IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NEW YORK

JAZZ PHARMACEUTICALS IRELAND LIMITED and PHARMA MAR, S.A., Plaintiffs, v. INVAGEN PHARMACEUTICALS, INC., CIPLA USA, INC., CIPLA (EU) LIMITED, and CIPLA LIMITED, Defendants.	Civil Action No. 24-cv-6416

COMPLAINT FOR PATENT INFRINGEMENT

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

Defendants

3. 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.

4. 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 York and throughout the United States.

5. 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.

6. 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 York and throughout the United States.

7. 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.

8. 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 York and throughout the United States.

9. 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.

10. 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 York and throughout the United States.

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

12. 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).

13. On information and belief, the 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 Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

14. On information and belief, the 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.

NATURE OF THE ACTION

15. 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 No. 219605 (the InvaGen ANDA) with the United States Food and Drug Administration ("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

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

17. This Court has personal jurisdiction over the Defendants by virtue of the fact that, *inter alia*, the 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 York and throughout the United States.

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

19. This Court has personal jurisdiction over InvaGen. On information and belief, InvaGen is incorporated in New York, regularly and continuously conducts business in New York, and has a principal place of business at 7 Oser Avenue, Hauppauge, New York 11788. InvaGen has an active business entity status registered with the state of New York under the business entity identification number 2980487 and has a corporate agent for service of process at One Commerce Plaza, 99 Washington Avenue, Suite 805-A, Albany, New York 12210-2822.

20. 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.*, *UCB, Inc. et al. v. InvaGen Pharm., Inc.*, CA. No. 15-cv-06919 (E.D.N.Y. *filed* Dec. 04, 2015); *Shire Development LLC et al. v. InvaGen Pharm., Inc.*, C.A. No. 14-cv-07263 (E.D.N.Y. *filed* Dec. 12, 2014); *Genzyme Corp. v. Invagen Pharm., Inc.*, C.A. No. 12-cv-01931 (E.D.N.Y. *filed* Apr. 19, 2012).

21. This Court has personal jurisdiction over Cipla USA. On information and belief, Cipla USA regularly and continuously conducts business in New York, Cipla USA has an active business entity status registered with the state of New York under the business entity identification number 5641567, and has a corporate agent for service of process at One Commerce Plaza, 99 Washington Avenue, Suite 805-A, Albany, New York 12210-2822.

22. Additionally, on information and belief, Cipla USA and InvaGen have a common online presence within the Cipla USA website, and Cipla USA identifies all manufacturing units on its website as InvaGen units, including three out of four InvaGen units located in Hauppauge, Long Island, New York. 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

York. On information and belief, Cipla USA and InvaGen share officers and employees. On information and belief, InvaGen and Cipla USA are alter egos.

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

24. 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.

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

26. 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.

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

28. Venue is proper in this Judicial District for InvaGen as it is incorporated in New York and therefore resides in this Judicial District.

29. Venue is proper in this Judicial District for Cipla USA. On information and belief, Cipla USA has an active business entity identification number in the State of New York (5641567), has employees in New York, maintains regular and established places of business at its InvaGen manufacturing facilities in Hauppauge, Long Island, New York, within this Judicial District, and has designated a registered agent for service of process at One Commerce Plaza, 99 Washington Avenue, Suite 805-A, Albany, New York 12210–2822. Furthermore, on information and belief, based on Cipla USA's connections to New York, discoverable information in its possession, custody, or control regarding the InvaGen ANDA will likely show that Cipla USA engaged in activities in New York and within this Judicial District relevant to the preparation and/or submission of the InvaGen ANDA and therefore committed acts of infringement within this Judicial District

30. 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.

31. Venue is further proper in this Court as to the 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 York.

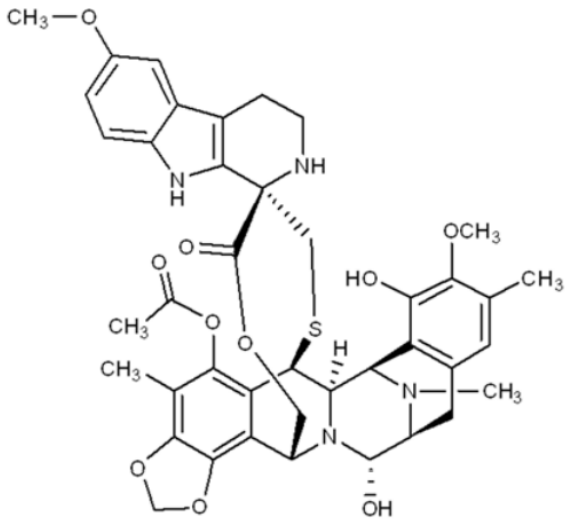
THE ZEPZELCA® NDA

32. 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.

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

34. 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

35. 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.

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

37. 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.

38. Pharma Mar owns the '615 Patent.

39. 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 PATENT INFRINGEMENT COUNT I

40. By a letter dated July 30, 2024 ("InvaGen Notice Letter"), the 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.

41. On information and belief, the 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®.

42. 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.

43. The InvaGen 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 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.

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

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

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

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

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

49. On information and belief, following FDA approval of the InvaGen ANDA, the 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.

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

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

COUNT I – INFRINGEMENT OF THE '615 PATENT

52. Plaintiffs incorporate each of the preceding paragraphs 1-51 as if fully set forth herein.

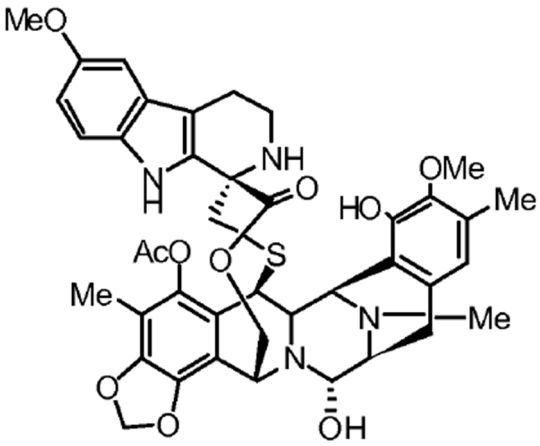
53. By submitting the InvaGen ANDA to the FDA to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of InvaGen's Generic Product throughout the United States, including New York, prior to expiration of the '615

Patent, the Defendants committed an act of infringement of the '615 Patent under 35 U.S.C. § 271(e)(2)(A).

54. 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.

55. On information and belief, the 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 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 Defendants will infringe one or more claims of the '615 Patent.

56. 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.

57. On information and belief, the 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 Notice Letter.

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

59. On information and belief, the 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.

60. On information and belief, the 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the 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 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 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 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 attorney 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 12, 2024

s/*Damien N. Dombrowski*

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