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. _____
ZYDUS WORLDWIDE DMCC, CADILA HEALTHCARE LTD. d/b/a ZYDUS CADILA, and TEVA PHARMACEUTICALS USA, INC.	)	
Defendants.	)	

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") and Cadila Healthcare Limited dba Zydus Cadila ("Zydus Cadila") (collectively "Zydus Defendants"), and Teva Pharmaceuticals USA, Inc. ("Teva") (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. 8,246,979 ("the '979 Patent"); 8,246,980 ("the '980 Patent"); 8,617,591 ("the '591 Patent"); and 6,884,434 ("the '434 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 Teva is a Delaware corporation having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

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 '979 Patent; the '980 Patent; the '591 Patent; and the '434 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 personal jurisdiction over Teva. Teva is a Delaware corporation. In addition, on information and belief, Teva, directly or through its affiliates and agents, develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States including in this judicial district.

13. On information and belief, 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 the Zydus Defendants and ANDA No. 209473 was assigned to Zydus Worldwide.

15. Accordingly, on information and belief, Defendant Zydus Worldwide plans 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.

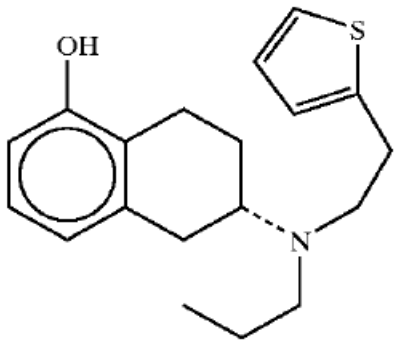
16. On information and belief, the Zydus Defendants continue to work together and act as one entity in seeking FDA approval of ANDA No. 209473.

17. On information and belief, Teva developed the ANDA Products and has provided support to the the Zydus Defendants in connection with the ANDA Products and with proceedings in the FDA regarding ANDA No. 209473.

PLAINTIFFS' PATENTS AND APPROVED NEUPRO® DRUG PRODUCT

18. 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.

19. 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:



20. 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.

21. 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.

22. 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.

23. The ’979, ’980, ’591, and ’434 Patents are listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for Neupro®.

24. On August 21, 2012, the USPTO duly and lawfully issued the ’979 Patent, entitled “Transdermal Delivery System for the Administration of Rotigotine.” A true and correct copy of the ’979 Patent is attached as Exhibit A.

25. On August 21, 2012, the USPTO duly and lawfully issued the ’980 Patent, entitled “Transdermal Delivery System.” A true and correct copy of the ’980 Patent is attached as Exhibit B.

26. On December 31, 2013, the USPTO duly and lawfully issued the ’591 Patent, entitled “Transdermal Delivery System for the Administration of Rotigotine.” A true and correct copy of the ’591 Patent is attached as Exhibit C.

27. 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 D.

28. Each of the ’979, ’980, ’591, and’434 Patents is owned or co-owned by one or more of Plaintiffs UCB Ireland, UCB Pharma, and LTS.

DEFENDANTS’ ANDA

29. 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 '979, '980, '591, and '434 Patents.

30. On information and belief, subsequent to filing, Teva transferred rights in the Defendants' ANDA to the Zydus Defendants and that ANDA was assigned to Defendant Zydus Worldwide.

31. 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')". ("Notice Letter"). The 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 submitting the Defendants' ANDA is to manufacture and market the ANDA Products before the expiration of the '979, '980, '591, and '434. The Notice Letter also stated that the Paragraph IV certification alleges that the '979, '980, '591, and '434 Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

32. On information and belief, Teva has developed the ANDA Products, has assisted with and participated in the preparation and submission of the Defendants' ANDA, has provided material support to the preparation and submission of the Defendants' ANDA, and has supported prosecution of the Defendants' ANDA.

33. On information and belief, if FDA approves the Defendants' ANDA, the Zydus 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.

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

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

COUNT I: CLAIM FOR INFRINGEMENT OF THE '979 PATENT

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

37. On information and belief, Defendants have submitted or caused the submission of the Defendants' ANDA to FDA, and continue to seek FDA approval of the Defendants' ANDA.

38. Defendants have infringed the '979 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 '979 Patent. In the Notice Letter, Zydus has not asserted non-infringement of claims 1-4 or claims 7-18 of the '979 Patent.

39. The Zydus 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 '979 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209473, the Zydus 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 one or more claims of the '979 Patent.

40. On information and belief, upon FDA approval of ANDA No. 209473, the Zydus Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. The Zydus 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, the Zydus 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 '979 Patent. In addition, on information and belief, the Zydus Defendants will encourage acts of direct infringement with knowledge of the '979 Patent and knowledge that they are encouraging infringement.

41. Defendants had actual and constructive notice of the '979 Patent prior to filing the Defendants' ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '979 Patent would constitute an act of infringement of the '979 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 '979 Patent. In addition, Defendants filed the Defendants'

ANDA without adequate justification for asserting the ’979 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 ’979 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

42. Plaintiffs will be irreparably harmed if the Zydus Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’979 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 ’980 PATENT

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

44. On information and belief, Defendants have submitted or caused the submission of the Defendants’ ANDA to FDA, and continue to seek FDA approval of the Defendants’ ANDA.

45. Defendants have infringed the ’980 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 ’980 Patent. In the Notice Letter, Zydus has not asserted non-infringement of claim 17 of the ‘980 Patent.

46. The Zydus 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 ’980 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209473, the Zydus 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 one or more claims of the ’980 Patent.

47. On information and belief, upon FDA approval of ANDA No. 209473, the Zydus Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. The Zydus 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, the Zydus 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 ’980 Patent. In addition, on information and belief, the Zydus Defendants will encourage acts of direct infringement with knowledge of the ’980 Patent and knowledge that they are encouraging infringement.

48. Defendants had actual and constructive notice of the ’980 Patent prior to filing the Defendants’ ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the ’980 Patent would constitute an act of infringement of the ’980 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 ’980 Patent. In addition, Defendants filed the Defendants’ ANDA without adequate justification for asserting the ’980 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 ’980 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

49. Plaintiffs will be irreparably harmed if the Zydus Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’980 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 III: CLAIM FOR INFRINGEMENT OF THE ’591 PATENT

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

51. On information and belief, Defendants have submitted or caused the submission of the Defendants’ ANDA to FDA, and continue to seek FDA approval of the Defendants’ ANDA.

52. Defendants have infringed the ’591 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 ’591 Patent. In the Notice Letter, Zydus has not asserted non-infringement of claims 1-4, 6-7, 10-18, or 20-30 of the ‘591 Patent.

53. The Zydus 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 ’591 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209473, the Zydus 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 one or more claims of the ’591 Patent.

54. On information and belief, upon FDA approval of ANDA No. 209473, the Zydus Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. The Zydus 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, the Zydus 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 '591 Patent. In addition, on information and belief, the Zydus Defendants will encourage acts of direct infringement with knowledge of the '591 Patent and knowledge that they are encouraging infringement.

55. Defendants had actual and constructive notice of the '591 Patent prior to filing the Defendants' ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '591 Patent would constitute an act of infringement of the '591 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 '591 Patent. In addition, Defendants filed the Defendants' ANDA without adequate justification for asserting the '591 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 '591 Patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

56. Plaintiffs will be irreparably harmed if the Zydus Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the '591 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 IV: CLAIM FOR INFRINGEMENT OF THE '434 PATENT

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

58. On information and belief, Defendants have submitted or caused the submission of the Defendants' ANDA to FDA, and continue to seek FDA approval of the Defendants' ANDA.

59. 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.

60. The Zydus 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, the Zydus 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.

61. On information and belief, upon FDA approval of ANDA No. 209473, the Zydus Defendants will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. The Zydus 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, the Zydus

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, the Zydus Defendants will encourage acts of direct infringement with knowledge of the ’434 Patent and knowledge that they are encouraging infringement.

62. Defendants had actual and constructive notice of the ’434 Patent prior to filing 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.

63. Plaintiffs will be irreparably harmed if the Zydus 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.

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 of ANDA No. 209473 to FDA seeking to market the Defendants' ANDA Products, have infringed the '979, '980, '591, and '434 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 '979, '980, '591, and '434 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 '979, '980, '591, and '434 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 '979, '980, '591, and '434 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

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