IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JAZZ PHARMACEUTICALS IRELAND LIMITED, and PHARMA MAR, S.A., Plaintiffs, v. RK PHARMA, INC.; APICORE US LLC; ARCHIS PHARMA LLC; and VGYAAN PHARMACEUTICALS LLC., Defendants.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Jazz Pharmaceuticals Ireland Limited ("Jazz") and Pharma Mar, S.A. ("Pharma Mar") (collectively, "Plaintiffs"), for their Complaint against Defendants RK Pharma, Inc. ("RK"), Apicore US LLC ("Apicore"), Archis Pharma LLC ("Archis"), and Vgyaan Pharmaceuticals LLC ("Vgyaan") (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 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.

4. 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 Delaware and throughout the United States.

5. 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.

6. 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 Delaware and throughout the United States.

7. 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.

8. 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 Delaware and throughout the United States.

9. 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.

10. 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 Delaware and throughout the United States.

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

12. 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.

13. On information and belief, the 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.

NATURE OF THE ACTION

14. 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. 219731 (the RK 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

15. 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.

16. 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 Delaware and throughout the United States.

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

18. This Court has personal jurisdiction over RK. RK is incorporated in Delaware. On information and belief, RK regularly and continuously conducts business in Delaware, including by selling pharmaceutical products in Delaware. RK has a Delaware business entity status registered with the state of Delaware under the business entity identification number 6784284 and has a corporate agent for service of process at 108 West 13th Street, Suite 100, Wilmington,

Delaware 19801. 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 Delaware. On information and belief, RK, Apicore, Archis, and Vgyaan are alter egos.

19. 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 a civil action initiated in this jurisdiction, including, *e.g., Newron Pharmaceuticals SpA et al. v. Aurobindo Pharma Limited et al.*, CA. No. 21-cv-00843 (D. Del. *filed* Jun. 10, 2021).

20. This Court has personal jurisdiction over Apicore. Apicore is incorporated in Delaware. On information and belief, Apicore regularly and continuously conducts business in Delaware. Apicore has a Delaware business entity identification number 5549828 and has a corporate agent for service of process at Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801.

21. 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 civil actions initiated in this jurisdiction, including, but not limited to, *e.g., H. Lundbeck A/S et al v. Apicore US LLC*, CA. No. 18-cv-01034 (D. Del. *filed* Jul. 12, 2018); *H. Lundbeck A/S et al. v. Apotex Inc. et al.*, CA. No. 18-cv-00088 (D. Del. *filed* Jan. 12, 2018); *Apicore US LLC v. Pfizer Inc.*, CA. No. 16-cv-01174 (D. Del. *filed* Dec. 12, 2016).

22. This Court has personal jurisdiction over Archis. Archis is incorporated in Delaware. On information and belief, Archis regularly and continuously conducts business in Delaware. Archis has a Delaware business entity identification number 3791144 and has a

corporate agent for service of process at Corporation Trust Center 1209 Orange Street, Wilmington, Delaware 19801, the same as Apicore.

23. This Court has personal jurisdiction over Vgyaan. On information and belief, Vgyaan regularly and continuously conducts business in Delaware, including commercializing RK's drug products within Delaware and throughout the United States.

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

25. Venue is proper in this Judicial District for RK. On information and belief, RK is incorporated in and therefore resides in Delaware.

26. Venue is proper in this Judicial District for Apicore. On information and belief, Apicore is incorporated in and therefore resides in Delaware.

27. Venue is proper in this Judicial District for Archis. On information and belief, Archis is incorporated in and therefore resides in Delaware.

28. Venue is proper in this Judicial District for Vgyaan. On information and belief, based on Vgyaan's connections to Delaware, discoverable information in its possession, custody, or control regarding the RK ANDA will likely show that Vgyaan engaged in activities in Delaware relevant to the preparation and/or submission of the RK ANDA and therefore committed acts of infringement within this Judicial District.

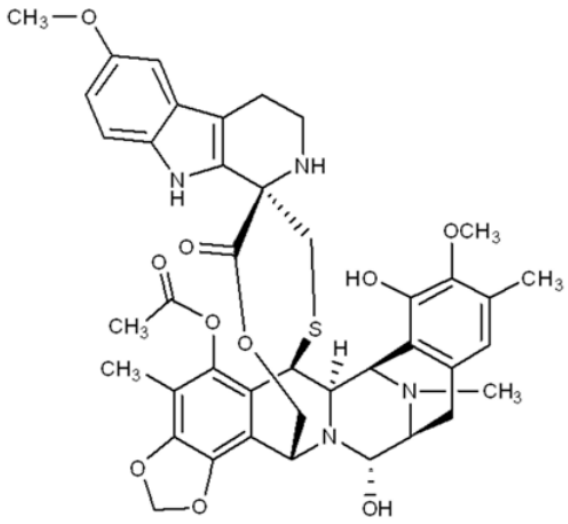
29. Venue is further proper in this Judicial District as to the Defendants because, *inter alia*, they have committed, aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Plaintiffs, which manufacture Zepzelca®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

THE ZEPZELCA® NDA

30. 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.

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

32. 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

33. 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.

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

35. 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.

36. Pharma Mar owns the '615 Patent.

37. 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

38. By a letter dated August 12, 2024 ("RK Notice Letter"), the 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.

39. On information and belief, the 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®.

40. 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.

41. The RK 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 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.

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

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

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

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

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

47. On information and belief, following FDA approval of the RK ANDA, the 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.

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

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

COUNT I – INFRINGEMENT OF THE '615 PATENT

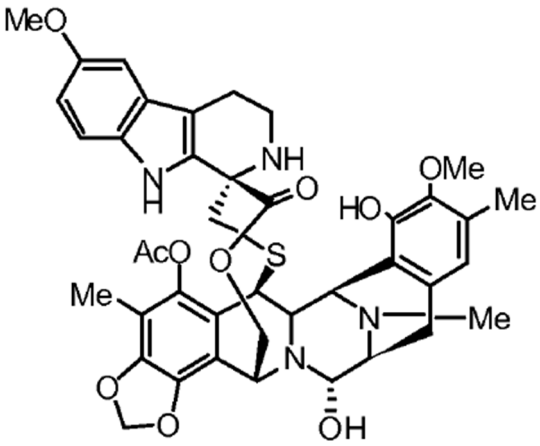
50. Plaintiffs incorporate each of the preceding paragraphs 1-49 as if fully set forth herein.

51. 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 Delaware, 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).

52. 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.

53. On information and belief, the 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 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.

54. 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.

55. 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 RK Notice Letter.

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

57. On information and belief, the 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.

58. 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.

59. 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. 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 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 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 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

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

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