IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB PHARMA GMBH, RESEARCH CORPORATION TECHNOLOGIES, INC. and HARRIS FRC CORPORATION,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc., UCB Pharma GmbH, Research Corporation Technologies, Inc., and Harris FRC Corporation, (hereinafter "Plaintiffs"), for their Complaint against defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva"), hereby allege as follows:

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 Pharma GmbH ("UCB Pharma") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Alfred Nobel Strasse 10, 40789 Monheim, Germany. UCB Pharma was formerly known as Schwarz Pharma AG ("Schwarz").

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 5210 East Williams Circle, Suite 240, Tucson, Arizona 85711-4410.

4. Plaintiff Harris FRC Corporation ("Harris") is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 2137 State Highway 35, Holmdel, New Jersey 07733.

5. On information and belief, defendant Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 10454-1090.

6. On information and belief, Teva USA is a wholly-owned subsidiary and agent of defendant Teva Ltd. On information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

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 Teva'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 Teva USA. On information and belief, Teva 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, Teva USA holds Pharmacy Wholesale Licenses from the State of Delaware under License Nos. A4-0001681, A4-0001468 and A4-0001447. On information and belief, Teva USA holds Distributor/Manufacturer Licenses for Controlled Substances Registration from the State of Delaware under License Nos. A4-DM-006546 and DM-0007115. On information and belief, Teva 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 and having engaged in systematic and continuous contacts with the State of Delaware.

9. This Court has jurisdiction over Teva Ltd. On information and belief, Teva 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 Teva USA. On information and belief, Teva Ltd. and Teva 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 Teva Ltd.'s generic products. On information and belief, Teva Ltd. has purposely availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitting to personal jurisdiction in this Court and having engaged in systematic and continuous contacts with the State of Delaware.

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

CLAIM FOR RELIEF – PATENT INFRINGEMENT

11. 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 022253 on October 28, 2008. UCB, Inc. lists the '551 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA 022253.

12. 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 022254 on October 28, 2008. UCB, Inc. lists the '551 patent in the Orange Book for NDA 022254.

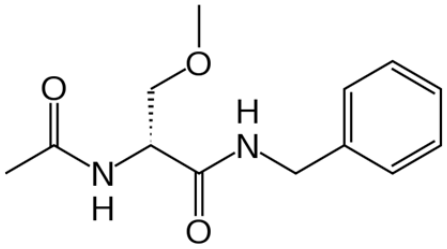
13. UCB, Inc. holds approved NDA No. 022255 for Vimpat® oral solution (10 mg/ mL dosage strength), which oral solution contains the active ingredient lacosamide. The FDA approved NDA 022255 on April 20, 2010. UCB, Inc. lists the '551 patent in the Orange Book for NDA 022255.

14. Vimpat® tablets and oral solution are indicated 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 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.

15. 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.

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

17. 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:



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

19. 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.

20. 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.

21. 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.

22. Harris exclusively sublicensed to 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.

23. 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.

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

25. On information and belief, Teva USA submitted to the FDA ANDA No. 204999 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("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.

26. The subjects of ANDA No. 204999 are referred to as "Teva USA's ANDA Products."

27. Teva 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 Teva USA's ANDA Products before the expiration of the '551 patent.

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

29. On information and belief, when Teva 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.

30. On information and belief, Teva USA made and included in its ANDA a certification under 21 U.S.C. § 355(j)(2)(B)(iv)(II) that, in its opinion and to the best of its knowledge, the '551 patent is invalid and/or will not infringed.

31. On May 30, 2013, RCT received a letter from Teva USA dated May 29, 2013, purporting to be a Notice of Certification for ANDA No. 204999 under Section 505(j)(2)(B)(ii) of the Act, 21 U.S.C. § 355(j)(2)(B)(ii), and 21 C.F.R. § 314.95(c)(1).

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

33. The commercial manufacture, use, offer for sale, sale and/or import of Teva USA's ANDA Products will infringe one or more claims of the '551 patent.

34. 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 204999 be a date that is not earlier than March 17, 2022, the expiration date of the '551 patent, including any extensions.

35. Plaintiffs are entitled to an award of damages for any commercial manufacture, use, offer for sale, sale and/or import of Teva USA's ANDA Products and any act committed by Teva USA 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 Pharma, RCT and Harris, pray for a judgment in their favor and against defendants Teva USA and Teva Ltd., and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Teva has infringed one or more claims of the '551 patent by Teva USA's filing of ANDA No. 204999 seeking approval for the commercial manufacture, use, offer for sale, sale and/or import of Teva USA's ANDA Products before the expiration of the '551 patent;

B. A judgment that the manufacture, use, offer for sale, sale and/or import of Teva 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 Teva 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 Teva 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. 204999 relating to Teva USA's ANDA Products 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 Teva 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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