IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and UCB BIOPHARMA SRL, Plaintiffs, v. PRINSTON PHARMACEUTICAL INC. and ZHEJIANG HUAHAI PHARMACEUTICAL CO., LTD., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc. and UCB Biopharma SRL (collectively, "UCB"), by their undersigned attorneys, bring this action against Defendants Prinston Pharmaceutical Inc. ("Prinston") and Zhejiang Huahai Pharmaceutical Co., Ltd. ("Zhejiang Huahai" and together, "Defendants") and hereby allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, arises from Prinston's submission to the FDA of ANDA No. 218573 ("Prinston's ANDA" or "Defendants' ANDA") by which Defendants seek approval to market generic versions of UCB's pharmaceutical product Briviact® (brivaracetam) prior to the expiration of U.S. Patent No. 6,911,461 (the "Patent-in-Suit").[1]

[1] As discussed further below in paragraphs 35–41, the Honorable Colm F. Connolly has already rejected an obviousness challenge to claim 5 of the '461 Patent, which claims the active ingredient in Briviact®. *See UCB, Inc. v. Annora Pharma Priv. Ltd.*, C.A. No. 20-987-CFC, 2023 WL 5274566 (D. Del. Aug. 16, 2023). UCB did not name Prinston as a defendant in that lawsuit because Prinston had not yet announced its intention to market a generic version of Briviact® and served notice of its Paragraph IV certification to the '461 Patent.

THE PARTIES

UCB

2. Plaintiff UCB Inc. is a corporation organized and existing under the laws of the State of Delaware with its principal place of business at 1950 Lake Park Drive, Smyrna, Georgia 30080.

3. Plaintiff UCB Biopharma SRL is a corporation organized and existing under the laws of Belgium, having an office and place of business at Allée de la Recherche 60, B-1070 Brussels, Belgium.

Defendants

4. On information and belief, Prinston is a corporation organized and existing under the laws of Delaware, having its principal place of business at 700 Atrium Dr., Somerset, New Jersey 08873.

5. On information and belief, Zhejiang Huahai is a corporation organized and existing under the laws of the People's Republic of China, having its principal place of business at Xunqiao, Linhai, Zhejiang 317024, China.

6. On information and belief, Zhejiang Huahai is the holder of FDA Drug Master File No. 37524 for brivaracetam.

7. On information and belief, Prinston is a wholly-owned subsidiary of Zhejiang Huahai.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

8. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271.

9. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338.

Personal Jurisdiction

Prinston

10. This Court has personal jurisdiction over Prinston because, *inter alia*, Prinston is a corporation organized and existing under the laws of the State of Delaware.

11. This Court has personal jurisdiction over Prinston because, on information and belief, it, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly-owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Prinston's generic version of Briviact® in the State of Delaware upon approval of Prinston's ANDA.

12. On information and belief, Prinston is in the business of manufacturing, marketing, importing, distributing, and/or selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Prinston manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

13. On information and belief, Prinston sells pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly-owned subsidiaries, agents, and/or alter egos.

14. On information and belief, Prinston plans to sell its generic version of Briviact® in the State of Delaware, list its generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of its generic version of Briviact® in

the State of Delaware, either directly or through one or more of its wholly-owned subsidiaries, agents, and/or alter egos.

15. On information and belief, Prinston knows and intends that its proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Prinston intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

16. Prinston has engaged in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *AbbVie Inc. v. Prinston Pharmaceutical Inc. et al.*, C.A. No. 23-607-JLH, D.I. 10 (D. Del. Aug. 2, 2023); *Galderma Laboratories, L.P., et al. v. Prinston Pharmaceutical, Inc.*, C.A. No. 22-1166-SB, D.I. 10 (D. Del. Sept. 29, 2022).

Zhejiang Huahai

17. This Court has personal jurisdiction over Zhejiang Huahai because, on information and belief, it, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly-owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Prinston's generic version of Briviact® in the State of Delaware upon approval of Prinston's ANDA.

18. On information and belief, Zhejiang Huahai is in the business of manufacturing, marketing, importing, distributing, and/or selling pharmaceutical drug products, including generic drug products, either directly or through subsidiaries, agents, and/or alter egos, which Zhejiang

Huahai manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district. Zhejiang Huahai's website states: "Huahai Pharmaceutical is the first Chinese pharmaceutical company that passed the US FDA certification for finished pharmaceutical products, obtained the ANDA approval for product developed by itself, and materialized the large-scale sales of finished dosages in the United States." (https://en.huahaipharm.com/qyjj/index.aspx, accessed Feb. 8, 2024).

19. On information and belief, Zhejiang Huahai sells pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly-owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Zhejiang Huahai plans to sell Prinston's generic version of Briviact® in the State of Delaware, list Prinston's generic version of Briviact® on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of Prinston's generic version of Briviact® in the State of Delaware, either directly or through one or more of its wholly-owned subsidiaries, agents, and/or alter egos.

21. On information and belief, Zhejiang Huahai knows and intends that Prinston's proposed generic version of Briviact® will be distributed and sold in Delaware and will thereby displace sales of Briviact®, causing injury to UCB. Zhejiang Huahai intends to take advantage of its established channels of distribution in Delaware for the sale of Prinston's proposed generic version of Briviact®.

22. Zhejiang Huahai has engaged in patent litigation concerning FDA-approved drug products in this judicial district, has not contested personal jurisdiction or venue in such litigation in this judicial district, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this Court. *See, e.g.*, *AbbVie Inc. v. Prinston*

Pharmaceutical Inc. et al., C.A. No. 23-607-JLH, D.I. 10 (D. Del. Aug. 2, 2023); *Astellas Pharma Inc. et al. v. Sandoz Inc. et al.*, C.A. No. 20-1589-JFB-CJB, D.I. 225 (D. Del. Nov. 30, 2021).

23. In the alternative, this Court has personal jurisdiction over Zhejiang Huahai pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Zhejiang Huahai is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zhejiang Huahai has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Prinston's ANDA to the FDA, and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States including in this judicial district, such that this Court's exercise of jurisdiction over Zhejiang Huahai satisfies due process.

Venue

24. Venue is proper in this district for Prinston because it is a corporation organized and existing under the laws of the State of Delaware. 28 U.S.C. §§ 1391 and 1400(b).

25. Venue is proper in this district for Zhejiang Huahai pursuant to 28 U.S.C. §§ 1391 because, *inter alia*, it is a corporation organized and existing under the laws of the People's Republic of China and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

THE PATENT-IN-SUIT

26. The '461 Patent, entitled "2-oxo-l-pyrrolidine Derivatives, Processes for Preparing Them and Their Uses," was duly and lawfully issued by the USPTO on June 28, 2005. UCB Biopharma SRL is the owner of all right, title, and interest in the '461 Patent. A true and correct copy of the '461 Patent is attached hereto as Exhibit A.

BRIVIACT®

27. Briviact® is indicated for the treatment of partial-onset seizures in patients 1 month of age and older. Briviact® is indicated for treatment by tablet or oral solution in patients 1 month

of age and older and for treatment by injection in patients 16 years and older. Briviact® may reduce the number of partial-onset seizures and may provide additional seizure control.

28. UCB, Inc. holds approved New Drug Application ("NDA") No. 205836 for Briviact® tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths).

29. UCB, Inc. holds approved NDA No. 205837 for Briviact® intravenous solution (50 mg/5 mL dosage strength).

30. UCB, Inc. holds approved NDA No. 205838 for Briviact® oral solution (10 mg/mL dosage strength).

31. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the Patent-in-Suit is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA Nos. 205836, 205837, and 205838.

PARAGRAPH IV NOTICE

32. On information and belief, Prinston purports to have sent UCB a Notice Letter dated January 10, 2024 ("Prinston's Notice Letter"), stating that ANDA No. 218573 contains a Paragraph IV certification alleging that the '461 Patent is invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

33. Prinston's Notice Letter further states that Prinston submitted ANDA No. 218573 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets as a purported generic version of Briviact® tablets before the expiration of the '461 Patent.

34. Prinston has not yet provided its ANDA to UCB or its counsel. On information and belief, if the FDA approves Prinston's ANDA, Prinston will manufacture, offer for sale, or sell the generic products listed in Prinston's ANDA ("Prinston's ANDA Product"), within the United States, including within the State of Delaware, or will import Prinston's ANDA Product into the

United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Prinston's ANDA Product will directly infringe the Patent-in-Suit and Prinston will actively induce and/or contribute to their infringement.

PRIOR BRIVIACT® LITIGATION

35. UCB previously filed suit against various defendants for infringement of the Patent-in-Suit. *UCB, Inc. et al. v. Annora Pharma Private Ltd. et al.*, C.A. No. 20-987-CFC (consol.), D.I. 1 (D. Del. July 24, 2020); *UCB Inc. et al. v. Sunshine Lake Pharma Co., Ltd. et al.*, C.A. No. 20-1343-CFC, D.I. 1 (D. Del. Oct. 2, 2020) (collectively, "Briviact I").

36. On May 21, 2021, the defendants in Briviact I agreed by stipulation that their proposed ANDA products infringed claims 1–5 of the '461 Patent. *UCB, Inc. et al. v. Annora Pharma Private Ltd. et al.*, C.A. No. 20-987-CFC (consol.), D.I. 90 (D. Del. May 21, 2021).

37. Before trial, UCB narrowed its infringement allegations to claim 5 of the '461 Patent.

38. Claim 5 of the '461 Patent covers brivaracetam, the active ingredient in Briviact.

39. Beginning on November 14, 2022, this Court held a four-day bench trial in Briviact I. *UCB, Inc. et al. v. Annora Pharma Private Ltd. et al.*, C.A. No. 20-987-CFC (consol.), D.I. 230–33 (D. Del.).

40. At trial in Briviact I, the sole issue before this Court was the validity of claim 5 of the '461 Patent over an obviousness challenge under 35 U.S.C. § 103.

41. On August 16, 2023, in an 84-page opinion, this Court found claim 5 of the '461 Patent not invalid. *See UCB, Inc. v. Annora Pharma Priv. Ltd.*, C.A. No. 20-987-CFC, D.I. 246, 2023 WL 5274566 (D. Del. Aug. 16, 2023).

COUNT I
INFRINGEMENT OF THE '461 PATENT BY DEFENDANTS

42. UCB restates, realleges, and incorporates by reference paragraphs 1–41 as if fully set forth herein.

43. Defendants have infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Prinston's ANDA with a Paragraph IV certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, and sale of a generic version of Briviact® tablets prior to the expiration of the '461 Patent. Claims 1 and 5 of the '461 Patent encompass brivaracetam, claim 2 of the '461 Patent encompasses pharmaceutical compositions comprising brivaracetam, and claims 3 and 4 of the '461 Patent encompass a method of treating epilepsy, among other conditions, comprising administering a therapeutic dose of brivaracetam.

44. In Prinston's Notice Letter, Prinston has not contested infringement of any claims of the '461 Patent.

45. Defendants' commercial manufacture, use, offer to sell, or sale of Prinston's ANDA Product before the expiration of the '461 Patent would infringe claims 1–5 of the '461 Patent under 35 U.S.C. § 271.

46. UCB is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Prinston's ANDA to be a date which is not any earlier than the expiration date of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent.

REQUEST FOR RELIEF

WHEREFORE, UCB prays for a judgment in its favor and against Defendants and respectfully requests the following relief:

(A) A judgment that Defendants have infringed one or more claims of the Patent-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 218573;

(B) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Prinston's ANDA Product would constitute infringement of the Patent-in-Suit pursuant to 35 U.S.C. § 271;

(C) Entry of preliminary and permanent injunctions enjoining Defendants, their officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in active concert or participation with any of them or on their behalf, from commercially manufacturing, using, offering for sale, or selling Prinston's ANDA Product within the United States, or importing Prinston's ANDA Product into the United States, until the expiration of the Patent-in-Suit, including any extensions, adjustments, and exclusivities applicable to the Patent-in-Suit, and from otherwise infringing the claims of the Patent-in-Suit;

(D) An order that the effective date of any approval of Prinston's ANDA be a date that is not earlier than the expiration of the Patent-in-Suit, including any extensions, adjustments, and exclusivities associated with the Patent-in-Suit;

(E) An award of damages or other monetary relief, together with interest, pursuant to 35 U.S.C. § 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Prinston's ANDA Product, or any product that infringes the Patent-in-Suit prior to the expiration of the Patent-in-Suit including any extensions, adjustments, and exclusivities applicable to the Patent-in-Suit;

(F) A judgment and order finding that this is an exceptional case within the meaning of 35 U.S.C. § 285 and awarding to UCB its reasonable attorneys' fees;

(G) Awarding UCB its costs and expenses in this action; and

(H) Granting any and all other relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Megan E. Dellinger

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February 8, 2024