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. _____
HETERO USA INC. and HETERO LABS LIMITED,	)	
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 Hetero USA Inc. ("Hetero USA") and Hetero Labs Limited ("Hetero Labs"), (collectively, "Hetero"), 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 Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

6. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Labs. On information and belief, Hetero Labs is a corporation organized and existing under the laws of the India, having a principal place of business at 7-2-A2, Industrial Estates, Sanath Nagar, Hyderabad – 500018, Andhra Pradesh, India.

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 Hetero USA'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 Hetero USA. On information and belief, Hetero USA, directly or through its affiliates and agents, develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. On information and belief, upon receiving FDA approval, Hetero USA intends to market and sell the proposed generic products at issue in this

litigation in this judicial district. On information and belief, Hetero 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 ANDA and the same patent (*UCB Inc. v. Hetero USA Inc.*, C.A. No. 13-1213-LPS (D. Del.) at D.I. 27, ¶¶ 8, 10), and having availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

9. This Court has jurisdiction over Hetero Labs. On information and belief, Hetero Labs, directly or through its affiliates and agents, including Hetero USA, develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. On information and belief, upon receiving FDA approval, Hetero Labs intends to market and sell the proposed generic products at issue in this litigation in this judicial district. On information and belief, Hetero Labs and Hetero USA are agents of each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceutical products throughout the United States including in this judicial district. On information and belief, Hetero Labs 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 ANDA and the same patent (*UCB Inc. v. Hetero USA Inc.*, C.A. No. 13-1213-LPS (D. Del.) at D.I. 27, ¶¶ 9, 10), and having availed itself of the jurisdiction of this Court by asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware.

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

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 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 '551patent in the Orange Book for NDA No. 022254.

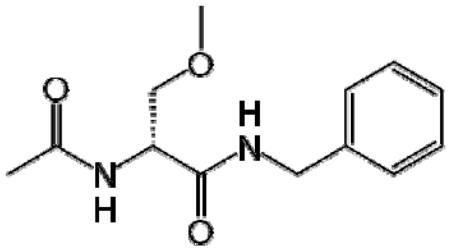
14. UCB, Inc. holds approved NDA No. 022255 for Vimpat® oral solution (10 mg/mL dosage strength), which oral solution contains the active ingredient lacosamide. The FDA approved NDA No. 022255 on April 20, 2010. UCB, Inc. lists the '551 patent in the Orange Book for NDA No. 022255.

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, Hetero USA submitted to the FDA ANDA No. 204787 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.

28. The subjects of ANDA No. 204787 are referred to as "Hetero USA's ANDA Products."

29. Hetero USA 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 Hetero USA's ANDA Products 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 Hetero USA's ANDA Products before the expiration of the '551 patent, Hetero USA has committed an act of infringement of the '551 Patent under 35 U.S.C. § 271(e)(2).

31. On information and belief, when Hetero USA 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, Hetero USA 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 be infringed.

33. On June 18, 2013, UCB, Inc. received a letter from Hetero USA dated June 17, 2013, purporting to be a Notice of Certification for ANDA No. 204787 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. On July 10, 2013, Plaintiffs brought suit against Hetero for infringement of the '551 Patent under 35 U.S.C. § 271(e)(2), based on the filing of ANDA No. 204787. D.I. 1 in C.A. No. 13-1213-LPS (D. Del.).

35. On December 15, 2014, the Court held a Markman hearing in the consolidated case (C.A. No. 13-1206-LPS). The Court issued its Markman opinion on May 14, 2015. D.I. 241 in C.A. 13-1206-LPS.

36. On December 16, 2014, Hetero stipulated that Hetero USA's ANDA Products or the administration of Hetero USA's ANDA Products will infringe claims 9, 10, and 13 of the '551 patent. D.I. 196 in C.A. No. 13-1306-LPS.

37. Hetero removed the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) from ANDA No. 204787, and the parties stipulated to dismissal of Hetero from that action on October 1, 2015 (D.I. 252 in C.A. No. 13-1206-LPS), less than six weeks before trial. *See* "Minute Entries" for Nov. 9, 10, 12, and 13, 2015 in C.A. No. 13-1206-LPS. In that stipulation, Hetero represented to Plaintiffs and the Court that it "amended ANDA No. [204787][1] to remove the certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to U.S. Reissue Patent No. RE38,551" because it was "no longer seeking FDA approval of ANDA No. [204787] prior to the expiration of this patent." D.I. 252 in C.A. No. 13-1206-LPS.

38. As of October 1, 2015, all fact and expert discovery had been completed. *See* D.I. 19 (Proposed Scheduling Order) in C.A. No. 13-1206-LPS, D.I. 227, D.I. 243. After Hetero's dismissal, the Plaintiffs and the remaining defendants in the consolidated action filed the pre-trial order, conducted the trial, and completed post-trial briefing. *See* Docket, C.A. No. 13-1206-LPS. Those parties are presently awaiting the Court's ruling. *See id.*

39. Seven months after Hetero represented in the stipulation of dismissal that it was "no longer seeking FDA approval of ANDA No. [204787] prior to the expiration of th[e '551] patent" (D.I. 252 in C.A. No. 13-1206-LPS), Plaintiffs received letters from Hetero USA dated May 4, 2016, purporting to be a Notice of Certification for ANDA No. 204787 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).

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[1] Due to a typographical error in the stipulation provided by counsel for Hetero, the stipulation refers to ANDA No. 205011. D.I. 252 in C.A. No. 13-1206-LPS. ANDA No. 205011 was filed by Accord. *See* D.I. 1 in C.A. No. 13-1206-LPS.

40. On information and belief, Hetero USA has again 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 be infringed.

41. Hetero USA's 2016 Notice Letter does not assert any new bases for purported invalidity not raised in the earlier litigation; indeed, the substantive invalidity allegations detailed in Hetero USA's 2013 and 2016 Notice Letters are word-for-word identical.

42. Hetero USA's letter alleges that the active ingredient in Hetero USA's ANDA Products for which it seeks approval is lacosamide.

43. The commercial manufacture, use, offer for sale, sale and/or import of Hetero USA's ANDA Products will infringe at least claims 9, 10, and 13 of the '551 patent.

44. 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. 204787 be a date that is not earlier than March 17, 2022, the expiration date of the '551 patent, including any extensions.

45. Plaintiffs are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or import of Hetero USA's ANDA Products and any act committed by Hetero 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).

PRAYER FOR RELIEF

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

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Hetero has infringed one or more claims of the '551 patent by the filing of ANDA No. 204787 seeking FDA approval for the commercial manufacture, use, offer for sale, sale and/or import of Hetero USA's ANDA Products before the expiration of the '551 patent;

B. Judgment that the manufacture, use, offer for sale, sale and/or import of Hetero USA's ANDA Products will infringe the '551 patent;

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

D. A permanent injunction restraining and enjoining Hetero and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer for sale, sale and/or import, of Hetero USA's ANDA Products, 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. 204787 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 Hetero 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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