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. 14-1083 (SLR) (SRF)
WATSON LABORATORIES, INC. and ACTAVIS LABORATORIES UT, 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 Watson Laboratories, Inc. and Actavis Laboratories UT, Inc. (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. 206348 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. 6,699,498 ("the '498 Patent"); 6,884,434 ("the '434 Patent"); 7,413,747 ("the '747 Patent"); 8,617,591 ("the '591 Patent"); 8,232,414 ("the '414 Patent"); and 8,932,665 ("the '665 Patent"). Plaintiffs seek declaratory and 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 Watson Laboratories, Inc. is a corporation organized and existing under the laws of the State of Nevada, having places of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054, and at 311 Bonnie Circle, Corona, CA 92880.

7. On information and belief, Defendant Actavis Laboratories UT, Inc., formerly known as Watson Laboratories, Inc., is a corporation organized and existing under the laws of the State of Delaware, having places of business at 575, 577, and 579 Chipeta Way, Salt Lake City, Utah.

JURISDICTION AND VENUE

8. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and alleges infringement of the '498 Patent; the '434 Patent; the '747 Patent; and the '591 Patent, and imminent infringement of the '414 Patent and the '665 Patent. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

9. On information and belief, this Court has personal jurisdiction over Defendant Watson Laboratories, Inc. because, *inter alia*, the company regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. On information and belief, Defendant Watson Laboratories, Inc. derives substantial revenue from the sale of products to customers in Delaware.

10. On further information and belief, Defendant Watson Laboratories, Inc. develops generic drug products and prepares and submits ANDAs. In pursuing these activities, on information and belief, Defendant Watson Laboratories, Inc. does not and cannot operate independently and instead works in concert with one or more affiliates that are incorporated in the State of Delaware. For example, to prepare ANDA No. 206348, on information and belief, Defendant Watson Laboratories, Inc. worked in concert with its affiliate, Defendant Actavis Laboratories UT, Inc.; and Defendant Actavis Laboratories UT, Inc. researched, developed, manufactured, analyzed, tested, and packaged the products that are the subject of ANDA No. 206348. On information and belief, Defendant Watson Laboratories, Inc. could not have

developed the products that are the subject of ANDA No. 206348, and therefore could not have prepared and submitted ANDA No. 206348, without acting in concert with its affiliate.

11. Thus, on information and belief, Defendants acted as one entity with respect to the preparation of ANDA No. 206348. On further information and belief, Defendants continue to work together and act as one entity in seeking FDA approval of ANDA No. 206348.

12. On further information and belief, Defendant Watson Laboratories, Inc. working in concert with its Delaware affiliate, prepared and submitted ANDA No. 206348 to FDA with the intention of seeking to market the products described in the ANDA as generic versions of Neupro® throughout the United States, including within this judicial district. Accordingly, on information and belief, Defendant Watson Laboratories, Inc. 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. On further information and belief, the purported generic versions of Neupro® that Defendant Watson Laboratories, Inc. intends to market, distribute, and sell within Delaware will be manufactured, tested, and packaged by Defendant Actavis Laboratories UT, Inc.

13. On further information and belief, Defendant Watson Laboratories, Inc. regularly engages in patent litigation concerning FDA-approved branded drug products in this judicial district. *See, e.g., Takeda Pharma. USA., Inc. v. Watson Labs., Inc.*, No. 14-268; *Fresenius Kabi USA, LLC v. Watson Labs., Inc.*, No. 14-161; *Sanoji v. Watson Labs., Inc.*, No. 14-265.

14. On information and belief, Defendant Watson Laboratories, Inc. has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in

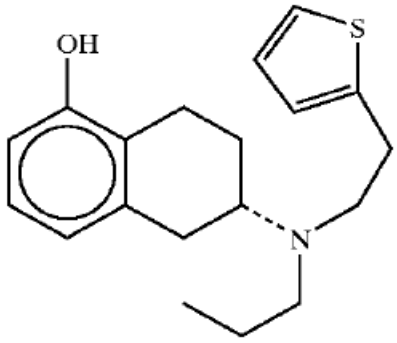
this Court. *See, e.g.*, *Takeda Pharma. USA., Inc. v. Watson Labs., Inc.*, No. 14-268; *Fresenius Kabi USA, LLC v. Watson Labs., Inc.*, No. 14-161.

15. On information and belief, this Court has personal jurisdiction over Defendant Actavis Laboratories UT, Inc. because, *inter alia*, the company is incorporated in the State of 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 ’498, ’434, ’747,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 March 2, 2004, the United States Patent and Trademark Office (“USPTO”) duly and lawfully issued the ’498 Patent, entitled “Transdermal Therapeutic Systems Having Improved Stability and Their Production.” A true and correct copy of the ’498 Patent is attached as Exhibit A.

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 B.

24. 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 C.

25. 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 D.

26. On July 31, 2012, the USPTO duly and lawfully issued the ’414 Patent, entitled “Polymorphic Form of Rotigotine and Process for Production.” A true and correct copy of the ’414 Patent is attached as Exhibit E.

27. On January 13, 2015, the USPTO duly and lawfully issued the ’665 Patent, entitled “Method for Preventing the Crystallisation of Pharmaceuticals in a Polymer Film.” A true and correct copy of the ’665 Patent is attached as Exhibit F.

28. Each of the ’498, ’434, ’747,’591, ’414, and ’665 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, Defendants submitted or caused to be submitted ANDA No. 206348 (“Watson 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 ’498, ’434, ’747, ’591, ’414, and ’665 Patents.

30. On information and belief, on or about July 8, 2014, Defendant Watson Laboratories, Inc. (Nevada) sent Plaintiffs a “Notification of Certification for U.S. Patent Nos. 6,699,498; 6,884,434; 7,413,747; 8,246,979; 8,246,980 and 8,617,591 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act” (“Notice Letter”). The Notice Letter represented that Defendant Watson Laboratories, Inc. (Nevada) had submitted to FDA the Watson ANDA and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Watson ANDA before the expiration of the patents listed in the Orange Book for NDA No. 021829. Hence, Defendants’

purpose in submitting the Watson ANDA is to manufacture and market the ANDA Products before the expiration of the '498, '434, '747,and '591 Patents. The Notice Letter also stated that the Paragraph IV certification alleges that the '498, '434, '747,and '591 Patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

31. On information and belief, Defendants have assisted with and participated in the preparation and submission of the Watson ANDA, have provided material support to the preparation and submission of the Watson ANDA, and intend to support the further prosecution of the Watson ANDA.

32. On information and belief, if FDA approves the Watson 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.

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

34. This action was 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 '498 PATENT

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

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

37. Defendants have infringed the ’498 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Watson ANDA with a Paragraph IV certification and seeking FDA approval of the Watson ANDA prior to the expiration of the ’498 Patent.

38. 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 ’498 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206348, 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 ’498 Patent.

39. Defendants had actual and constructive notice of the ’498 Patent prior to filing the Watson ANDA, and were aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the ’498 Patent would constitute an act of infringement of the ’498 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 ’498 Patent. In addition, Defendants filed the Watson ANDA without adequate justification for asserting the ’498 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 ’498 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 ’498 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 '434 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 submitted or caused the submission of the Watson ANDA to FDA, and continue to seek FDA approval of the Watson ANDA.

43. Defendants have infringed the '434 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Watson ANDA with a Paragraph IV certification and seeking FDA approval of the Watson ANDA prior to the expiration of the '434 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 '434 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206348, 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 '434 Patent.

45. On information and belief, upon FDA approval of ANDA No. 206348, 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.

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

47. 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 III: CLAIM FOR INFRINGEMENT OF THE ’747 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 Watson ANDA to FDA, and continue to seek FDA approval of the Watson ANDA.

50. Defendants have infringed the ’747 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Watson ANDA with a Paragraph IV certification and seeking FDA approval of the Watson ANDA prior to the expiration of the ’747 Patent.

51. 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 ’747 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206348, 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 ’747 Patent.

52. On information and belief, upon FDA approval of ANDA No. 206348, 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 ’747 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the ’747 Patent and knowledge that they are encouraging infringement.

53. Defendants had actual and constructive notice of the ’747 Patent prior to filing the Watson 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 Watson 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.

54. 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 IV: CLAIM FOR INFRINGEMENT OF THE '591 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 Watson ANDA to FDA, and continue to seek FDA approval of the Watson ANDA.

57. Defendants have infringed the '591 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Watson ANDA with a Paragraph IV certification and seeking FDA approval of the Watson ANDA prior to the expiration of the '591 Patent.

58. 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. 206348, 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.

59. On information and belief, upon FDA approval of ANDA No. 206348, 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 '591 Patent. In addition, on information and belief, Defendants will encourage acts of direct infringement with knowledge of the '591 Patent and knowledge that they are encouraging infringement.

60. Defendants had actual and constructive notice of the '591 Patent prior to filing the Watson 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 Watson 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.

61. 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.

COUNT V: CLAIM FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’414 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 Watson ANDA to FDA, and continue to seek FDA approval of the Watson ANDA.

64. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to commercially manufacture the ANDA Products prior to the expiration of the ’414 Patent.

65. Defendants’ commercial manufacture within the United States of the ANDA Products would infringe one or more claims of the ’414 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206348, Defendants will commercially manufacture the ANDA Products within the United States, and will thereby infringe one or more claims of the ’414 Patent.

66. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants’ commercial manufacture of the ANDA Products will infringe one or more claims of the ’414 Patent.

67. Plaintiffs should be granted a declaratory judgment that the commercial manufacture of the ANDA Products would infringe one or more claims of the ’414 Patent.

68. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’414 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 VI: CLAIM FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’665 PATENT

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

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

71. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to commercially manufacture the ANDA Products prior to the expiration of the ’665 Patent.

72. Defendants’ commercial manufacture within the United States of the ANDA Products would infringe one or more claims of the ’665 Patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 206348, Defendants will commercially manufacture the ANDA Products within the United States, and will thereby infringe one or more claims of the ’665 Patent.

73. Accordingly, there is a real, substantial, and continuing case or controversy between Plaintiffs and Defendants regarding whether Defendants’ commercial manufacture of the ANDA Products will infringe one or more claims of the ’665 Patent.

74. Plaintiffs should be granted a declaratory judgment that the commercial manufacture of the ANDA Products would infringe one or more claims of the ’665 Patent.

75. Plaintiffs will be irreparably harmed if Defendants are not enjoined from infringing the ’665 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. 206348 to FDA seeking to market the Watson ANDA Products, have infringed the ’498, ’434, ’747,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 Watson ANDA, or inducing or contributing to such conduct, would constitute infringement of the ’498, ’434, ’747,’591, ’414, and ’665 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 ’498, ’434, ’747, ’591, ’414, and ’665 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. 206348 shall be a date that is not earlier than the last expiration date of any of the ’498, ’434, ’747,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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