IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC. and UCB BIOPHARMA SRL,	)	
	)	
Plaintiffs,	)	
	)	
v.	)	C.A. No. _____
	)	
ANNORA PHARMA PRIVATE LIMITED,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc. and UCB Biopharma SRL (collectively, "UCB"), by their undersigned attorneys, bring this action against Defendant Annora Pharma Private Ltd. ("Annora") 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 Annora's submission to the United States Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 218048 ("Annora's ANDA"); by which Annora seeks approval to market a generic version of UCB's pharmaceutical product Briviact® (brivaracetam) (oral solution) prior to the expiration of U.S. Patent No. 6,911,461 ("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.

Annora

4. On information and belief, Defendant Annora Pharma Private Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist. Telangana State 502313, India.

JURISDICTION AND VENUE

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

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

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

8. On information and belief, Annora 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 Annora manufactures, distributes, markets, and/or sells throughout the United States and in this judicial district.

9. On information and belief, Annora 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.

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

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

12. Annora has previously consented to personal jurisdiction in this judicial district in current litigation concerning an earlier Annora ANDA, which sought approval to engage in the commercial manufacture, use, or sale of a purported generic version of Briviact® tablets before the expiration of the same '461 Patent at issue here. *See UCB, Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-987-CFC, D.I. 39 (D. Del. Oct. 9, 2020) ("*UCB v. Annora I*").

13. In November 2022, a bench trial was held in *UCB v. Annora I*. The parties are currently engaged in post-trial briefing.

14. In addition, Annora 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.*, *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-277-CFC, D.I. 8 (D. Del. Apr. 27, 2020); *Amgen Inc. v. Annora Pharma Private Ltd.*, C.A. No. 20-122-CFC, D.I. 9 (D. Del. Mar. 26, 2020); *Vifor Fresenius Med. Care Renal Pharma Ltd. v. Annora Pharma Private Ltd.*, C.A. No. 18-1996-MN, D.I. 12 (D. Del. Mar. 1, 2019); *Boehringer Ingelheim Pharms. Inc. v. Annora Pharma Private Ltd.*, C.A. No. 18-1786-CFC-SRF, D.I. 19 (D. Del. Jan. 18, 2019).

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

16. Venue is proper in this district for Annora pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Annora is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district pursuant to 28 U.S.C. § 1391(c)(3).

THE '461 PATENT

17. 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® ORAL SOLUTION

18. Briviact® oral solution is indicated for the treatment of partial-onset seizures in patients 1 month of age and older. Briviact® oral solution may reduce the number of partial-onset seizures and may provide additional seizure control.

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

20. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '461 Patent is listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA No. 205838.

ANNORA'S PARAGRAPH IV NOTICE

21. On information and belief, Annora sent UCB a Notice Letter dated February 17, 2023 ("Annora's Notice Letter"), stating that ANDA No. 218048 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(B)(vii)(IV) (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.

22. Annora's Notice Letter further states that Annora submitted ANDA No. 218048 to the FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, or sale of brivaracetam oral solution (10 mg/mL dosage strength) as a purported generic version of Briviact® oral solution before the expiration of the '461 Patent.

23. On information and belief, if the FDA approves Annora's ANDA, Annora will manufacture, offer for sale, or sell the generic product listed in Annora's ANDA ("Annora's ANDA Product"), within the United States, including within the State of Delaware, or will import Annora's ANDA Product into the United States, including the State of Delaware. The

manufacture, use, offer for sale, sale, or importation of Annora's ANDA Product will directly infringe the '461 Patent and Annora will actively induce and/or contribute to their infringement.

* * *

24. UCB commences this action within 45 days of receiving Annora's Notice Letter.

COUNT I
INFRINGEMENT OF THE '461 PATENT BY ANNORA

25. UCB restates, realleges, and incorporates by reference paragraphs 1–24 as if fully set forth herein.

26. Annora has infringed claims 1–5 of the '461 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Annora'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® oral solution 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 Annora's Notice Letter, Annora has not contested infringement of claims 1–5 of the '461 Patent.

27. Annora's commercial manufacture, use, offer to sell, or sale of Annora'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.

28. 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 Annora'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 Annora and respectfully requests the following relief:

(A) A judgment that Annora has infringed one or more claims of the '461 Patent under 35 U.S.C. § 271(e)(2) by submitting ANDA No. 218048;

(B) A judgment that the commercial manufacture, use, offer to sell, or sale, or importation into the United States, of Annora's ANDA Product, or inducing or contributing to such conduct, would constitute infringement of the '461 Patent pursuant to 35 U.S.C. § 271;

(C) Entry of preliminary and permanent injunctions enjoining Annora, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in active concert or participation with Annora or on Annora's behalf, from commercially manufacturing, using, offering for sale, or selling Annora's ANDA Product within the United States, or importing Annora's ANDA Product into the United States, until the expiration of the '461 Patent, including any extensions, adjustments, and exclusivities applicable to the '461 Patent, and from otherwise infringing the claims of the '461 Patent;

(D) An order that the effective date of any approval of Annora's ANDA be a date that is not earlier than the expiration of the '461 Patent, including any extensions, adjustments, and exclusivities associated with the '461 Patent;

(E) An award of damages or other monetary relief, together with interest, pursuant to 35 U.S.C. § 271(e)(4)(C), if Annora engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Annora's ANDA Product, or any product that infringes the '461 Patent, or induces or contributes to such conduct, prior to the expiration of the '461 Patent including any extensions, adjustments, and exclusivities applicable to the '461 Patent;

(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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