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. _____
MYLAN TECHNOLOGIES, INC., MYLAN PHARMACEUTICALS, INC., and MYLAN, 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 Mylan Technologies, Inc. ("MTI"), Mylan Pharmaceuticals, Inc. ("MPI"), and Mylan, Inc. (collectively "Mylan" or "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. 209982 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"); 7,413,747 ("the '747 Patent"); 8,246,979 ("the '979 Patent"); 8,246,980 ("the '980 Patent"); and 8,617,591

("the '591 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. Defendant MTI is a West Virginia corporation with a principal place of business at 110 Lake St., St. Albans, VT. Upon information and belief, MTI is a wholly-owned subsidiary of Mylan, Inc.

7. Defendant MPI is a West Virginia corporation with a principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. MPI maintains a registered agent in Delaware. MPI may be served with process in Delaware via the Corporation Service Company, 2711 Centerville Road, Suite 400, Wilmington, DE 19808. Upon information and belief, MPI is a wholly-owned subsidiary of Mylan, Inc.

8. Defendant Mylan, Inc. is a Pennsylvania corporation with a principal place of business at 1000 Mylan Boulevard, Canonsburg, Pennsylvania 15317.

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; the '747 Patent; the '979 Patent; the '980 Patent; and the '591 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/or 1400(b).

10. This Court has personal jurisdiction over MTI. On information and belief, MTI, 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, MTI 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, MTI has engaged in systematic and continuous contacts with the State of Delaware. MTI has registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware and on information and belief holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy. MTI is accordingly "at home" in this judicial district.

11. This Court has jurisdiction over MPI. MPI has registered to do business in Delaware and maintains a registered agent in Delaware, and MPI may be served with process in Delaware via its registered agent, the Corporation Service Company, 2711 Centerville Road,

Suite 400, Wilmington, DE 19808. Further, MPI has registered pursuant to Del. Code. Ann. Tit. 24 § 2540 to distribute generic pharmaceutical products in Delaware and on information and belief holds current and valid "Distributor/Manufacturer CSR" and "Pharmacy-Wholesale" licenses from the Delaware Board of Pharmacy. MPI has also availed itself of the protections of this Court as a plaintiff in this District. MPI is accordingly "at home" in this judicial district.

12. This Court has jurisdiction over Mylan, Inc. Mylan, Inc, directly or through its affiliates and agents including its subsidiaries MTI and MPI, 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, Mylan intends to market and sell the ANDA Products in this judicial district. On information and belief, Mylan, Inc., MPI, and MTI 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.

13. This Court further has jurisdiction because on information and belief, Mylan has purposefully availed itself of the privilege of doing business in Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States including the State of Delaware, and/or by selling, directly or through its agents, pharmaceutical products in the State of Delaware. Upon information and belief, Defendants are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States including in Delaware.

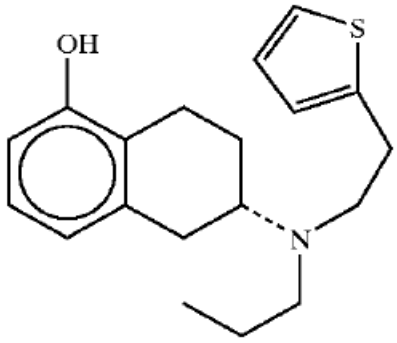
14. On information and belief, MTI, MPI, and Mylan, Inc. work together and act as one entity in seeking FDA approval of ANDA No. 209982.

15. On information and belief, Mylan 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.

PLAINTIFFS' PATENTS AND APPROVED NEUPRO® DRUG PRODUCT

16. 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.

17. 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:



18. 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.

19. 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.

20. 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.

21. The ’434, ’747, ’979, ’980, and ’591 Patents are listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the “Orange Book”) for Neupro®.

22. 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.

23. On August 19, 2008, the USPTO duly and lawfully issued the ’747 Patent, entitled “Transdermal Therapeutic System for Treating Parkinsonism.” A true and correct copy of the ’747 Patent is attached as Exhibit B.

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 C.

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 D.

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 E.

27. Each of the ’434, ’747, ’979, ’980, and ’591 Patents is owned or co-owned by one or more of Plaintiffs UCB Ireland, UCB Pharma, and LTS.

THE MYLAN ANDA

28. On information and belief, Mylan submitted or caused to be submitted ANDA No. 209982 (“the Mylan 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, ’747, and ’434 Patents.

29. On information and belief, on or about February 27, 2017, Defendant MTI sent Plaintiffs a letter purporting to provide notice of certification concerning the ’434, ’747, ’979, ’980, and ’591 Patents pursuant to Section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act and 21 C.P.R. §§ 314.94 and 314.95. (the “Notice Letter”). The Notice Letter further represented that MTI 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 Mylan ANDA before the expiration of the patents listed in the Orange Book for NDA No. 021829. Hence, Mylan’s purpose in submitting its ANDA is to manufacture and market the ANDA Products before the expiration of the’434, ’747. ’979, ’980, and ’591 Patents. The Notice Letter also stated that the Paragraph IV certification alleges that the ’434, ’747, ’979, ’980, and

'591 Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

30. On information and belief, MPI and Mylan, Inc. have assisted with and participated in the preparation and submission of the Mylan ANDA and the development of the ANDA Products, have provided material support to the preparation and submission of the Mylan ANDA, and have supported prosecution of the Mylan ANDA.

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

33. 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 '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 submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

36. Defendants have infringed the '434 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '434 Patent. In the Notice Letter, MTI has not asserted non-infringement of claims 1-3, 5, 7, and 14-15 of the '434 Patent.

37. Mylan's 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. 209982, Mylan 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 '434 Patent.

38. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan 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, Mylan 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, Mylan will encourage acts of direct infringement with knowledge of the '434 Patent and knowledge that they are encouraging infringement.

39. Defendants had knowledge of the '434 Patent prior to filing the Mylan 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 Mylan 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 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 '747 PATENT

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

42. On information and belief, Defendants submitted or caused the submission of the Mylan ANDA to FDA, and continue to seek FDA approval of the Mylan ANDA.

43. Defendants have infringed the '747 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '747 Patent. In the Notice Letter, MTI has not asserted non-infringement of claims 1-6, 8-11, and 13 of the '747 Patent.

44. Mylan's 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 '747 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 209982, Mylan 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 ’747 Patent.

45. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan 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, Mylan 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 ’747 Patent. In addition, on information and belief, Mylan will encourage acts of direct infringement with knowledge of the ’747 Patent and knowledge that they are encouraging infringement.

46. Defendants had knowledge of the ’747 Patent prior to filing the Mylan ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the ’747 Patent would constitute an act of infringement of the ’747 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 ’747 Patent. In addition, Defendants filed the Mylan ANDA without adequate justification for asserting the ’747 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 ’747 Patent renders this case “exceptional” as that term is set forth in 35 U.S.C. § 285.

47. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing, and from actively inducing or contributing to the infringement of the ’747 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 '979 PATENT

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

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

50. Defendants have infringed the '979 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the '979 Patent. In the Notice Letter, Mylan has not asserted non-infringement of claims 1-5 or claims 7-18 of the '979 Patent.

51. Mylan's 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. 209982, Mylan 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.

52. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan 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, Mylan 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, Mylan will encourage acts of direct infringement with knowledge of the '979 Patent and knowledge that they are encouraging infringement.

53. Mylan had knowledge of the '979 Patent prior to filing the Mylan ANDA, and was 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. Mylan had 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, Mylan filed its 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. Mylan's 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.

54. Plaintiffs will be irreparably harmed if 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 IV: CLAIM FOR INFRINGEMENT OF THE '980 PATENT

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

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

57. Defendants have infringed the ’980 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the Mylan ANDA prior to the expiration of the ’980 Patent. In the Notice Letter, MTI has not asserted non-infringement of claim 17 of the ’980 Patent.

58. Mylan’s 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. 209982, Mylan 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.

59. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan 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, Mylan 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, Mylan will encourage acts of direct infringement with knowledge of the ’980 Patent and knowledge that they are encouraging infringement.

60. Defendants had knowledge of the ’980 Patent prior to filing the Mylan 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 Mylan 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.

61. Plaintiffs will be irreparably harmed if 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 V: CLAIM FOR INFRINGEMENT OF THE ’591 PATENT

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

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

64. Defendants have infringed the ’591 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Mylan ANDA with a Paragraph IV certification and seeking FDA approval of the

Mylan ANDA prior to the expiration of the '591 Patent. In the Notice Letter, MTI has not asserted non-infringement of claims 1-3, 6-17, or 20-30 of the '591 Patent.

65. Mylan's 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. 209982, Mylan 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.

66. On information and belief, upon FDA approval of ANDA No. 209982, Mylan will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Mylan 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, Mylan 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, Mylan will encourage acts of direct infringement with knowledge of the '591 Patent and knowledge that they are encouraging infringement.

67. Defendants had knowledge of the '591 Patent prior to filing the Mylan 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 Mylan 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.

68. Plaintiffs will be irreparably harmed if 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.

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. 209982 to the FDA seeking to market the ANDA Products, have infringed the ’434, ’747, ’979, ’980, and ’591 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 Mylan ANDA, or inducing or contributing to such conduct, would constitute infringement of the ’434, ’747, ’979, ’980, and ’591 Patents by Defendants pursuant to 35 U.S.C. §§ 271(a), (b) and (c);

(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, '747,'979, '980, and'591 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. 209982 shall be a date that is not earlier than the last expiration date of any of the '434, '747, '979, '980, and '591 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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