IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UCB, INC., UCB MANUFACTURING IRELAND LIMITED, UCB PHARMA GMBH, and LTS LOHMANN THERAPIE-SYSTEME AG,	)	
Plaintiffs.	)	
v.	)	C.A. No. 16-1023 (LPS)
ZYDUS WORLDWIDE DMCC, CADILA HEALTHCARE LTD. d/b/a ZYDUS CADILA, ZYDUS PHARMACEUTICALS USA, INC.	)	
Defendants.	)	

AMENDED AND SUPPLEMENTAL COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs UCB, Inc., UCB Manufacturing Ireland Limited, UCB Pharma GmbH, and LTS Lohmann Therapie-Systeme AG (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendants Zydus Worldwide DMCC ("Zydus Worldwide"), Cadila Healthcare Limited dba Zydus Cadila ("Zydus Cadila"), and Zydus Pharmaceuticals USA, Inc. ("Zydus USA") (collectively "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.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, arises from Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 209473 to the United States Food and Drug Administration ("FDA"). Through this ANDA, Defendants seek approval to market generic versions of the pharmaceutical product Neupro® prior to the expiration of United States Patent Nos.; 6,884,434 ("the '434 Patent") and 9,925,150 ("the '150 Patent"). Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, and any other relief the Court deems just and proper.

THE PARTIES

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

3. Plaintiff UCB Manufacturing Ireland Limited ("UCB Ireland") is a corporation organized and existing under the laws of Republic of Ireland, having an office and place of business at Shannon Industrial Estate, Shannon, Co. Clare, Ireland.

4. 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.

5. Plaintiff LTS Lohmann Therapie-Systeme AG ("LTS") is a corporation organized and existing under the laws of the Federal Republic of Germany, having an office and place of business at Lohmannstrasse 2, 56626 Andernach, Germany.

6. On information and belief, Defendant Zydus Worldwide is a company organized and existing under the laws of the United Arab Emirates, with a principal place of business at Armada Tower 2, P2, Cluster P, 9 Floor, Office 908, Al Thanyah 5, Hadaeq Mohammed Bin Rashid, Dubai, United Arab Emirates.

7. On information and belief, defendant Zydus Cadila is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Tower, Satellite Cross Roads, Ahmedabad, 380015, Gujarat, India.

8. On information and belief, defendant Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business at 73 Route 31 North, Pennington, New Jersey 08534.

JURISDICTION AND VENUE

9. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the'434 Patent and the '150 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331and 1338. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Zydus Worldwide. On information and belief, Zydus Worldwide, 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, Zydus Worldwide intends to market and sell the proposed generic products at issue in this litigation, Rotigotine Transdermal System (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours) ("ANDA Products") throughout the United States, including in this judicial district. On information and belief, Zydus Worldwide has engaged in systematic and continuous contacts with the State of Delaware.

11. This Court has jurisdiction over Zydus Cadila. On information and belief, Zydus Cadila, directly or through its affiliates and agents including its subsidiaries Zydus Worldwide and Zydus Pharmaceuticals (USA), Inc., 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, Zydus Cadila intends to market and sell the ANDA Products in this judicial district. On information and belief, Zydus Cadila and Zydus Worldwide 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. Zydus Cadila has previously

submitted to personal jurisdiction in this Court, and has 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. (*See, e.g.*, *UCB, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 13-1220-LPS (D. Del.) at D.I. 12, ¶ 8 & at 12–16).

12. This Court has jurisdiction over Zydus USA. On information and belief, Zydus 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, Zydus USA intends to market and sell the proposed generic products at issue in this litigation in this judicial district. Zydus 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 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, (*See, e.g.*, *UCB, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 13-1220-LPS (D. Del.) at D.I. 12, ¶ 8 & at 12–16).

13. On information and belief, Teva Pharmaceuticals USA, Inc. ("Teva"), working in concert with its affiliates, developed or caused to be developed the ANDA Products and prepared and submitted ANDA No. 209473 to FDA with the intention of seeking to market the ANDA Products as generic versions of Neupro® throughout the United States, including within this judicial district.

14. On information and belief, after developing the ANDA Products and submitting ANDA No. 209473, Teva has transferred rights to that ANDA to Defendants and ANDA No. 209473 was assigned to Zydus Worldwide.

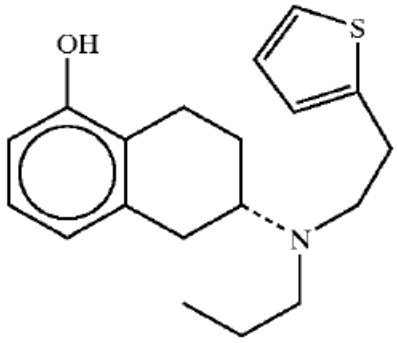
15. Accordingly, on information and belief, Defendants plan to market and sell purported generic versions of Neupro® in Delaware, list purported generic versions of Neupro® on Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of purported generic versions of Neupro® in Delaware.

16. On information and belief, Defendants continue to work together and act as one entity in seeking FDA approval of ANDA No. 209473 and will act as one entity in marketing the ANDA Products throughout the United States, including in this judicial district.

PLAINTIFFS' PATENTS AND APPROVED NEUPRO® DRUG PRODUCT

17. Plaintiffs make and sell Neupro® (Rotigotine Transdermal System), a treatment for the signs and symptoms of idiopathic Parkinson's disease ("PD") and moderate-to-severe Restless Legs Syndrome ("RLS"). PD affects movement, producing motor symptoms such as tremor, slowed movement, rigidity, and postural instability. PD can also cause neuropsychiatric disturbances, including disorders of speech, cognition, mood, behavior, and thought. RLS is characterized by uncomfortable or odd sensations in a person's limbs, which cause an irresistible urge to move the body for temporary relief.

18. Neupro® is the first FDA-approved product containing rotigotine, a synthetic dopamine agonist. In PD, neurodegeneration results in the loss of dopamine-producing neurons and reduced activity within certain dopaminergic pathways, and restoring activity to these systems with a dopamine agonist such as rotigotine may improve the clinical signs of PD. Rotigotine is also called (6S)-6-{propyl[2-(2-thienyl)ethyl]amino}-5,6,7,8-tetrahydro-1-naphthalenol; or (-)-5,6,7,8-tetrahydro-6-[propyl-[2-(2-thienyl)ethyl]amino]-1-naphthalenol, and has the following formula:



19. Neupro® is also the first FDA-approved transdermal treatment for PD. Neupro® is a transdermal system that provides continuous delivery of rotigotine for 24 hours following application to intact skin. The product is a thin, matrix-type transdermal system composed of three layers: a backing film, drug matrix, and protective liner. The liner protects the drug matrix during storage and is removed just prior to application. Neupro® is approved and marketed in six different strengths: 1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours and 8 mg/24 hours.

20. Neupro®'s transdermal delivery of rotigotine has been shown to provide stable plasma levels of rotigotine over 24 hours, which may prevent or reduce long-term motor complications and motor fluctuations that are associated with unstable or fluctuating dopaminergic stimulation. Neupro® also offers other advantages. For example, by delivering drug via transdermal application, Neupro® bypasses gastrointestinal complications that may be associated with PD. In addition, Neupro®'s once-daily formulation for 24 hours of treatment may improve early morning and nighttime symptoms of PD, as well as patient compliance.

21. Plaintiff UCB, Inc. is the holder of New Drug Application ("NDA") No. 021829 for Neupro® (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours). FDA initially approved NDA No. 021829 in May 2007, for the treatment of signs and symptoms of early stage idiopathic PD. Following manufacturing and process changes

to address product stability, and following additional clinical trials, in April 2012, FDA approved a new formulation of Neupro® for additional indications, *i.e.*, for the treatment of the signs and symptoms of advanced stage idiopathic PD, and for the treatment for moderate-to-severe RLS. In its April 2012 approval of Neupro®, FDA granted Neupro® three years of regulatory exclusivity pursuant to 21 C.F.R. 314.108.

22. The'434 and '150 Patents are listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for Neupro®.

23. On April 26, 2005, the USPTO duly and lawfully issued the '434 Patent, entitled "Transdermal Therapeutic System Which Contains a D2 Agonist and Which is Provided for Treating Parkinsonism, and a Method for the Production Thereof." A true and correct copy of the '434 Patent is attached as Exhibit A.

24. On March 27, 2018, the USPTO duly and lawfully issued the '150 Patent, entitled "Polyvinylpyrrolidone for the Stabilization of a Solid Dispersion of the Non-Crystalline Form of Rotigotine." A true and correct copy of the '150 Patent is attached as Exhibit B.

25. Each of the '434 and '150 Patents is owned or co-owned by one or more of Plaintiffs UCB Ireland, UCB Pharma, and LTS.

DEFENDANTS' ANDA

26. On information and belief, Teva submitted or caused to be submitted ANDA No. 209473 ("Defendants' ANDA") to FDA under 21 U.S.C. § 355(j), in order to obtain approval to engage in the commercial manufacture, use or sale of Rotigotine Transdermal System (1 mg/24 hours, 2 mg/24 hours, 3 mg/24 hours, 4 mg/24 hours, 6 mg/24 hours, and 8 mg/24 hours)

("ANDA Products"), as purported generic versions of Neupro®, prior to the expiration of the'434 and '150 Patents.

27. On information and belief, subsequent to filing, Teva transferred rights in the Defendants' ANDA to Defendants and that ANDA was assigned to Defendant Zydus Worldwide, which stands in the shoes of Teva with respect to Defendants' ANDA.

28. On information and belief, on or about September 19, 2016, Defendant Zydus Worldwide sent Plaintiffs a letter stating "Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act, on behalf of Zydus Worldwide DMCC ('Zydus') you are hereby notified that Abbreviated New Drug Application No. 209473 ('the Zydus ANDA') has been submitted to the United States Food and Drug Administration ('FDA') under 21 U.S.C. § 355(j), which contains data from bioavailability or bioequivalence studies to obtain approval to engage in the commercial manufacture, use or sale of rotigotine transdermal system, 1 mg, 2 mg, 3 mg, 4 mg, 6 mg, 8 mg ('the Zydus ANDA Product')". ("September 2016 Notice Letter"). The September 2016 Notice Letter further represented that Defendant Zydus Worldwide had submitted to FDA a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Defendants' ANDA before the expiration of the patents listed in the Orange Book for NDA No. 021829. Hence, Defendants' purpose in taking ownership and pursuing approval of the Defendants' ANDA is to manufacture and market the ANDA Products before the expiration of the '434 Patent. The September 2016 Notice Letter also stated that the Paragraph IV certification alleges that the '434 Patent is invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

29. On information and belief, on or about April 30, 2018, Defendant Zydus USA, on behalf of Defendant Zydus Worldwide, sent Plaintiffs a second letter ("April 2018 Notice Letter") representing that Defendant Zydus Worldwide had submitted to FDA a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Defendants' ANDA before the expiration of the '150 Patent. Hence, Defendants' purpose in taking ownership and pursuing approval of Defendants' ANDA is to manufacture and market the ANDA Products before the expiration of the '150 Patent. The April 2018 Notice Letter also stated that the Paragraph IV certification alleges that the '150 Patent is invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

30. In the April 2018 Notice Letter, Zydus did not contend that it would not infringe any claim of the '150 Patent if valid and enforceable.

31. On information and belief, if FDA approves the Defendants' ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States.

32. On information and belief, if FDA approves the Defendants' ANDA, Defendants will actively induce or contribute to the manufacture, use, offer for sale, or sale of the ANDA Products.

33. This action was brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the September 2016 Notice Letter.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '434 PATENT

34. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

35. On information and belief, Defendants have caused the submission of the Defendants' ANDA to FDA, are the owners of Defendants' ANDA, and continue to seek FDA approval of the Defendants' ANDA.

36. Defendants have infringed at least Claim 1 of the '434 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Defendants' ANDA with a Paragraph IV certification and seeking FDA approval of the Defendants' ANDA prior to the expiration of the '434 Patent.

37. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '434 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209473, Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of at least claim 1 of the '434 Patent.

38. On information and belief, upon FDA approval of ANDA No. 209473, Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Defendants will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using and applying the ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '434 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '434 Patent and knowledge that they are encouraging infringement.

39. Defendants had actual and constructive notice of the '434 Patent prior to taking ownership of the Defendants' ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '434 Patent would constitute an act of infringement of the '434 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '434 Patent. In addition, Defendants filed the Defendants' ANDA without adequate justification for asserting the '434 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants' conduct in certifying invalidity and non-infringement with respect to the '434 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

40. Plaintiffs will be irreparably harmed if the Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '434 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '150 PATENT

41. Plaintiffs restate, reallege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

42. On information and belief, Defendants have caused the submission of the Defendants' ANDA to FDA, are the owners of Defendants' ANDA, and continue to seek FDA approval of the Defendants' ANDA.

43. Defendants have infringed at least Claim 2 of the '150 Patent under 35 U.S.C. § 271(e)(2)(A) by seeking FDA approval of the Defendants' ANDA prior to the expiration of the '150 Patent.

44. Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe, and would actively induce and contribute to infringement of the '150 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209473, the Defendants will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of at least claim 2 of the '150 Patent.

45. On information and belief, upon FDA approval of ANDA No. 209473, Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Defendants will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using and applying the ANDA Products. Accordingly, Defendants will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '150 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '150 Patent and knowledge that they are encouraging infringement.

46. Defendants had actual and constructive notice of the '150 Patent at least since its issue date, and were aware that the request for FDA approval prior to the expiration of the '150 Patent would constitute an act of infringement of the '150 Patent. Defendants have no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the

ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the ’150 Patent. In addition, Defendants are without adequate justification for asserting the ’150 Patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Defendants’ conduct in certifying invalidity and non-infringement with respect to the ’150 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

47. Plaintiffs will be irreparably harmed if the Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’150 Patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) The entry of judgment, in favor of Plaintiffs and against Defendants, that Defendants, through their submission and continued efforts to obtain approval of ANDA No. 209473 to FDA seeking to market the Defendants’ ANDA Products, have infringed the ’434 and ’150 Patents under 35 U.S.C. § 271(e)(2)(A);

(B) The entry of judgment, in favor of Plaintiffs and against Defendants, declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in the Defendants’ ANDA, or inducing or contributing to such conduct, would constitute infringement of the ’434 and ’150 Patents by Defendants pursuant to 35 U.S.C. §§ 271(a), (b), (c) and (g);

(C) The entry of a permanent injunction, enjoining Defendants and their officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons acting in concert, participation, or in privity with Defendants, and their successors or assigns, from infringing, inducing infringement of, and contributing to the infringement of any claims of the '434 and '150 Patents by making, using, selling, offering for sale, or importing the ANDA Products in the United States;

(D) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 209473 shall be a date that is not earlier than the last expiration date of any of the '434 and '150 Patents, or any later expiration of exclusivity for any of the patents, including any extensions or regulatory exclusivities;

(E) The entry of judgment declaring that Defendants' acts render this case an exceptional case, and awarding Plaintiffs their attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(F) An award to Plaintiffs of their costs and expenses in this action; and

(G) Such other and further relief as the Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Derek J. Fahnestock

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May 30, 2018

CERTIFICATE OF SERVICE

I hereby certify that on May 30, 2018, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on May 30, 2018, upon the following in the manner indicated:

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