IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB BIOPHARMA SPRL, RESEARCH CORPORATION TECHNOLOGIES, INC. and HARRIS FRC CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc., UCB BioPharma SPRL, Research Corporation Technologies, Inc., and Harris FRC Corporation (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against defendants Aurobindo Pharma Ltd. ("Aurobindo Ltd.") and Aurobindo Pharma USA, Inc. ("Aurobindo USA") (collectively, "Aurobindo"), hereby allege as follows:

THE PARTIES

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

2. Plaintiff UCB BioPharma SPRL ("UCB BioPharma") is a corporation organized and existing under the laws of Belgium, having a principal place of business at Allée de la Recherche 60, Brussels, 1070, Belgium.

3. Plaintiff Research Corporation Technologies, Inc. ("RCT") is a nonprofit corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6440 N. Swan Road, Suite 200, Tucson, AZ 85718.

4. Plaintiff Harris FRC Corporation ("Harris") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Continental Drive, Suite 401, Newark, DE 19713.

5. On information and belief, defendant Aurobindo Ltd. is a corporation organized and existing under the laws of India, having its principal place of business at Plot # 2, Maitrivihar, Ameerpet, Hyderabad - 500038, Telagana, India.

6. On information and belief, defendant Aurobindo USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurobindo USA is a wholly owned subsidiary of Aurobindo Ltd.

JURISDICTION AND VENUE

7. This is an action for patent infringement of United States Reissued Patent No. RE 38,551 ("the '551 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Aurobindo Ltd.'s filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. §355(j), seeking United States Food and Drug Administration ("FDA") approval to market generic pharmaceutical products. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has jurisdiction over Aurobindo Ltd. On information and belief, Aurobindo Ltd., develops, formulates, manufactures, markets and sells pharmaceutical

drug products, including generic drug products, throughout the United States and in this judicial district, through various directly or indirectly owned operating subsidiaries, including its wholly owned subsidiary Aurobindo USA. On information and belief, upon receiving FDA approval, Aurobindo Ltd. intends to market and sell the proposed generic products at issue in this litigation in this judicial district. On information and belief, Aurobindo Ltd. and Aurobindo USA work in concert for purposes of developing, formulating, manufacturing, marketing and selling its generic drug products throughout the United States, including Delaware, and Delaware is a likely destination of Aurobindo Ltd.'s generic products. On information and belief, Aurobindo Ltd. has purposely availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court, including consenting to personal jurisdiction in a case involving the same patent and the same active pharmaceutical ingredient (*UCB Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 13-1210-LPS (D. Del.) at D.I. 14, ¶¶ 8, 10), and having engaged in systematic and continuous contacts with the State of Delaware.

9. On information and belief, Aurobindo USA is in the business of, among other things, formulating, developing, manufacturing, marketing and selling generic copies of branded pharmaceutical products for the U.S. market, including in this judicial district. On information and belief, upon receiving FDA approval, Aurobindo USA intends to market and sell the proposed generic products at issue in this litigation in this judicial district. On information and belief, Aurobindo USA holds a Pharmacy Wholesale License from the State of Delaware under License No. A4-0001270. On information and belief, Aurobindo USA holds a Distributor/Manufacturer License for Controlled Substances Registration from the State of Delaware under License No. DM-00006550. On information and belief, Aurobindo USA has purposely availed itself of the rights and benefits of the laws of the State of Delaware, having

previously submitted to personal jurisdiction in this Court, including consenting to personal jurisdiction in a case involving the same patent and the same active pharmaceutical ingredient (*UCB Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 13-1210-LPS (D. Del.) at D.I. 14, ¶¶ 9, 10), and having engaged in systematic and continuous contacts with the State of Delaware.

10. This Court has personal jurisdiction over Aurobindo by virtue of, *inter alia*, the above-mentioned facts.

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 28 U.S.C. § 1400(b).

CLAIM FOR RELIEF – PATENT INFRINGEMENT

12. UCB, Inc. holds approved New Drug Application ("NDA") No. 022253 for Vimpat® tablets (50 mg, 100 mg, 150 mg, and 200 mg dosage strengths), which tablets contain the active ingredient lacosamide. The FDA approved NDA No. 022253 on October 28, 2008. UCB, Inc. lists the '551 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 022253.

13. UCB, Inc. holds approved NDA No. 022254 for Vimpat® intravenous solution (200 mg/20 mL dosage strength), which solution contains the active ingredient lacosamide. The FDA approved NDA No. 022254 on October 28, 2008. UCB, Inc. lists the '551 patent in the Orange Book for NDA No. 022254.

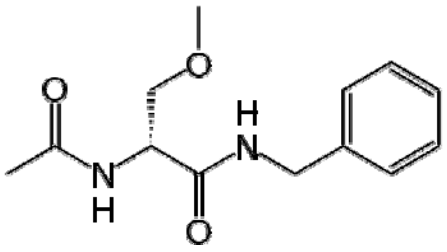
14. UCB, Inc. holds approved NDA No. 022255 for Vimpat® oral solution (10 mg/mL dosage strength), which oral solution contains the active ingredient lacosamide. The FDA approved NDA No. 022255 on April 20, 2010. UCB, Inc. lists the '551 patent in the Orange Book for NDA No. 022255.

15. Vimpat® tablets and oral solution are indicated as both monotherapy and as adjunctive therapy in the treatment of partial-onset seizures in people with epilepsy aged 17 years and older. Vimpat® intravenous solution is indicated as both monotherapy and as adjunctive therapy in the treatment of partial-onset seizures in people with epilepsy aged 17 years and older when oral administration is temporarily not feasible.

16. The United States Patent and Trademark Office ("PTO") legally issued the '551 patent, entitled "Anticonvulsant Enantiomeric Amino Acid Derivatives" on July 6, 2004. A copy of the '551 patent is attached as Exhibit A.

17. The '551 patent is a reissue of United States Patent No. 5,773,475, which the PTO legally issued on June 30, 1998.

18. The '551 patent claims, *inter alia*, lacosamide, which is known chemically as (R)-2-acetamido-N-benzyl-3-methoxypropionamide (under IUPAC nomenclature), and as (R)-N-benzyl-2-acetamido-3-methoxypropionamide. The chemical structure of lacosamide is:



19. The '551 patent also claims a therapeutic composition comprising lacosamide, and a method of treating central nervous system disorders in a human.

20. The PTO issued a Certificate Extending Patent Term Under 35 U.S.C. § 156. With the patent term extension, the '551 patent expires on March 17, 2022. A copy of the Certificate Extending Patent Term for the '551 patent is attached as Exhibit B.

21. The ’551 patent is assigned to RCT, and RCT is the owner of the ’551 patent as recorded by the PTO at Reel 008538, Frame 0093.

22. RCT granted an exclusive patent license, subsequently amended, to Harris under, *inter alia*, the ’551 patent to make and have made, use, sell, offer to sell and import lacosamide in a territory co-extensive with Harris’ patent rights. Under the amended license agreement, RCT granted Harris the right to sublicense its rights under the licensed patents, including the ’551 patent.

23. Harris exclusively sublicensed to Schwarz Pharma AG (“Schwarz”), under know how and licensed patents, including the ’551 patent, the right to make, have made, use, sell and import lacosamide for the purpose of Schwarz’s making, having made, using importing or selling products containing lacosamide, worldwide, excluding Japan, for the treatment of diseases in humans.

24. UCB S.A. acquired Schwarz and all its rights in lacosamide. The license agreement entered into by and between Harris and Schwarz was restated, amended, and effective for all countries of the world, by and among Harris, UCB Pharma GmbH, formerly acting under its name Schwarz, and UCB S.A.

25. UCB Pharma GmbH subsequently transferred its exclusive sublicense to the ’551 patent to UCB BioPharma SPRL.

26. UCB, Inc. markets and sells Vimpat® tablets and oral and intravenous solution in the United States.

27. On information and belief, Aurobindo Ltd. submitted to the FDA ANDA No. 209224 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to engage

in the commercial manufacture, use, offer for sale, sale and/or import of a generic oral solution of lacosamide (10 mg/mL dosage strength).

28. The subjects of ANDA No. 209224 are referred to as "Aurobindo's Oral Solution ANDA Product."

29. Aurobindo Ltd. submitted its ANDA to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale and/or import of Aurobindo's Oral Solution ANDA Product before the expiration of the '551 patent.

30. By filing its ANDA under 21 U.S.C. § 355(j) for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, offer for sale, sale and/or import of Aurobindo's Oral Solution ANDA Product before the expiration of the '551 patent, Aurobindo Ltd. has committed an act of infringement under 35 U.S.C. § 271(e)(2).

31. On information and belief, when Aurobindo Ltd. filed its ANDA, it was aware of the '551 patent and that the filing of its ANDA with the request for its approval prior to the expiration of the '551 patent was an act of infringement of that patent.

32. On information and belief, Aurobindo Ltd. made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '551 patent is invalid and/or will not infringed.

33. Plaintiffs received letters from Aurobindo Ltd. dated May 3, 2016, purporting to be a Notice of Certification for ANDA No. 209224 under Section 505(j)(2)(B) of the Act, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95(c)(1).

34. Aurobindo Ltd.'s letter alleges that the active ingredient in Aurobindo's Oral Solution ANDA Product for which it seeks approval is lacosamide.

35. The commercial manufacture, use, offer for sale, sale and/or import of Aurobindo's Oral Solution ANDA Product will infringe at least claims 9, 10, and 13 of the '551 patent.

36. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of any approval of ANDA No. 209224 be a date that is not earlier than March 17, 2022, the expiration date of the '551 patent, including any extensions.

37. Plaintiffs are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or import of Aurobindo's Oral Solution ANDA Product and any act committed by Defendants with respect to the subject matter claimed in the '551 patent, which act is not within the limited exclusions of 35 U.S.C. § 271(e)(1).

38. On information and belief, Aurobindo Ltd. previously submitted to the FDA ANDA No. 204994 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale and/or import of generic lacosamide tablets containing 50 mg, 100 mg, 150 mg, and 200 mg of lacosamide in a tablet dosage form ("Aurobindo's Tablet ANDA Products"), and made and included in ANDA No. 204994 a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in its opinion and to the best of its knowledge, the '551 patent is invalid and/or will not infringed.

39. On June 12, 2013, RCT received a letter from Aurobindo Ltd. dated June 11, 2013 ("Aurobindo's 2013 Notice Letter"), purporting to be a Notice of Certification for ANDA No. 204994 under Section 505(j)(2)(B) of the Act, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95(c)(1).

40. Aurobindo's 2013 Notice Letter alleged that the active ingredient in Aurobindo's Tablet ANDA Products is lacosamide, the same alleged active ingredient in Aurobindo's Oral Solution ANDA Product.

41. On July 10, 2013, Plaintiffs brought an action against Aurobindo for infringement of the '551 patent based on the filing of ANDA No. 204994 for Aurobindo's Tablet ANDA Products. D.I. 1 in C.A. No. 13-1210-LPS (D. Del.).

42. On December 24, 2014, Aurobindo stipulated that its Tablet ANDA Products or the administration of its Tablet ANDA Products will infringe claims 9, 10, and 13 of the '551 patent. D.I. 203 in C.A. No. 13-1306-LPS.

43. Trial in that action (as consolidated in C.A. No. 13-1206-LPS (D. Del.)) was conducted from November 9, 2015 through November 13, 2015. "Minute Entries" for Nov. 9, Nov. 10, Nov. 12, and Nov. 13, 2015 in C.A. No. 13-1206-LPS. Post-trial briefing has been completed (D.I. 277 in C.A. No. 13-1206-LPS), and the parties are awaiting the Court's ruling. Aurobindo remains a party to that action. *See* Dockets in C.A. No. 13-1206-LPS, 13-1210-LPS.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs UCB, Inc., UCB BioPharma, RCT and Harris pray for a judgment in their favor and against defendants Aurobindo Ltd. and Aurobindo USA, and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Aurobindo has infringed one or more claims of the '551 patent by Aurobindo Ltd.'s filing of ANDA No. 209224 seeking FDA approval for the commercial manufacture, use, offer for sale, sale and/or import of Aurobindo's Oral Solution ANDA Product before the expiration of the '551 patent;

B. A judgment that the manufacture, use, offer for sale, sale and/or import of Aurobindo's Oral Solution ANDA Product will infringe the '551 patent;

C. A judgment declaring that the '551 patent remains valid and enforceable;

D. A permanent injunction restraining and enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale and/or import, of Aurobindo's Oral Solution ANDA Product, as claimed in the '551 patent, until the expiration of the '551 patent or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of ANDA No. 209224 be a date that is not earlier than the expiration of the right of exclusivity under the '551 patent, or any later date of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the '551 patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts;

G. A determination that this case is "exceptional" under 35 U.S.C. § 285, and an award of attorneys' fees;

H. Costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

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