Cipla Limited ("Cipla Limited") (collectively, "InvaGen Defendants"); Zydus Lifesciences Global FZE ("Zydus FZE"), Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Limited") (collectively, "Zydus Defendants"); RK Pharma, Inc. ("RK"), Apicore US LLC ("Apicore"), Archis Pharma LLC ("Archis"), and Vgyaan Pharmaceuticals LLC ("Vgyaan") (collectively, "RK Defendants"); and MSN Pharmaceuticals, Inc. ("MSNPI") and MSN Laboratories Pvt. Ltd. ("MSN Labs") (collectively, "MSN Defendants") (all collectively, "Defendants"), hereby allege as follows:

THE PARTIES

Plaintiffs

1. Plaintiff Jazz is a corporation organized and existing under the laws of Ireland, having a principal place of business at Fifth Floor, Waterloo Exchange, Waterloo Road, Dublin, N37 AX84, Ireland.

2. Plaintiff Pharma Mar is a corporation organized and existing under the laws of Spain, having a principal place of business at Avenida De Los Reyes, 1, 28770 - Colmenar Viejo, Madrid, Spain.

Sandoz

3. On information and belief, Defendant Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540, United States.

4. On information and belief, Sandoz, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

5. On information and belief, Sandoz has prepared and filed ANDA No. 219515 ("Sandoz ANDA") and will be involved in the manufacture, importation, marketing, and/or sale of the drug that is the subject of the Sandoz ANDA, if approved by the FDA.

InvaGen Defendants

6. On information and belief, Defendant InvaGen is a corporation organized and existing under the laws of New York, having a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788, United States.

7. On information and belief, Defendant InvaGen, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

8. On information and belief, Defendant Cipla USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059, United States.

9. On information and belief, Cipla USA, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

10. On information and belief, Defendant Cipla EU is a corporation organized and existing under the laws of United Kingdom, having a principal place of business at 3rd Floor, 364-366 Kensington High Street, London, W14 8NS, United Kingdom.

11. On information and belief, Cipla EU, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling

generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

12. On information and belief, Defendant Cipla Limited is a corporation organized and existing under the laws of India, having a principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

13. On information and belief, Cipla Limited, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

14. On information and belief, InvaGen is a wholly owned subsidiary of Cipla EU, which is a wholly owned subsidiary of Cipla Limited.

15. On information and belief, Cipla USA is a wholly owned subsidiary of InvaGen. In an IPR petition to the PTAB, InvaGen represented that it "has a 100% fully owned subsidiary named Cipla USA Inc." *See* Petition for *Inter Partes* Review of U.S. Patent No. 10,828,310, *InvaGen Pharmaceuticals, Inc. v. Bayer Pharma*, Case IPR2022-01515 (P.T.A.B. Sept. 8, 2022).

16. On information and belief, the InvaGen Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. On information and belief, the acts of the InvaGen Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

17. On information and belief, the InvaGen Defendants have cooperated and assisted in the preparation and filing of Abbreviated New Drug Application ("ANDA") No. 219605 ("InvaGen ANDA") and will be involved in the manufacture, importation, marketing, and/or sale

of the drug that is the subject of the InvaGen ANDA, if approved by the United States Food and Drug Administration ("FDA").

Zydus Defendants

18. On information and belief, Defendant Zydus FZE is a corporation organized and existing under the laws of Dubai, United Arab Emirates, having a principal place of business at Fzjo B2601, Jebel Ali Free Zone Dubai, Dubai, United Arab Emirates.

19. On information and belief, Zydus FZE, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

20. On information and belief, Defendant Zydus USA is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534, United States.

21. On information and belief, Zydus USA, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

22. On information and belief, Defendant Zydus Limited is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar) Nr. Vaishnodevi Circle, Ahmedabad, Gujarat 382481, India.

23. On information and belief, Zydus Limited, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling

generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

24. On information and belief, Zydus FZE and Zydus USA are wholly owned subsidiaries of Zydus Limited.

25. On information and belief, the Zydus Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. On information and belief, the acts of the Zydus Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

26. On information and belief, the Zydus Defendants have cooperated and assisted in the preparation and filing of ANDA No. 219582 ("Zydus ANDA") and will be involved in the manufacture, importation, marketing, and/or sale of the drug that is the subject of the Zydus ANDA, if approved by the FDA.

RK Defendants

27. On information and belief, Defendant RK is a corporation organized and existing under the laws of Delaware, having a principal place of business at 401 North Middletown Road, Building 215/215A, Pearl River, New York 10965, United States.

28. On information and belief, RK, by itself and/or through its affiliates and agents, is in the business of, *inter alia,* manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

29. On information and belief, Defendant Apicore is a corporation organized and existing under the laws of Delaware, having a principal place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

30. On information and belief, Apicore, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

31. On information and belief, Defendant Archis is a corporation organized and existing under the laws of Delaware, having a principal place of business at 15 Corporate Place South, Suite 108, Piscataway, New Jersey 08854, United States.

32. On information and belief, Archis, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

33. On information and belief, Defendant Vgyaan is a corporation organized and existing under the laws of New Jersey, having a principal place of business at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558, United States.

34. On information and belief, Vgyaan, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

35. On information and belief, Apicore, Archis, and Vgyaan are wholly owned subsidiaries of RK.

36. On information and belief, the RK Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. On information and belief, the acts of the RK Defendants complained of

herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

37. On information and belief, the RK Defendants have cooperated and assisted in the preparation and filing of ANDA No. 219731 ("RK ANDA") and will be involved in the manufacture, importation, marketing, and/or sale of the drug that is the subject of the RK ANDA, if approved by the FDA.

MSN Defendants

38. On information and belief, Defendant MSNPI is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854, United States.

39. On information and belief, MSNPI, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

40. On information and belief, Defendant MSN Labs is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No. C-24, SanathNagar Industrial Estate, SanathNagar, Hyderabad, Telangana 500018, India.

41. On information and belief, MSN Labs, by itself and/or through its affiliates and agents, is in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

42. On information and belief, MSNPI is a wholly owned subsidiary of MSN Labs.

43. On information and belief, the MSN Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic

products within the United States. On information and belief, the acts of the MSN Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

44. On information and belief, the MSN Defendants have cooperated and assisted in the preparation and filing of ANDA No. 219771 ("MSN ANDA") and will be involved in the manufacture, importation, marketing, and/or sale of the drug that is the subject of the MSN ANDA, if approved by the FDA.

NATURE OF THE ACTION

45. This is a civil action for the infringement of United States Patent No. 7,763,615 ("the '615 Patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Defendants' filing of ANDA Nos. 219605, 219582, 219515, 219731, and 219771 with the FDA seeking approval to market generic versions of the pharmaceutical product Zepzelca® (lurbinectedin) for injection, for intravenous use, 4 mg/vial, before the expiration of the '615 Patent, *i.e.*, Plaintiffs' patent covering Zepzelca®.

JURISDICTION AND VENUE

46. This Court has jurisdiction over the subject matter of this action, including Counts I – V against the Defendants, pursuant to 28 U.S.C. §§ 1331 and 1338.

Sandoz

47. This Court has personal jurisdiction over Sandoz by virtue of the fact that, *inter alia*, Sandoz has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

48. This Court has personal jurisdiction over Sandoz by virtue of the fact that, on information and belief, Sandoz, either directly or through its affiliates, regularly and continuously

does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. On information and belief, the Sandoz conducts marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if the Sandoz ANDA is approved, Sandoz will market and sell its generic version of Zepzelca® in New Jersey.

49. This Court has personal jurisdiction over Sandoz. On information and belief, Sandoz regularly and continuously conducts business in New Jersey. Sandoz has an active business entity status registered with the state of New Jersey under the business entity identification number 0101056767, a principal place of business at 100 College Road West, Princeton, New Jersey 08540, and a corporate agent for service of process at Princeton South Corporate Center, Suite 160, 100 Charles Ewing Blvd, Ewing, New Jersey 08628. Sandoz's New Jersey business entity registration also identifies its officers and directors as having the address 100 College Road West, Princeton, New Jersey 08540.

50. This Court further has personal jurisdiction over Sandoz by virtue of the fact that Sandoz has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *Merck Sharp & Dohme BV*, *et al. v. Sandoz, Inc.*, *et al.*, CA. No. 20-cv-03117 (D.N.J. *filed* Mar. 20, 2020); *Celgene Corp. v. Sandoz Inc.*, CA. No. 18-cv-11026 (D.N.J. *filed* Jun. 26, 2018); *Allergan Sales, LLC*, *et al. v. Sandoz, Inc.*, *et al.*, CA. No. 17-cv-10129 (D.N.J. *filed* Oct. 30, 2017); *Boehringer Ingelheim Pharm., Inc.*, *et*

al. v. Sandoz Inc., CA. No. 17-cv-08825 (D.N.J. *filed* Oct. 20, 2017); *Mitsubishi Tanabe Pharma Corp.*, *et al. v. MSN Labs. Pvt. Ltd.*, *et al.*, CA. No. 17-cv-05302 (D.N.J. *filed* Jul. 20, 2017).

51. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

52. Venue is proper in this Judicial District for Sandoz. On information and belief, Sandoz has active business entity identification number in the State of New Jersey (0101056767), has employees in New Jersey, and maintains a regular and established place of business in New Jersey at 100 College Road West, Princeton, New Jersey 08540. In Sandoz's business registrations for New Jersey (as well as for California, Florida, and Vermont), the "Principals" and "Officers and Directors" of Sandoz are identified as Keren Haruvi (President), Karen McDonnell (Secretary, Vice President), Mohammad Obeidat (COO), Edward Stueck (Vice President), and Martin Bischof (Director), and the address provided for all these individuals is 100 College Road West, Princeton, New Jersey 08540. Furthermore, on information and belief, based on Sandoz's connections to New Jersey, discoverable information in its possession, custody, or control regarding the Sandoz ANDA will likely show that Sandoz engaged in activities in New Jersey relevant to the preparation and/or submission of the Sandoz ANDA and therefore committed acts of infringement within this Judicial District.

53. Venue is further proper in this Court as to Sandoz because, *inter alia*, Sandoz has committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Zepzelca® for sale and use throughout the United States, including within the State of New Jersey.

InvaGen Defendants

54. This Court has personal jurisdiction over the InvaGen Defendants by virtue of the fact that, *inter alia*, the InvaGen Defendants have committed the tortious act of patent infringement

pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

55. This Court has personal jurisdiction over the InvaGen Defendants by virtue of the fact that, on information and belief, the InvaGen Defendants, either directly or through their affiliates, regularly and continuously do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and/or derive substantial revenue from services or things used or consumed in New Jersey, including by selling their pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. On information and belief, the InvaGen Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if the InvaGen ANDA is approved, the InvaGen Defendants will market and sell their generic version of Zepzelca® in New Jersey.

56. This Court has personal jurisdiction over InvaGen. On information and belief, InvaGen regularly and continuously conducts business in New Jersey. InvaGen has an active business entity status registered with the state of New Jersey under the business entity identification number 0450360045 and has a corporate agent for service of process at 208 West State Street, Trenton, New Jersey 08608. InvaGen's New Jersey business entity registration also identifies its officers and directors as having the address 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059, which is the address of its wholly owned subsidiary Cipla USA.

57. This Court further has personal jurisdiction over InvaGen by virtue of the fact that InvaGen has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions

initiated in this jurisdiction, including, but not limited to, *e.g.*, *Jazz Pharm. Research UK Ltd. f/k/a GW Research Ltd. v. Apotex Inc.*, *et al.*, CA. No. 23-cv-23141 (D.N.J. *filed* Dec. 15, 2023); *Sumitomo Dainippon Pharma Co., Ltd. v. Aurobindo Pharma Ltd.*, *et al.*, CA. No. 18-cv-2620 (D.N.J. *filed* Feb. 23, 2018); *Mitsubishi Tanabe Pharma Corp.*, *et al. v. InvaGen Pharm., Inc.*, CA. No. 17-cv-06375 (D.N.J. *filed* Aug. 23, 2017); *Sumitomo Dainippon Pharma Co., Ltd.*, *et al. v. InvaGen Pharm., Inc.*, CA. No. 15-cv-00281 (D.N.J. *filed* Jan. 14, 2015); *Shire Development LLC*, *et al v. InvaGen Pharm., Inc.*, CA. No. 15-cv-00367 (D.N.J. *filed* Dec. 12, 2014).

58. This Court has personal jurisdiction over Cipla USA. On information and belief, Cipla USA regularly and continuously conducts business in New Jersey and has a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Cipla USA has an active business entity status registered with the state of New Jersey under the business entity identification number 0450318628 and has a corporate agent for service of process at 208 West State Street, Trenton, New Jersey 08608.

59. This Court further has personal jurisdiction over Cipla USA by virtue of the fact that Cipla USA has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *Teva Branded Pharmaceutical Products R&D, Inc.*, *et al. v. Cipla USA, Inc.*, *et al.*, CA. No. 24-cv-00909 (D.N.J. *filed* Feb. 16, 2024); *Jazz Pharm. Research UK Ltd. f/k/a GW Research Ltd. v. Apotex Inc.*, *et al.*, CA. No. 23-cv-23141 (D.N.J. *filed* Dec. 15, 2023); *Cubist Pharm. LLC f/k/a Cubist Pharm., Inc. v. Cipla USA, Inc.*, *et al.*, CA. No. 19-cv-12920 (D.N.J. *filed* May. 24, 2019).

60. Additionally, on information and belief, InvaGen's online presence resides within Cipla USA's website, and all the manufacturing sites identified on Cipla USA's website are InvaGen units. On information and belief, InvaGen and Cipla USA work in concert to market and sell generic pharmaceutical products throughout the United States, including in New Jersey. On information and belief, Cipla USA and InvaGen share officers and employees. On information and belief, InvaGen and Cipla USA are alter egos.

61. This Court has personal jurisdiction over Cipla EU. On information and belief, Cipla EU regularly and continuously transacts business within New Jersey, either directly or through its subsidiaries—InvaGen and Cipla USA, companies having active business entity statuses registered with New Jersey—including by selling pharmaceutical products in New Jersey.

62. Alternatively, this Court may exercise jurisdiction over Cipla EU pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Cipla EU is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cipla EU has sufficient contacts with the United States as a whole, including, but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla EU satisfies due process.

63. This Court has personal jurisdiction over Cipla Limited. On information and belief, Cipla Limited regularly and continuously transacts business within New Jersey, either directly or through its subsidiaries—InvaGen and Cipla USA, companies having active business entity statuses registered with New Jersey—including by selling pharmaceutical products in New Jersey.

64. This Court further has personal jurisdiction over Cipla Limited by virtue of the fact that Cipla Limited has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims

in civil actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *Teva Branded Pharm. Products R&D, Inc.*, *et al v. Cipla USA, Inc.*, *et al.*, CA. No. 24-cv-05856 (D.N.J. *filed* May. 06, 2024); *Jazz Pharm. Research UK Ltd. f/k/a GW Research Ltd. v. Apotex Inc.*, *et al.*, CA. No. 23-cv-23141 (D.N.J. *filed* Dec. 15, 2023); *Celgene Corp.*, *v. Cipla Ltd.*, CA. No. 19-cv-14731 (D.N.J. *filed* Jul. 03, 2019).

65. Alternatively, this Court may exercise jurisdiction over Cipla Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Cipla Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Cipla Limited has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla Limited satisfies due process.

66. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

67. Venue is proper in this Judicial District for InvaGen. On information and belief, InvaGen has an active business entity identification number in the State of New Jersey (0450360045), has employees in New Jersey, and maintains a regular and established place of business in New Jersey at 10 Independence Boulevard, Suite 300, Warren New Jersey 07059. In InvaGen's business registrations for New Jersey (as well as for California, Florida, Massachusetts, and Vermont), the "Principals" and "Officers and Directors" of InvaGen are identified as Arunesh Verma (President, CEO, Director), Deepak Agarwal (CFO, Treasurer, Director), Umang Vohra (Director), Srinivas Mallavarapu (Director), Robert Stewart (Independent Director), Anup Dad (Secretary, Treasurer), and Marc Falkin (CEO), and the address provided for all these individuals is Cipla USA's principal address, *i.e.*, 10 Independence Boulevard, Suite 300, Warren, New Jersey

07059. Online third-party company profiles (*e.g.*, Moody's Analytics) also give the "contact information" for InvaGen as the above Warren, New Jersey address. Furthermore, on information and belief, based on InvaGen's connections to New Jersey, discoverable information in its possession, custody, or control regarding the InvaGen ANDA will likely show that InvaGen engaged in activities in New Jersey relevant to the preparation and/or submission of the InvaGen ANDA and therefore committed acts of infringement within this Judicial District.

68. Venue is proper in this Judicial District for Cipla USA. On information and belief, Cipla USA has its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. On information and belief, Cipla USA has an active business entity identification number in the State of New Jersey (0450318628), has employees in New Jersey, and maintains a regular and established place of business in New Jersey at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. In Cipla USA's business registration for New Jersey (as well as for New York), the "Principals" and "Officers and Directors" of Cipla USA are identified as Arunesh Verma (CEO, Director), Deepak Agarwal (CFO), Umang Vohra (President, Director), Robert Stewart (Director), Biplab Mazumdar (Secretary, Treasurer), and AS Kumar (Director), and the address provided for all these individuals is 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Online third-party company profiles (*e.g.*, Moody's Analytics) also give the "contact information" for InvaGen as the above Warren, New Jersey address. Furthermore, on information and belief, based on Cipla USA's connections to New Jersey, discoverable information in its possession, custody, or control regarding the InvaGen ANDA will likely show that Cipla USA engaged in activities in New Jersey relevant to the preparation and/or submission of the InvaGen ANDA and therefore committed acts of infringement within this Judicial District.

69. Venue is proper in this Judicial District for Cipla EU and Cipla Limited because, *inter alia*, they both are foreign corporations not residing in any United States district and may be sued in any judicial district.

70. Venue is further proper in this Court as to the InvaGen Defendants because, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Zepzelca® for sale and use throughout the United States, including within the State of New Jersey.

Zydus Defendants

71. This Court has personal jurisdiction over the Zydus Defendants by virtue of the fact that, *inter alia*, the Zydus Defendants have committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

72. This Court has personal jurisdiction over the Zydus Defendants by virtue of the fact that, on information and belief, the Zydus Defendants, either directly or through their affiliates, regularly and continuously do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and/or derive substantial revenue from services or things used or consumed in New Jersey, including by selling their pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. On information and belief, the Zydus Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if the Zydus ANDA is approved, the Zydus Defendants will market and sell their generic version of Zepzelca® in New Jersey.

73. This Court has personal jurisdiction over Zydus FZE. On information and belief, Zydus FZE regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Zydus USA, a New Jersey corporation—including selling pharmaceutical products in New Jersey. On information and belief, Zydus FZE and Zydus USA work in concert to market and sell generic pharmaceutical products throughout the United States, including in New Jersey. On information and belief, Zydus FZE and Zydus USA are alter egos.

74. Alternatively, this Court may exercise jurisdiction over Zydus FZE pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Zydus FZE is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus FZE has sufficient contacts with the United States as a whole, including, but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, directly or through related entities, such that this Court's exercise of jurisdiction over Zydus FZE satisfies due process.

75. This Court has personal jurisdiction over Zydus USA. On information and belief, Zydus USA is incorporated in and regularly and continuously conducts business in New Jersey. Zydus USA has an active business entity status registered with the state of New Jersey under the business entity identification number 0100915422 and has a principal place of business at 73 Route 31 North, Pennington, New Jersey, 08534. Zydus USA's New Jersey business entity registration also identifies its officers and directors as having the address 73 Route 31 North, Pennington, New Jersey 08534.

76. This Court further has personal jurisdiction over Zydus USA by virtue of the fact that Zydus USA has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil

actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *Astellas Pharma Inc.*, *et al. v. Zydus Pharm. (USA) Inc.*, *et al.*, CA. No. 22-cv-04499 (D.N.J. *filed* Jul. 08, 2022); *Merck Sharp & Dohme BV*, *et al. v. Aurobindo Pharma USA, Inc.*, *et al.*, CA. No. 20-cv-02576 (D.N.J. *filed* Mar. 10, 2020); *Sumitomo Dainippon Pharma Co., Ltd.*, *et al. v. Aurobindo Pharma Ltd.*, *et al.*, CA. No. 18-cv-02620 (D.N.J. *filed* Feb. 23, 2018); *Impax Labs., Inc. v. Zydus Pharm. (USA) Inc.*, *et al.*, CA. No. 17-cv-13476 (D.N.J. *filed* Dec. 21, 2017); *Mitsubishi Tanabe Pharma Corp.*, *et al. v. Sandoz Inc.*, *et al.*, CA. No. 17-cv-05319 (D.N.J. *filed* Jul. 20, 2017); *Boehringer Ingelheim Pharm. Inc.*, *et al. v. Accord Healthcare, Inc. et al.*, CA. No. 16-cv-00852 (D.N.J. *filed* Feb. 17, 2016); *Otsuka Pharm. Co., Ltd. v. Zydus Pharm. USA Inc.*, CA. No. 14-cv-07252 (D.N.J. *filed* Nov. 20, 2014).

77. This Court has personal jurisdiction over Zydus Limited. On information and belief, Zydus Limited regularly and continuously transacts business within New Jersey, either directly or through its wholly owned subsidiaries—Zydus FZE and Zydus USA, the latter a New Jersey corporation—including by selling pharmaceutical products in New Jersey.

78. This Court further has personal jurisdiction over Zydus Limited by virtue of the fact that Zydus Limited has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *Aragon Pharm., Inc.*, *et al. v. Zydus Worldwide DMCC*, *et al.*, CA. No. 23-cv-01685 (D.N.J. *filed* Mar. 24, 2023)*; Merck Sharp & Dohme BV*, *et al. v. Aurobindo Pharma USA, Inc.*, *et al.*, CA. No. 20-cv-02576 (D.N.J. *filed* Mar. 10, 2020).

79. Alternatively, this Court may exercise jurisdiction over Zydus Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b)

Zydus Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Limited has sufficient contacts with the United States as a whole, including, but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Zydus Limited satisfies due process.

80. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

81. Venue is proper in this Judicial District for Zydus FZE and Zydus Limited because, *inter alia*, they both are foreign corporations not residing in any United States district and may be sued in any judicial district.

82. Venue is proper in this Judicial District for Zydus USA. On information and belief, Zydus USA is incorporated in, and therefore resides in, New Jersey.

83. Venue is further proper in this Court as to the Zydus Defendants because, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Zepzelca® for sale and use throughout the United States, including within the State of New Jersey.

RK Defendants

84. This Court has personal jurisdiction over the RK Defendants by virtue of the fact that, *inter alia*, the RK Defendants have committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

85. This Court has personal jurisdiction over the RK Defendants by virtue of the fact that, on information and belief, the RK Defendants, either directly or through their affiliates, regularly and continuously do or solicit business in New Jersey, engage in other persistent courses

of conduct in New Jersey, and/or derive substantial revenue from services or things used or consumed in New Jersey, including by selling their pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. On information and belief, the RK Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if the RK ANDA is approved, the RK Defendants will market and sell their generic version of Zepzelca® in New Jersey.

86. This Court has personal jurisdiction over RK. On information and belief, RK regularly and continuously conducts business in New Jersey, either directly or through its subsidiaries—Apicore, Archis, and Vgyaan, companies incorporated and/or having principal places of business in New Jersey—including by selling pharmaceutical products in New Jersey. On information and belief, RK, Apicore, Archis, and Vgyaan work in concert to market and sell generic pharmaceutical products throughout the United States, including in New Jersey. On information and belief, RK, Apicore, Archis, and Vgyaan are alter egos.

87. This Court further has personal jurisdiction over RK by virtue of the fact that RK has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *American Regent, Inc. f/k/a Luitpold Pharm., Inc. v. RK Pharma, Inc.*, *et al.*, CA. No. 24-cv-01169 (D.N.J. *filed* Feb. 28, 2024); *American Regent, Inc. f/k/a Luitpold Pharm., Inc. v. Somerset Therapeutics, LLC*, *et al.*, CA. No. 24-cv-01022 (D.N.J. *filed* Feb. 22, 2024).

88. This Court has personal jurisdiction over Apicore. On information and belief, Apicore regularly and continuously conducts business in New Jersey and has a principal place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

89. This Court further has personal jurisdiction over Apicore by virtue of the fact that Apicore has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in a civil action initiated in this jurisdiction, including, *e.g.*, *Aurobindo Pharma USA, Inc.*, *et al. v. Apicore US LLC*, *et al.*, CA. No. 16-cv-03358 (D.N.J. *filed* Jun. 09, 2016).

90. This Court has personal jurisdiction over Archis. On information and belief, Archis regularly and continuously conducts business in New Jersey and has a principal place of business at 15 Corporate Place South, Piscataway, New Jersey 08854.

91. This Court has personal jurisdiction over Vgyaan. On information and belief, Vgyaan is incorporated in and regularly and continuously conducts business in New Jersey. Vgyaan has an active business entity status registered with the state of New Jersey under the business entity identification number 0600406976, a principal place of business at 23 Orchard Road, Suite 180, Skillman, New Jersey 08558,and has a corporate agent for service of process at 23 Cornflower Court, Suite 200, Belle Mead, New Jersey 08502.

92. This Court further has personal jurisdiction over Vgyaan by virtue of the fact that Vgyaan has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in a civil action initiated in this jurisdiction, including, *e.g.*, *Actelion Pharmaceuticals Ltd.*, *et al. v. MSN Pharmaceuticals Inc.*, *et al.*, C.A. No. 20-cv-03859 (D.N.J. *filed* Apr. 09, 2020).

93. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

94. Venue is proper in this Judicial District for RK. On information and belief, RK has employees in New Jersey and maintains regular and established places of business in New Jersey at 49 Napoleon Court, Somerset, New Jersey 08873; 15 Corporate Place South, Piscataway, New Jersey 08854; and 23 Orchard Road, Suite 180, Skillman, New Jersey 08558. On information and belief, the identified "Principals" and "Officers and Directors" of RK Pharma are Ravishanker Kovi (Executive Chairman) and Naveen Paladugu (COO, Director), who are also on executive committees of Apicore and Archis, respectively, and the addresses provided for these individuals are the Somerset, New Jersey and Piscataway, New Jersey addresses of Apicore and Archis, above. The New York State Division of Corporations "Entity Information" registration form for RK states that the "Principal Executive Office Address" for RK is 1 Tower Center Blvd, 2300, East Brunswick, New Jersey 08816. Furthermore, on information and belief, based on RK's connections to New Jersey, discoverable information in its possession, custody, or control regarding the RK ANDA will likely show that RK engaged in activities in New Jersey relevant to the preparation and/or submission of the RK ANDA and therefore committed acts of infringement within this Judicial District.

95. Venue is proper in this Judicial District for Apicore. On information and belief, Apicore has employees in New Jersey and maintains a regular and established place of business in New Jersey at 49 Napoleon Court, Somerset, New Jersey 08873. Furthermore, on information and belief, based on Apicore's connections to New Jersey, discoverable information in its possession, custody, or control regarding the RK ANDA will likely show that Apicore engaged in activities in New Jersey relevant to the preparation and/or submission of the RK ANDA and therefore committed acts of infringement within this Judicial District.

96. Venue is proper in this Judicial District for Archis. On information and belief, Archis has employees in New Jersey and maintains a regular and established place of business in New Jersey at 15 Corporate Place South, Suite 108, Piscataway, New Jersey 08854. Furthermore, on information and belief, based on Archis's connections to New Jersey, discoverable information in its possession, custody, or control regarding the RK ANDA will likely show that Archis engaged in activities in New Jersey relevant to the preparation and/or submission of the RK ANDA and therefore committed acts of infringement within this Judicial District.

97. Venue is proper in this Judicial District for Vgyaan. On information and belief, Vgyaan is incorporated in, and therefore resides in, New Jersey.

98. Venue is further proper in this Court as to the RK Defendants because, *inter alia*, the RK Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Zepzelca® for sale and use throughout the United States, including within the State of New Jersey.

MSN Defendants

99. This Court has personal jurisdiction over the MSN Defendants by virtue of the fact that, *inter alia*, the MSN Defendants have committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of New Jersey and throughout the United States.

100. This Court has personal jurisdiction over the MSN Defendants by virtue of the fact that, on information and belief, the MSN Defendants, either directly or through their affiliates, regularly and continuously do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and/or derive substantial revenue from services or things used or consumed in New Jersey, including by selling their pharmaceutical products in New Jersey and,

therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. On information and belief, the MSN Defendants conduct marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to New Jersey residents that are continuous and systematic. On information and belief, if the MSN ANDA is approved, the MSN Defendants will market and sell their generic version of Zepzelca® in New Jersey.

101. This Court further has personal jurisdiction over the MSN Defendants by virtue of the fact that both MSN Defendants have previously submitted to the jurisdiction of this Court and purposefully availed themselves of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction, including, but not limited to, *e.g.*, *Merck Sharp & Dohme BV*, *et al. v. Aurobindo Pharma USA, Inc.*, *et al.*, CA. No. 20-cv-2576 (D.N.J. *filed* Mar. 10, 2020); *Boehringer Ingelheim Pharm., Inc.*, *et al. v. HEC Pharm Group*, *et al.*, CA. No. 15-cv-5982 (D.N.J. *filed* Aug. 04, 2015).

102. This Court has personal jurisdiction over MSNPI. On information and belief, MSNPI regularly and continuously conducts business in New Jersey. On information and belief, MSNPI has its principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSNPI has an active business entity status registered with the state of New Jersey under the business entity identification number 0400627791 and has a corporate agent for service of process at 20 Duke Road, Piscataway, New Jersey 08854.

103. This Court has personal jurisdiction over MSN Labs by virtue of the fact that, on information and belief, MSN Labs regularly and continuously transacts business within New Jersey, either directly or through its wholly owned subsidiary, MSNPI, a company having its

principal place of business in New Jersey, including by selling pharmaceutical products in New Jersey.

104. Alternatively, this Court may exercise jurisdiction over MSN Labs pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) MSN Labs is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) MSN Labs has sufficient contacts with the United States as a whole, including, but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Labs satisfies due process.

105. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

106. Venue is proper in this Judicial District for MSNPI. On information and belief, MSNPI has active business entity identification number in the State of New Jersey (0400627791), has employees in New Jersey, and maintains a regular and established place of business in New Jersey at 20 Duke Road, Piscataway, New Jersey 08854. Furthermore, on information and belief, based on MSNPI's connections to New Jersey, discoverable information in its possession, custody, and/or control regarding the MSN ANDA will likely show that MSNPI engaged in activities in New Jersey relevant to the preparation and/or submission of the MSN ANDA and therefore committed acts of infringement within this Judicial District.

107. Venue is proper in this Judicial District for MSN Labs because, *inter alia*, MSN Labs is a foreign corporation not residing in any United States district and may be sued in any judicial district.

108. Venue is further proper in this Court as to both MSN Defendants because, *inter alia*, MSN Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to

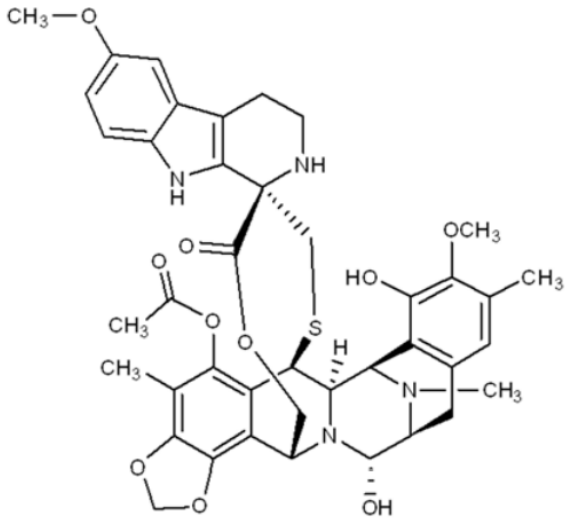
Plaintiffs, which manufacture Zepzelca® for sale and use throughout the United States, including within the State of New Jersey.

THE ZEPZELCA® NDA

109. Pharma Mar USA, Inc., a wholly owned subsidiary of Pharma Mar, filed New Drug Application ("NDA") No. 213702 for "Zepzelca® (lurbinectedin) injection, 4 mg lyophilized powder in a single-dose vial." The FDA granted accelerated approval for NDA No. 213702 on June 15, 2020, for the treatment of adult patients with metastatic small cell lung cancer ("SCLC") with disease progression on or after platinum-based chemotherapy.

110. Pharma Mar USA, Inc. transferred and assigned NDA No. 213702 to Jazz.

111. Lurbinectedin is a compound that can be referred to by any of several chemical names, including (1'R,6R,6aR,7R,13S,14S,16R)-8,14-dihydroxy-6',9-dimethoxy-4,10,23-trimethyl-19-oxo-2',3',4',6,7,9',12,13,14,16-decahydro-6aH-spiro[7,13-azano-6,16-(epithiopropanooxymethano)[1,3]dioxolo[7,8]isoquinolino[3,2-b][3]benzazocine-20,1'-pyrido[3,4-b]indol]-5-yl acetate, and has the following chemical structure:



THE PATENT-IN-SUIT

112. On July 27, 2010, the '615 Patent, entitled "Ecteinascidin Analogs for Use as Antitumour Agents," was duly and legally issued to Pharma Mar. A true and correct copy of the '615 Patent is attached hereto as Exhibit A.

113. The '615 Patent claims, *inter alia*, lurbinectedin, pharmaceutical compositions comprising lurbinectedin, and methods of treatment comprising administering lurbinectedin.

114. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '615 Patent is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") for Zepzelca® for intravenous use, 4 mg/vial.

115. Pharma Mar owns the '615 Patent.

116. Pursuant to an agreement, as amended, entered into between Pharma Mar and Jazz, Jazz was granted an exclusive license to the '615 Patent, with the right to sue for infringement of the '615 Patent in the United States.

ACTS GIVING RISE TO THE PATENT INFRINGEMENT COUNTS

Sandoz

117. By a letter dated August 9, 2024 ("Sandoz's Notice Letter"), Sandoz informed Plaintiffs that it had submitted the Sandoz ANDA to the FDA seeking approval to manufacture, use, and/or sell "Lurbinectedin for injection, 4mg/vial" ("Sandoz's Generic Product") prior to the expiration of the '615 Patent.

118. On information and belief, Sandoz submitted the Sandoz ANDA to the FDA under § 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use, or sale of Sandoz's Generic Product as a generic version of Zepzelca®.

119. On information and belief, the Sandoz ANDA seeks FDA approval of Sandoz's Generic Product for the indication of treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

120. Sandoz's Notice Letter also advised Plaintiffs that Sandoz's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Sandoz's opinion, certain claims of the '615 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, sale, and/or use of Sandoz's Generic Product.

121. Sandoz's Notice Letter does not allege non-infringement of the '615 Patent.

122. By not identifying non-infringement defenses for the '615 Patent, Sandoz admits Sandoz's Generic Product meets all limitations of its claims.

123. Sandoz's Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, 103, or 112, or unenforceability for any claim of the '615 Patent.

124. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, 103, or 112, or unenforceability for any claim of the '615 Patent, Sandoz admits that the '615 Patent is valid under 35 U.S.C. §§ 101, 102, 103, and 112 and enforceable.

125. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Sandoz regarding the infringement, validity, and enforceability of the '615 Patent.

126. On information and belief, following FDA approval of the Sandoz ANDA, Sandoz will make, use, offer to sell, or sell Sandoz's Generic Product throughout the United States, and/or import such a generic product into the United States.

127. On information and belief, following FDA approval of the Sandoz ANDA, Sandoz intends to directly benefit from sales of Sandoz's Generic Product.

128. Plaintiffs are commencing this action against Sandoz within 45 days of receiving Sandoz's Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

InvaGen Defendants

129. By a letter dated July 30, 2024 ("InvaGen Defendants' Notice Letter"), the InvaGen Defendants informed Plaintiffs that they had submitted the InvaGen ANDA to the FDA seeking approval to manufacture, use, and/or sell "Lurbinectedin for injection, 4 mg/vial" ("InvaGen's Generic Product") prior to the expiration of the '615 Patent.

130. On information and belief, the InvaGen Defendants submitted the InvaGen ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA"), seeking approval to engage in the commercial manufacture, use, and sale of InvaGen's Generic Product as a generic version of Zepzelca®.

131. On information and belief, the InvaGen ANDA seeks FDA approval of InvaGen's Generic Product for the indication of treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

132. The InvaGen Defendants' Notice Letter also advised Plaintiffs that InvaGen's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv) that, in the InvaGen Defendants' opinion, certain claims of the '615 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, sale, and/or use of InvaGen's Generic Product.

133. The InvaGen Defendants' Notice Letter does not allege non-infringement of certain claims of the '615 Patent.

134. By not identifying non-infringement defenses for certain claims of the '615 Patent, the InvaGen Defendants admit InvaGen's Generic Product meets all limitations of those claims.

135. The InvaGen Defendants' Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability for any claim of the '615 Patent.

136. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability for any claim of the '615 Patent, the InvaGen Defendants admit that the '615 Patent is valid under 35 U.S.C. §§ 101, 102, and 112 and enforceable.

137. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and the InvaGen Defendants regarding the infringement, validity, and enforceability of the '615 Patent.

138. On information and belief, following FDA approval of the InvaGen ANDA, the InvaGen Defendants will act in concert to make, use, offer to sell, or sell InvaGen's Generic Product throughout the United States, or import such a generic product into the United States.

139. On information and belief, following FDA approval of the InvaGen ANDA, the InvaGen Defendants intend to directly benefit from sales of InvaGen's Generic Product.

140. Plaintiffs are commencing this action against the InvaGen Defendants within 45 days of receiving the InvaGen Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

Zydus Defendants

141. By a letter dated August 1, 2024 ("Zydus Defendants' Notice Letter"), the Zydus Defendants informed Pharma Mar and Jazz that they had submitted the Zydus ANDA to the FDA seeking approval to manufacture, use, sell, offer to sell, and/or import "Lurbinectedin powder, intravenous, 4 mg/vial" ("Zydus' Generic Product") prior to the expiration of the '615 Patent.

142. On information and belief, the Zydus Defendants submitted the Zydus ANDA to the FDA under § 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use, sale, or importation of Zydus' Generic Product as a generic version of Zepzelca®.

143. On information and belief, the Zydus ANDA seeks FDA approval of Zydus' Generic Product for the indication of treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

144. The Zydus Defendants' Notice Letter also advised Pharma Mar and Jazz that Zydus' ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv) that, in the Zydus Defendants' opinion, certain claims of the '615 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, sale, and/or use of Zydus' Generic Product.

145. The Zydus Defendants' Notice Letter does not allege non-infringement of certain claims of the '615 Patent.

146. By not identifying non-infringement defenses for certain claims of the '615 Patent, the Zydus Defendants admit Zydus' Generic Product meets all limitations of those claims.

147. The Zydus Defendants' Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability for any claim of the '615 Patent.

148. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability for any claim of the '615 Patent, the Zydus Defendants admit that the '615 Patent is valid under 35 U.S.C. §§ 101, 102, and 112 and enforceable.

149. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and the Zydus Defendants regarding the infringement, validity, and enforceability of the '615 Patent.

150. On information and belief, following FDA approval of the Zydus ANDA, the Zydus Defendants will act in concert to make, use, offer to sell, or sell Zydus' Generic Product throughout the United States, or import such a generic product into the United States.

151. On information and belief, following FDA approval of the Zydus ANDA, the Zydus Defendants intend to directly benefit from sales of Zydus' Generic Product.

152. Plaintiffs are commencing this action against the Zydus Defendants within 45 days of receiving the Zydus Defendants' Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

RK Defendants

153. By a letter dated August 12, 2024 ("RK Defendants' Notice Letter"), the RK Defendants informed Plaintiffs that they had submitted the RK ANDA to the FDA seeking approval to manufacture, use, and/or sell "Lurbinectedin for injection (4 mg/vial) product" ("RK's Generic Product") prior to the expiration of the '615 Patent.

154. On information and belief, the RK Defendants submitted the RK ANDA to the FDA under § 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use, and sale of RK's Generic Product as a generic version of Zepzelca®.

155. On information and belief, the RK ANDA seeks FDA approval of RK's Generic Product for the indication of treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

156. The RK Defendants' Notice Letter also advised Plaintiffs that RK's ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv) that, in the RK Defendants' opinion, certain claims of the '615 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, sale, and/or use of RK's Generic Product.

157. The RK Defendants' Notice Letter does not allege non-infringement of certain claims of the '615 Patent.

158. By not identifying non-infringement defenses for certain claims of the '615 Patent, the RK Defendants admit RK's Generic Product meets all limitations of those claims.

159. The RK Defendants' Notice Letter does not allege invalidity under 35 U.S.C. §§ 101 or 102 or unenforceability for any claim of the '615 Patent.

160. By not identifying invalidity defenses under 35 U.S.C. §§ 101 or 102, or unenforceability for any claim of the '615 Patent, the RK Defendants admit that the '615 Patent is valid under 35 U.S.C. §§ 101 and 102 and enforceable.

161. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and the RK Defendants regarding the infringement, validity, and enforceability of the '615 Patent.

162. On information and belief, following FDA approval of the RK ANDA, the RK Defendants will act in concert to make, use, offer to sell, or sell RK's Generic Product throughout the United States, and/or import such a generic product into the United States.

163. On information and belief, following FDA approval of the RK ANDA, the RK Defendants intend to directly benefit from sales of RK's Generic Product.

164. Plaintiffs are commencing this action against the RK Defendants within 45 days of receiving the RK Defendants' Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

MSN Defendants

165. By a letter dated August 13, 2024 ("MSN Defendants' Notice Letter"), the MSN Defendants informed Pharma Mar and Jazz that the MSN Defendants had submitted the MSN ANDA to the FDA seeking approval to manufacture, use, and/or sell "Lurbinectedin for injection (4 mg/vial) product" ("MSN's Generic Product") prior to the expiration of the '615 Patent.

166. On information and belief, the MSN Defendants submitted the MSN ANDA to the FDA under § 505(j) of the FDCA, seeking approval to engage in the commercial manufacture, use, and/or sale of MSN's Generic Product as a generic version of Zepzelca®.

167. On information and belief, the MSN ANDA seeks FDA approval of MSN's Generic Product for the indication of treatment of adult patients with metastatic SCLC with disease progression on or after platinum-based chemotherapy.

168. The MSN Defendants' Notice Letter also advised Pharma Mar and Jazz that MSN Defendants' ANDA submission included certifications under 21 U.S.C. § 355(j)(2)(B)(iv) that, in the MSN Defendants' opinion, certain claims of the '615 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, sale, and/or use of MSN Defendants' Generic Product.

169. The MSN Defendants' Notice Letter does not allege non-infringement of certain claims of the '615 Patent.

170. By not identifying non-infringement defenses for certain claims of the '615 Patent, the MSN Defendants admit MSN's Generic Product meets all limitations of those claims.

171. The MSN Defendants' Notice Letter does not allege invalidity under 35 U.S.C. §§ 101, 102, or 112, or unenforceability for any claim of the '615 Patent.

172. By not identifying invalidity defenses under 35 U.S.C. §§ 101, 102, or 112, or unenforceability for any claim of the '615 Patent, the MSN Defendants admit that the '615 Patent is valid under 35 U.S.C. §§ 101, 102, and 112 and enforceable.

173. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and the MSN Defendants regarding the infringement, validity, and enforceability of the '615 Patent.

174. On information and belief, following FDA approval of the MSN ANDA, the MSN Defendants will act in concert to make, use, offer to sell, or sell MSN's Generic Product throughout the United States, and/or import such a generic product into the United States.

175. On information and belief, following FDA approval of the MSN ANDA, the MSN Defendants intend to directly benefit from sales of MSN's Generic Product.

176. Plaintiffs are commencing this action against the MSN Defendants within 45 days of receiving the MSN Defendants' Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I

(Infringement of the '615 Patent by Sandoz)

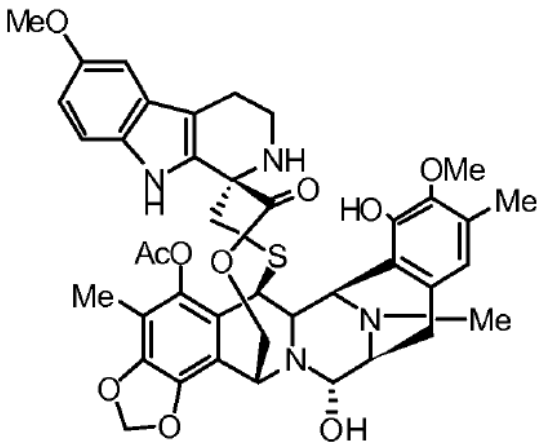
177. Plaintiffs incorporate each of the preceding paragraphs 1-176 as if fully set forth herein.

178. By submitting the Sandoz ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product throughout the United States, including New Jersey, prior to expiration of the '615 Patent, Sandoz committed an act of infringement of the '615 Patent under 35 U.S.C. § 271(e)(2)(A).

179. On information and belief, Sandoz's Generic Product, if approved by the FDA, will contain the compound lurbinectedin, which will constitute infringement of claims of the '615 Patent.

180. On information and belief, Sandoz's manufacture, use, sale, offer for sale, and/or importation into the United States of Sandoz's Generic Product prior to the expiration of the '615 Patent, including any applicable exclusivities or extensions, will directly infringe one or more claims of the '615 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, Sandoz will also indirectly infringe one or more of the claims of the '615 Patent under 35 U.S.C. § 271(b) and/or (c). Sandoz will infringe one or more claims of the '615 Patent.

181. On information and belief, Sandoz's Generic Product will directly and literally infringe at least Claim 22 of the '615 Patent which recites "[a] compound according to claim 1 of formula:"



182. On information and belief, Sandoz's Generic Product will infringe at least Claim 22 of the '615 Patent because Sandoz's Generic Product will contain lurbinectedin.

183. On information and belief, Sandoz was aware of the existence of the '615 Patent and its listing in the Orange Book as demonstrated by its reference to the '615 Patent in the Sandoz's Notice Letter.

184. On information and belief, Sandoz copied the claimed invention of the '615 Patent.

185. On information and belief, Sandoz knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product prior to patent expiry will infringe one or more claims of the '615 Patent.

186. On information and belief, Sandoz's statement of the factual and legal bases for its opinions regarding non-infringement and invalidity of the '615 Patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

187. Plaintiffs will be substantially and irreparably harmed by the infringing activities of Sandoz as described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT II

(Infringement of the '615 Patent by the InvaGen Defendants)

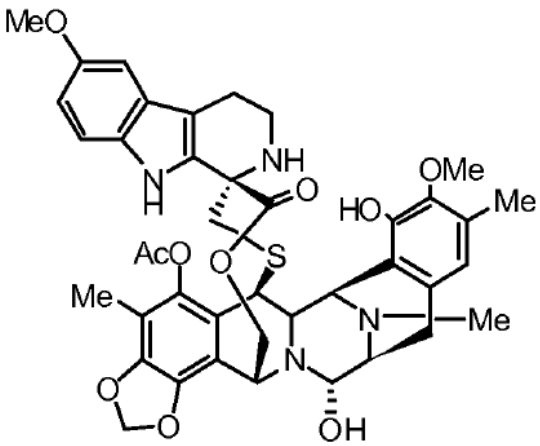
188. Plaintiffs incorporate each of the preceding paragraphs 1-176 as if fully set forth herein.

189. By submitting the InvaGen ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of InvaGen's Generic Product throughout the United States, including New Jersey, prior to expiration of the '615 Patent, the InvaGen Defendants committed an act of infringement of the '615 Patent under 35 U.S.C. § 271(e)(2)(A).

190. On information and belief, InvaGen's Generic Product, if approved by the FDA, will contain the compound lurbinectedin, which will constitute infringement of claims of the '615 Patent.

191. On information and belief, the InvaGen Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of InvaGen's Generic Product prior to the expiration of the '615 Patent, including any applicable exclusivities or extensions, will directly infringe one or more claims of the '615 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the InvaGen Defendants will also indirectly infringe one or more of the claims of the '615 Patent under 35 U.S.C. § 271(b) and/or (c). The InvaGen Defendants will infringe one or more claims of the '615 Patent.

192. On information and belief, InvaGen's Generic Product will directly and literally infringe at least Claim 22 of the '615 Patent which recites "[a] compound according to claim 1 of formula:"



.

On information and belief, InvaGen's Generic Product will infringe at least Claim 22 of the '615 Patent because InvaGen's Generic Product will contain lurbinectedin.

193. On information and belief, the InvaGen Defendants were aware of the existence of the '615 Patent and its listing in the Orange Book as demonstrated by their reference to the '615 Patent in the InvaGen Defendants' Notice Letter.

194. On information and belief, the InvaGen Defendants copied the claimed invention of the '615 Patent.

195. On information and belief, the InvaGen Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of InvaGen's Generic Product prior to patent expiry will infringe one or more claims of the '615 Patent.

196. On information and belief, the InvaGen Defendants' statement of the factual and legal bases for their opinions regarding non-infringement and invalidity of the '615 Patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

197. Plaintiffs will be substantially and irreparably harmed by the infringing activities of the InvaGen Defendants as described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT III

(Infringement of the '615 Patent by the Zydus Defendants)

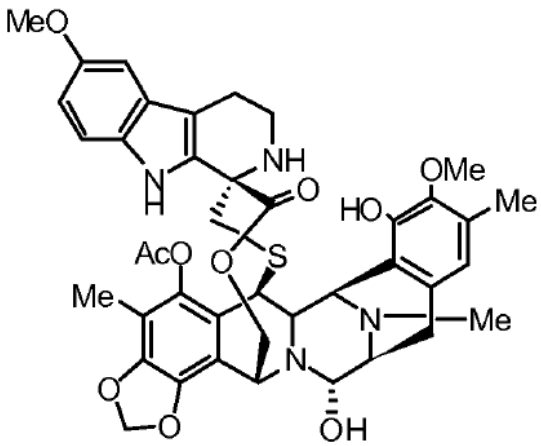
198. Plaintiffs incorporate each of the preceding paragraphs 1-176 as if fully set forth herein.

199. By submitting the Zydus ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus' Generic Product throughout the United States, including New Jersey, prior to expiration of the '615 Patent, the Zydus Defendants committed an act of infringement of the '615 Patent under 35 U.S.C. § 271(e)(2)(A).

200. On information and belief, Zydus' Generic Product, if approved by the FDA, will contain the compound lurbinectedin, which will constitute infringement of claims of the '615 Patent.

201. On information and belief, the Zydus Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of Zydus' Generic Product prior to the expiration of the '615 Patent, including any applicable exclusivities or extensions, will directly infringe one or more claims of the '615 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the Zydus Defendants will also indirectly infringe one or more of the claims of the '615 Patent under 35 U.S.C. § 271(b) and/or (c). The Zydus Defendants will infringe one or more claims of the '615 Patent.

202. On information and belief, Zydus' Generic Product will directly and literally infringe at least Claim 22 of the '615 Patent which recites "[a] compound according to claim 1 of formula:"



On information and belief, Zydus' Generic Product will infringe at least Claim 22 of the '615 Patent because Zydus' Generic Product will contain lurbinectedin.

203. On information and belief, the Zydus Defendants were aware of the existence of the '615 Patent and its listing in the Orange Book as demonstrated by their reference to the '615 Patent in the Zydus Defendants' Notice Letter.

204. On information and belief, the Zydus Defendants copied the claimed invention of the '615 Patent.

205. On information and belief, the Zydus Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of Zydus' Generic Product prior to patent expiry will infringe one or more claims of the '615 Patent.

206. On information and belief, the Zydus Defendants' statement of the factual and legal bases for their opinions regarding non-infringement and invalidity of the '615 Patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

207. Plaintiffs will be substantially and irreparably harmed by the infringing activities of the Zydus Defendants as described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV

(Infringement of the '615 Patent by the RK Defendants)

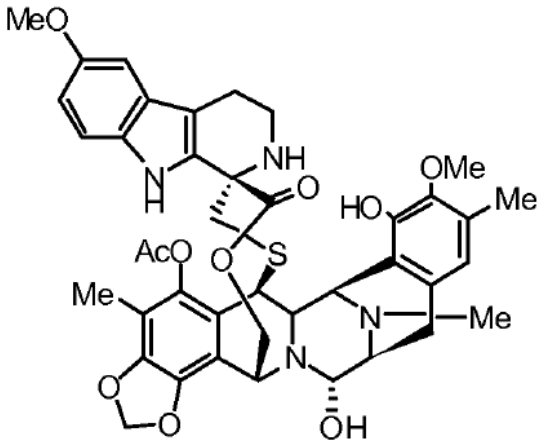
208. Plaintiffs incorporate each of the preceding paragraphs 1-176 as if fully set forth herein.

209. By submitting the RK ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of RK's Generic Product throughout the United States, including New Jersey, prior to expiration of the '615 Patent, the RK Defendants committed an act of infringement of the '615 Patent under 35 U.S.C. § 271(e)(2)(A).

210. On information and belief, RK's Generic Product, if approved by the FDA, will contain the compound lurbinectedin, which will constitute infringement of claims of the '615 Patent.

211. On information and belief, the RK Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of RK's Generic Product prior to the expiration of the '615 Patent, including any applicable exclusivities or extensions, will directly infringe one or more claims of the '615 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the RK Defendants will also indirectly infringe one or more of the claims of the '615 Patent under 35 U.S.C. § 271(b) and/or (c). The RK Defendants will infringe one or more claims of the '615 Patent.

212. On information and belief, RK's Generic Product will directly and literally infringe at least Claim 22 of the '615 Patent which recites "[a] compound according to claim 1 of formula:"



On information and belief, RK's Generic Product will infringe at least Claim 22 of the '615 Patent because RK's Generic Product will contain lurbinectedin.

213. On information and belief, the RK Defendants were aware of the existence of the '615 Patent and its listing in the Orange Book as demonstrated by their reference to the '615 Patent in the RK Defendants' Notice Letter.

214. On information and belief, the RK Defendants copied the claimed invention of the '615 Patent.

215. On information and belief, the RK Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of RK's Generic Product prior to patent expiry will infringe one or more claims of the '615 Patent.

216. On information and belief, the RK Defendants' statement of the factual and legal bases for their opinions regarding non-infringement and invalidity of the '615 Patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

217. Plaintiffs will be substantially and irreparably harmed by the infringing activities of the RK Defendants as described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT V

(Infringement of the '615 Patent by MSN Defendants)

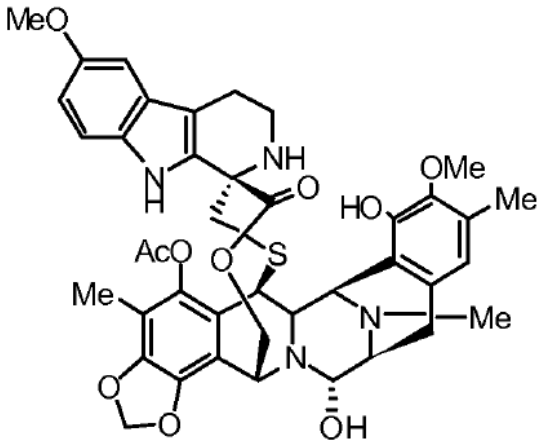
218. Plaintiffs incorporate each of the preceding paragraphs 1-176 as if fully set forth herein.

219. By submitting the MSN ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's Generic Product throughout the United States, including New Jersey, prior to expiration of the '615 Patent, the MSN Defendants committed an act of infringement of the '615 Patent under 35 U.S.C. § 271(e)(2)(A).

220. On information and belief, MSN's Generic Product, if approved by the FDA, will contain the compound lurbinectedin, which will constitute infringement of claims of the '615 Patent.

221. On information and belief, the MSN Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of MSN's Generic Product prior to the expiration of the '615 Patent, including any applicable exclusivities or extensions, will directly infringe one or more claims of the '615 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents. On information and belief, the MSN Defendants will also indirectly infringe one or more of the claims of the '615 Patent under 35 U.S.C. § 271(b) and/or (c). The MSN Defendants will infringe one or more claims of the '615 Patent.

222. On information and belief, MSN's Generic Product will directly and literally infringe at least Claim 22 of the '615 Patent which recites "[a] compound according to claim 1 of formula:"



On information and belief, MSN's Generic Product will infringe at least Claim 22 of the '615 Patent because MSN's Generic Product will contain lurbinectedin.

223. On information and belief, the MSN Defendants were aware of the existence of the '615 Patent and its listing in the Orange Book as demonstrated by their reference to the '615 Patent in the MSN Defendants' Notice Letter.

224. On information and belief, the MSN Defendants copied the claimed invention of the '615 Patent.

225. On information and belief, the MSN Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of MSN's Generic Product prior to patent expiry will infringe one or more claims of the '615 Patent.

226. On information and belief, the MSN Defendants' statement of the factual and legal bases for their opinions regarding non-infringement and invalidity of the '615 Patent is devoid of an objective good faith basis in either the facts or the law. This case is exceptional.

227. Plaintiffs will be substantially and irreparably harmed by the infringing activities of the MSN Defendants as described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

Against Sandoz

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that Sandoz infringed one or more claims of United States Patent No. 7,763,615 by its submission of ANDA No. 219515 (the Sandoz ANDA) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Sandoz's Generic Product before the expiration of the '615 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment that Sandoz's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Sandoz's Generic Product will infringe one or more claims of United States Patent No. 7,763,615 under 35 U.S.C. § 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Sandoz, and its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Sandoz's Generic Product prior to the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

D. An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219515 (the Sandoz ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

E. A Judgment that the claims of United States Patent No. 7,763,615 are valid and enforceable;

F. If Sandoz engages in the commercial manufacture, use, importation, offer for sale, and/or sale of Sandoz's Generic Product prior to expiration of the '615 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, with all costs and interest;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

H. An award of costs and expenses in this action; and

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

Against the InvaGen Defendants

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that the InvaGen Defendants infringed one or more claims of United States Patent No. 7,763,615 by their submission of ANDA No. 219605 (the InvaGen ANDA) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of InvaGen's Generic Product before the expiration of the '615 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment that the InvaGen Defendants' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of InvaGen's Generic Product will infringe one or more claims of United States Patent No. 7,763,615 under 35 U.S.C. § 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining the InvaGen Defendants, and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of InvaGen's Generic Product prior to the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

D. An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219605 (the InvaGen ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration

date of United States Patent No. 7,763,615, inclusive of any extensions;

E. A Judgment that the claims of United States Patent No. 7,763,615 are valid and enforceable;

F. If the InvaGen Defendants engage in the commercial manufacture, use, importation, offer for sale, and/or sale of InvaGen's Generic Product prior to expiration of the '615 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, with all costs and interest;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

H. An award of costs and expenses in this action; and

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

Against the Zydus Defendants

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that the Zydus Defendants infringed one or more claims of United States Patent No. 7,763,615 by their submission of ANDA No. 219582 (the Zydus ANDA) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Zydus' Generic Product before the expiration of the '615 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that the Zydus Defendants' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Zydus' Generic Product will infringe one or more claims of United States Patent No. 7,763,615 under 35 U.S.C. § 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining the Zydus Defendants, and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Zydus'

Generic Product prior to the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

D. An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219582 (the Zydus ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

E. A Judgment that the claims of United States Patent No. 7,763,615 are valid and enforceable;

F. If the Zydus Defendants engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Zydus' Generic Product prior to expiration of the '615 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, with all costs and interest;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

H. An award of costs and expenses in this action; and

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

Against the RK Defendants

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the RK Defendants infringed one or more claims of United States Patent No. 7,763,615 by their submission of ANDA No. 219731 (the RK ANDA) seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of RK's Generic Product before the expiration of the '615 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment that the RK Defendants' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of RK's Generic Product will infringe one or more

claims of United States Patent No. 7,763,615 under 35 U.S.C. § 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining the RK Defendants, and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of RK's Generic Product prior to the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

D. An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219731 (the RK ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

E. A Judgment that the claims of United States Patent No. 7,763,615 are valid and enforceable;

F. If the RK Defendants engage in the commercial manufacture, use, importation, offer for sale, and/or sale of RK's Generic Product prior to expiration of the '615 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, with all costs and interest;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

H. An award of costs and expenses in this action; and

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

Against the MSN Defendants

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A Judgment that the MSN Defendants infringed one or more claims of United States Patent No. 7,763,615 by their submission of ANDA No. 219771 (the MSN ANDA) seeking FDA

approval for the commercial manufacture, use, offer for sale, sale, and/or importation of MSN's Generic Product before the expiration of the '615 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A Judgment that the MSN Defendants' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of MSN's Generic Product will infringe one or more claims of United States Patent No. 7,763,615 under 35 U.S.C. § 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining the MSN Defendants, and their officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of MSN's Generic Product prior to the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

D. An Order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 219771 (the MSN ANDA) under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of United States Patent No. 7,763,615, inclusive of any extensions;

E. A Judgment that the claims of United States Patent No. 7,763,615 are valid and enforceable;

F. If the MSN Defendants engage in the commercial manufacture, use, importation, offer for sale, and/or sale of MSN's Generic Product prior to expiration of the '615 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement, with all costs and interest;

G. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

H. An award of costs and expenses in this action; and

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

Dated: September 11, 2024

s/ Charles M. Lizza

Charles M. Lizza
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520,
Newark, NJ 07102-5426
(973) 286-6715
clizza@saul.com

Attorneys for Plaintiffs

OF COUNSEL:

Dominick A. Conde (*phv* forthcoming)
Erin J.D. Austin
Damien N. Dombrowski (*phv* forthcoming)
VENABLE LLP
151 West 42nd Street
New York, NY 10036

Alvin Lee (*phv* forthcoming)
VENABLE LLP
600 Massachusetts Avenue NW
Washington, DC 20001

LOCAL CIVIL RULES 11.2 AND 40.1 CERTIFICATION

I hereby certify that, to the best of my knowledge, 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 11, 2024

s/ Charles M. Lizza
Charles M. Lizza
Sarah A. Sullivan
Alexander L. Callo
SAUL EWING LLP
One Riverfront Plaza
1037 Raymond Blvd., Suite 1520,
Newark, NJ 07102-5426
(973) 286-6715
clizza@saul.com

OF COUNSEL:

Dominick A. Conde (*phv* forthcoming)
Erin J.D. Austin
Damien N. Dombrowski (*phv* forthcoming)
VENABLE LLP
151 West 42nd Street
New York, NY 10036

Alvin Lee (*phv* forthcoming)
VENABLE LLP
600 Massachusetts Avenue NW
Washington, DC 20001

Attorney for Plaintiffs