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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

NOVEN THERAPEUTICS, LLC Plaintiff, vs. ACTAVIS LABORATORIES FL, INC., ACTAVIS PHARMA, INC., ANDRX CORP., and ACTAVIS, INC., Defendants.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Noven Therapeutics, LLC ("Noven" or "Plaintiff"), in its Complaint of patent infringement against Defendants Actavis Laboratories FL, Inc., Actavis Pharma, Inc., Andrx Corp., and Actavis, Inc. (collectively, "Actavis" or "Defendants"), states as follows:

THE PARTIES

1. Noven is a Delaware limited liability company with a principal place of business at 11960 S.W. 144th Street, Miami, Florida 33186.

2. Upon information and belief, defendant Actavis Laboratories FL, Inc. is a Florida corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Upon information and belief, defendant Actavis Laboratories FL, Inc. is in the business of preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the state of New Jersey.

4. Upon information and belief, defendant Actavis Pharma, Inc. is a Delaware corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

5. Upon information and belief, defendant Actavis Pharma, Inc. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

6. Upon information and belief, defendant Andrx Corp. is a Delaware corporation with a principal place of business at 4955 Orange Drive, Davie, FL 33314.

7. Upon information and belief, defendant Andrx Corp. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

8. Upon information and belief, defendant Actavis, Inc. is a Nevada corporation with a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. Upon information and belief, defendant Actavis, Inc. is in the business of marketing and distributing pharmaceutical products throughout the United States, including the state of New Jersey. Said pharmaceutical products include those products prepared by defendant Actavis Laboratories FL, Inc.

10. Upon information and belief, defendant Actavis Laboratories FL, Inc. is a wholly-owned subsidiary of defendant Andrx Corp. In turn, upon information and belief, defendants Andrx Corp. and Actavis Pharma, Inc. are wholly-owned subsidiaries of defendant Actavis, Inc.

NATURE OF THE ACTION

11. This is a civil action for patent infringement of U.S. Patent Nos. 5,874,447 (the "'447 patent"), 7,598,271 (the "'271 patent"), and 8,658,663 (the "'663 patent") (collectively, the "patents-in-suit"), arising under the United States Patent Laws, Title 35, United States Code § 100, *et. seq.*, and in particular under 35 U.S.C. § 271. This action relates to Abbreviated New Drug Application ("ANDA") No. 207139, which Defendants filed or caused to be filed under 21 U.S.C. § 355(j) with the United States Food and Drug Administration ("FDA"), for approval to market a generic copy of Noven's BRISDELLE® product, which is sold in the United States.

JURISDICTION AND VENUE

12. This is a civil action for patent infringement and declaratory judgment arising 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.

13. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. This Court has personal jurisdiction over Defendants by virtue of their specific acts in, and their systematic and continuous contacts with, the State of New Jersey.

15. Upon information and belief, Actavis Laboratories FL, Inc., Actavis Pharma, Inc., and Actavis, Inc. have their principal place of business in Parsippany, New Jersey.

16. Upon information and belief, Defendants are registered to do business in the state of New Jersey, and purposefully avail themselves of this forum by making, using, importing,

selling or offering to sell pharmaceutical products in the state of New Jersey, or causing others to do the same, and therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts.

17. Upon information and belief, Actavis, Inc., the parent company of the other Defendants in this matter, holds a current and valid New Jersey "Wholesale Drug & Medical Devices" registration, No. 5003854.

18. Upon information and belief, Defendants collectively share common directors, officers, and facilities, operate as agents of each other, and act in concert in the design, development, manufacture, distribution, and sale of pharmaceutical products throughout the United States, including New Jersey.

19. Upon information and belief, Defendants collectively participated in the preparation, development and filing of ANDA No. 207139 and its underlying subject matter, which occurred in the state of New Jersey.

20. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

21. The '447 patent, entitled "4-Phenylpiperidine Compounds for Treating Depression," was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 23, 1999. Noven is the owner of all title, right, and interest in and to the '447 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '447 patent is attached as Exhibit A.

22. The '271 patent, entitled "Crystalline Paroxetine Methane Sulfonate," was duly and legally issued by the USPTO on October 6, 2009 and a certificate of correction was issued on May 17, 2011. Noven is the owner of all title, right, and interest in and to the '271 patent by

assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '271 patent and certificate of correction is attached as Exhibit B.

23. The '663 patent, entitled "Method of Treating Thermoregulatory Dysfunction With Paroxetine," was duly and legally issued by the USPTO on February 25, 2014 and a certificate of correction was issued on October 7, 2014. Noven is the owner of all title, right, and interest in and to the '663 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A copy of the '663 patent and certificate of correction is attached as Exhibit C.

24. Noven is the holder of New Drug Application ("NDA") No. 204516 for the manufacture and sale of paroxetine mesylate capsules, which Noven markets and sells under the registered trademark BRISDELLE®. Pursuant to Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(1) ("FFD&C Act") and corresponding FDA regulations, Noven has listed the patents-in-suit in the FDA's Orange Book as covering the BRISDELLE® drug and methods for using it.

25. Upon information and belief, pursuant to FFD&C Act 21 U.S.C. § 505(j), Defendants filed ANDA No. 207139 with the FDA. Defendants' ANDA seeks FDA approval to market and sell within the United States a generic 7.5 mg paroxetine mesylate capsule product (the "generic product") prior to the expiration of the patents-in-suit.

26. Upon information and belief, Defendants' ANDA No. 207139 identified Noven's BRISDELLE® product and included a written certification, as required by FFD&C Act 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (the "Paragraph IV certification"), alleging that the claims of the patents-in-suit are invalid or otherwise will not be infringed by Defendants' generic product.

27. On or about September 4, 2014, Noven received a letter from Defendants purporting to be a written notice that Defendants have filed ANDA No. 207139 prior to the expiration of the patents-in-suit, pursuant to FFD&C Act 21 U.S.C. § 505(j)(2)(B)(iv) (the "Paragraph IV letter"). The Paragraph IV letter included notice of Defendants' allegations that the patents-in-suit are invalid, unenforceable and/or not infringed by Defendants' generic product.

28. Defendants' submission of ANDA No. 207139, including the Paragraph IV certification, to the FDA constitutes infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2). Moreover, Defendants' anticipated commercial manufacture, use, sale, offer for sale, or importation of the generic product will infringe the patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c).

29. Noven commenced this action within 45 days of receiving Defendants' Paragraph IV letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 5,874,447

30. Paragraphs 1-29 are incorporated by reference as though fully set forth herein.

31. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '447 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

32. Upon information and belief, Defendants will infringe the '447 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

33. Upon information and belief, Defendants will induce infringement of the '447 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '447 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

34. Upon information and belief, Defendants will contributorily infringe the '447 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '447 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

35. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '447 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

36. Upon information and belief, Defendants were aware of the '447 patent prior to filing ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '447 patent.

COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 5,874,447

37. Paragraphs 1-36 are incorporated by reference as though fully set forth herein.

38. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

39. There is an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

40. Defendants have made, and will continue to make, substantial preparation in the United States, including New Jersey, to manufacture, use, sell, offer to sell, or import the generic product upon the FDA's approval of ANDA No. 207139.

41. Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '447 patent will constitute direct, induced, and contributory infringement of said patent.

42. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '447 patent will constitute direct, induced, and contributory infringement of the '447 patent.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,598,271

43. Paragraphs 1-42 are incorporated by reference as though fully set forth herein.

44. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '271 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

45. Upon information and belief, Defendants will infringe the '271 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

46. Upon information and belief, Defendants will induce infringement of the '271 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '271 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

47. Upon information and belief, Defendants will contributorily infringe the '271 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '271 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

48. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '271 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

49. Upon information and belief, Defendants were aware of the '271 patent prior to filing ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '271 patent.

COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 7,598,271

50. Paragraphs 1-49 are incorporated by reference as though fully set forth herein.

51. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

52. There is an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

53. Defendants have made, and will continue to make, substantial preparation in the United States, including New Jersey, to manufacture, use, sell, offer to sell, or import the generic product upon the FDA's approval of ANDA No. 207139.

54. Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '271 patent will constitute direct, induced, and contributory infringement of said patent.

55. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '271 patent will constitute direct, induced, and contributory infringement of the '271 patent.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 8,658,663

56. Paragraphs 1-55 are incorporated by reference as though fully set forth herein.

57. Defendants' submission of ANDA No. 207139 and its Paragraph IV certification for FDA approval to commercially manufacture, use, sell, offer to sell, or import the generic product prior to the expiration of the '663 patent constitutes infringement under 35 U.S.C. § 271(e)(2).

58. Upon information and belief, Defendants will infringe the '663 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing the generic product in the United States upon the FDA's approval of ANDA No. 207139.

59. Upon information and belief, Defendants will induce infringement of the '663 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding and abetting acts of direct infringement of the '663 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 207139.

60. Upon information and belief, Defendants will contributorily infringe the '663 patent under 35 U.S.C. § 271(c) by making, using, selling, offering to sell, or importing the generic product in the United States, with knowledge of the '663 patent and that there is no substantial non-infringing use of the generic product, upon the FDA's approval of ANDA No. 207139.

61. Pursuant to 35 U.S.C. § 283 and 35 U.S.C. § 271(e)(4)(B), Noven is entitled to a permanent injunction against further infringement. Noven will be substantially and irreparably harmed if Defendants' direct, induced, and contributory infringement of the '663 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

62. Upon information and belief, Defendants were aware of the '663 patent prior to filing ANDA No. 207139, as well as the statutory provisions and regulations set forth in 21 U.S.C. § 355 and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that they would not be liable for infringing the '663 patent.

COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,658,663

63. Paragraphs 1-62 are incorporated by reference as though fully set forth herein.

64. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. There is an actual case or controversy such that the Court may hear Noven's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

66. Defendants have made, and will continue to make, substantial preparation in the United States, including New Jersey, to manufacture, use, sell, offer to sell, or import the generic product upon the FDA's approval of ANDA No. 207139.

67. Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '663 patent will constitute direct, induced, and contributory infringement of said patent.

68. Noven is entitled to a declaratory judgment that Defendants' anticipated manufacture, use, sale, offer to sell, or importation of the generic product prior to the expiration of the '663 patent will constitute direct, induced, and contributory infringement of the '663 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven respectfully prays for:

A. A judgment that Defendants have infringed the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 207139 under the FFD&C Act, and that the commercial manufacture, use, sale, offer for sale, and/or importation of the generic product before the expiration of the patents-in-suit will constitute acts of infringement of each of the patents-in-suit;

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 207139 shall be no earlier than the date on which the '447, '271, and '663 patents expire, including any regulatory extensions;

C. An injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, permanently enjoining Defendants, their officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, from engaging in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of any pharmaceutical product covered by any of the patents-in-suit;

D. A declaration under 28 U.S.C. § 2201 that if Defendants, their officers, agents, servants, employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert or participation with them or acting on their behalf, engage in the commercial manufacture, use, sale, offer to sell, and/or importation within the United States, of the generic products prior to the expiration of the patents-in-suit, such acts will constitute direct and/or indirect infringement of each of the patents-in-suit;

E. An award of damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) and/or § 284 as appropriate;

F. A finding that this is an exceptional case under 35 U.S.C. § 285, and that Noven be awarded reasonable attorneys' fees and costs; and

G. An award of any such other and further relief as the Court may deem just and proper.

Dated: October 16, 2014

Respectfully submitted,

By: */s/ Anne B. Sekel*

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: October 16, 2014

Respectfully submitted,

By: */s/ Anne B. Sekel*

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