IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and UCB BIOPHARMA SRL, Plaintiffs, v. SUNSHINE LAKE PHARMA CO., LTD. and HEC PHARM 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 Sunshine Lake Pharma Co., Ltd. and HEC Pharm Co., Ltd., (collectively, "Sunshine" or "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 Sunshine's submission to the FDA of ANDA No. 214748 ("Sunshine'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 Nos. 6,784,197 ("the '197 Patent"), 6,911,461 ("the '461 Patent"), and 8,492,416 ("the '416 Patent") (collectively, the "Patents-in-Suit").

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.

Sunshine

4. On information and belief, Sunshine Lake Pharma Co. Ltd. is a corporation organized and existing under the laws of the People's Republic of China, having its principal place of business at Northern Industry Road 1#, Song Shan Lake, Dongguan 523808 Guangdong, China.

5. On information and belief, HEC Pharm Co., Ltd. is a corporation organized and existing under the laws of the People's Republic of China, having its principal place of business at No. 62, Binjiang Road, Yidu, Hubei 443311 Yichang Hubei, China.

6. On information and belief, Sunshine Lake Pharma Co. Ltd. is a wholly-owned subsidiary of HEC Pharm Co., Ltd.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

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

Personal Jurisdiction

9. This Court has personal jurisdiction over Sunshine because, on information and belief, Sunshine, *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 Sunshine's generic version of Briviact® in the State of Delaware upon approval of Sunshine's ANDA.

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

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

12. On information and belief, Sunshine 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.

13. On information and belief, Sunshine 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. Sunshine intends to take advantage of its established channels of distribution in Delaware for the sale of its proposed generic version of Briviact®.

14. Sunshine Lake Pharma Co., Ltd. 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.*, *Gilead Sciences,*

Inc. v. Apotex, Inc. et al., C.A. No. 20-CV-00189 (D. Del. Feb. 7, 2020); *Bristol-Myers Squibb Co. et al. v. Sunshine Lake Pharma Co., Ltd., et al.*, C.A. No. 17-CV-00380 (D. Del. Apr. 5, 2017).

15. In the alternative, this Court has personal jurisdiction over Sunshine pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) as (a) UCB's claims arise under federal law; (b) Sunshine Lake Pharma Co. Ltd. and HEC Pharm Co. Ltd. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Sunshine Lake Pharma Co. Ltd. and HEC Pharm Co. Ltd. have sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Sunshine'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 Sunshine Lake Pharma Co. Ltd. and HEC Pharm Co. Ltd. satisfies due process.

16. Venue is proper in this district for Sunshine Lake Pharma Co. Ltd. and HEC Pharm Co. Ltd. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Sunshine Lake Pharma Co. Ltd. and HEC Pharm Co. Ltd. are corporations 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 PATENTS-IN-SUIT

17. The '197 Patent, entitled "2-oxo-l-pyrrolidine Derivatives, Processes for Preparing Them and Their Uses," was duly and lawfully issued by the United States Patent and Trademark Office ("USPTO") on August 31, 2004. UCB Biopharma SRL is the owner of all right, title, and interest in the '197 Patent. A true and correct copy of the '197 Patent is attached hereto as Exhibit A.

18. 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 B.

19. The '416 Patent, entitled "2-oxo-l-pyrrolidine Derivatives, Processes for Preparing Them and Their Uses," was duly and lawfully issued by the USPTO on July 23, 2013. UCB Biopharma SRL is the owner of all right, title, and interest in the '416 Patent. A true and correct copy of the '416 Patent is attached hereto as Exhibit C.

BRIVIACT®

20. Briviact® is indicated for the treatment of partial-onset seizures in patients 4 years of age and older. Briviact® is indicated for treatment by tablet or oral solution in patients 4 years 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.

21. 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).

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

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

24. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the Patents-in-Suit are 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

25. On information and belief, Sunshine purports to have sent UCB a Notice Letter dated July 9, 2020 ("Sunshine's July 9, 2020 Notice Letter"), stating that ANDA No. 214748 contains a Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable,

and/or will not be infringed by the manufacture, use, or sale of the generic product proposed in the ANDA.

26. Sunshine's July 9, 2020 Notice Letter further states that Sunshine submitted ANDA No. 214748 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam tablets (10 mg, 25 mg, 50 mg, 75 mg, and 100 mg dosage strengths) as a purported generic version of Briviact® tablets before the expiration of the Patents-in-Suit.

27. Sunshine has not yet provided its ANDA to UCB or its counsel. On information and belief, if the FDA approves Sunshine's ANDA, Sunshine will manufacture, offer for sale, or sell the generic products listed in Sunshine's ANDA ("Sunshine's ANDA Product"), within the United States, including within the State of Delaware, or will import Sunshine's ANDA Product into the United States, including the State of Delaware. The manufacture, use, offer for sale, sale, or importation of Sunshine's ANDA Product will directly infringe the Patents-in-Suit and Sunshine will actively induce and/or contribute to their infringement.

* * *

28. UCB previously filed suit against Annora Pharma Private Ltd., Apotex Inc., Apotex Corp., Aurobindo Pharma USA Inc., Lupin Limited, Micro Labs USA, Inc., Micro Labs Ltd., MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and Zydus Pharmaceuticals (USA) Inc. for infringement of the Patents-in-Suit. *UCB, Inc. et al. v. Annora Pharma Private Ltd. et al.*, C.A. No. 20-987-CFC (D. Del. July 24, 2020). That case is pending in this court.

COUNT I
INFRINGEMENT OF THE '197 PATENT BY SUNSHINE

29. UCB restates, realleges, and incorporates by reference paragraphs 1–28 as if fully set forth herein.

30. On information and belief, Sunshine submitted Sunshine's ANDA to the FDA, and thereby seeks FDA approval of Sunshine's ANDA Product.

31. Sunshine has infringed at least claims 1 and 21 of the '197 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sunshine'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 '197 Patent. At least claims 1 and 21 of the '197 Patent encompass brivaracetam. In Sunshine's July 9, 2020 Notice Letter, Sunshine has not contested infringement of claims 1 and 21 of the '197 Patent.

32. Sunshine's commercial manufacture, use, offer to sell, or sale of Sunshine's ANDA Product before the expiration of the '197 Patent would infringe one or more claims of the '197 Patent, including but not limited to claims 1 and 21, under 35 U.S.C. § 271.

33. 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 Sunshine's ANDA to be a date which is not any earlier than the expiration date of the '197 Patent, including any extensions, adjustments, and exclusivities associated with the '197 Patent.

COUNT II
INFRINGEMENT OF THE '461 PATENT BY SUNSHINE

34. UCB restates, realleges, and incorporates by reference paragraphs 1–33 as if fully set forth herein.

35. Sunshine has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sunshine'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. In Sunshine's July 9, 2020 Notice Letter, Sunshine has not contested infringement of the '461 Patent.

36. Sunshine's commercial manufacture, use, offer to sell, or sale of Sunshine'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.

37. 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 Sunshine'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.

COUNT III
INFRINGEMENT OF THE '416 PATENT BY SUNSHINE

38. UCB restates, realleges, and incorporates by reference paragraphs 1–37 as if fully set forth herein.

39. Sunshine has infringed claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Sunshine'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 '416 Patent. Claims 1 and 2 of the '416 Patent encompass a method of treating epilepsy comprising administering a therapeutic dose of brivaracetam. In Sunshine's July 9, 2020 Notice Letter, Sunshine has not contested infringement of claims 1 and 2 of the '416 Patent.

40. Sunshine's commercial manufacture, use, offer to sell, or sale of Sunshine's ANDA Product before the expiration of the '416 Patent would infringe claims 1 and 2 of the '416 Patent under 35 U.S.C. § 271.

41. 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 Sunshine's ANDA to be a date which is not any earlier than the expiration date of the '416 Patent, including any extensions, adjustments, and exclusivities associated with the '416 Patent.

REQUEST FOR RELIEF

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

(A) A judgment that Sunshine has infringed one or more claims of each of the Patents-in-Suit under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 214748;

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

(C) Entry of preliminary and permanent injunctions enjoining Sunshine, 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 Sunshine's ANDA Product within the United States, or importing Sunshine's ANDA Product into the United States, until the expiration of the Patents-in-Suit, including any extensions, adjustments, and exclusivities applicable to the Patents-in-Suit, and from otherwise infringing the claims of the Patents-in-Suit;

(D) An order that the effective date of any approval of Sunshine's ANDA be a date that is not earlier than the expiration of the Patents-in-Suit, including any extensions, adjustments, and exclusivities associated with the Patents-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 Sunshine engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Sunshine's ANDA Product, or any product that infringes one of the Patents-in-Suit prior to the expiration of the Patents-in-Suit including any extensions, adjustments, and exclusivities applicable to the Patents-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

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