IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NOVEN PHARMACEUTICALS, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
ACTAVIS LABORATORIES UT, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Noven Pharmaceuticals, Inc. ("Noven" or "Plaintiff"), for its Complaint for Patent Infringement against Defendant Actavis Laboratories UT, Inc. ("Actavis" or "Defendant") alleges as follows:

THE PARTIES

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

2. Upon information and belief, Actavis is a Delaware corporation having a place of business at 577 South Chipeta Way, Salt Lake City, Utah 84108.

3. Upon information and belief, Actavis is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including Delaware.

NATURE OF THE ACTION

4. This is a civil action for infringement of U.S. Patent Nos. 9,730,900 ("the '900 patent"), 9,724,310 ("the '310 patent"), and 9,833,419 ("the '419 patent") (collectively, "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.

5. This action relates to Abbreviated New Drug Application ("ANDA") Nos. 208893 and 206202, which Actavis filed or caused to be filed with the United States Food and Drug Administration ("FDA") under Federal Food, Drug, and Cosmetic Act ("FFD&C Act") § 505(j) (21 U.S.C. § 355(j)), for approval to market a generic copy of Noven's Minivelle® product (Estradiol Transdermal System) in a dosage strength of 0.025 mg/day (ANDA No. 208893) ("Actavis's 208893 ANDA Product"), as well as 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths (ANDA No. 206202) ("Actavis's 206202 ANDA Product") (collectively, "Actavis's ANDA Products"), throughout the United States.

6. Actavis's ANDA Nos. 208893 and 206202 are the subject of pending related actions, *Noven Pharms., Inc. v. Actavis Labs. UT, Inc.*, C.A. No. 15-249-LPS (D. Del.) and *Noven Pharms., Inc. v. Actavis Labs. UT, Inc.*, C.A. No. 16-465-LPS (D. Del.), which involve allegations by Noven that ANDA Nos. 208893 and 206202 infringe Noven's U.S. Patent No. 8,231,906, the parent patent to the patents-in-suit. On December 22, 2017, the Court issued an Order in C.A. No. 15-249-LPS (D. Del.) finding that Actavis had failed to prove that the asserted claims of U.S. Patent No. 8,231,906 were invalid due to obviousness.

JURISDICTION AND VENUE

7. This is a civil action for infringement arising under the Patent Laws of the United States, including 35 U.S.C. § 271.

8. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. Actavis is incorporated and resides in the State of Delaware for purposes of 28 U.S.C. § 1400(b).

11. This Court has personal jurisdiction over Actavis because, *inter alia*, Actavis, on information and belief: (1) has substantial, continuous, and systematic contacts with the State of Delaware; (2) intends to market, sell, and/or distribute Actavis's ANDA Products to the residents of the State of Delaware; (3) maintains a broad distribution network within this State; and/or (4) enjoys substantial income from sales of its generic pharmaceutical products in this State.

12. In addition, this Court has personal jurisdiction over Actavis by virtue of the fact that Actavis has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement, which has led to foreseeable harm and injury to Noven, which is incorporated in and exists under the laws of the State of Delaware.

13. Upon information and belief, Actavis has purposefully availed itself of this forum by making, using, importing, selling or offering to sell pharmaceutical products in the State of Delaware, or causing others to do the same, and therefore can reasonably expect to be subject to jurisdiction in the Delaware courts.

14. Upon information and belief, Actavis has substantial, continuous, and systematic contacts with the State of Delaware including Actavis's engagement in direct marketing, distribution, and/or sale of generic pharmaceutical drugs within the State of Delaware.

15. Upon information and belief, Actavis, and/or its subsidiaries, affiliates or agents, intends to engage in the commercial manufacture and sale of Actavis's ANDA Products, if approved by the FDA, before the expiration of the patents-in-suit throughout the United States, including in this Judicial District, and to derive substantial revenue therefrom.

16. Upon information and belief, Actavis, and/or its subsidiaries, affiliates or agents, intends to place Actavis's ANDA Products into the stream of commerce with the reasonable expectation or knowledge and the intent that such product will be purchased and used by consumers in this Judicial District.

17. Upon information and belief, Actavis regularly conducts and/or solicits business in the State of Delaware, engages in other persistent courses of conduct in this State, and/or derives substantial revenues from the services or products used or consumed in the State of Delaware.

18. Additionally, the business of Actavis involves challenging patents held by branded pharmaceutical companies, including in this Judicial District. Actavis has consented to jurisdiction and venue in this Court, and availed itself of the protections afforded by this Court, including by asserting claims and counterclaims in this Court.

19. Actavis has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted claims and counterclaims in this jurisdiction, including, *inter alia*, in the matters of *Actavis Labs. UT, Inc. v. Par Pharm., Inc.*, No. 15-0886 (D. Del.); *Noven Pharms., Inc. et al. v. Actavis Labs. UT, Inc.*, No. 15-249 (D. Del.); *Altergon SA et al. v. Actavis Labs. UT, Inc.*, No. 15-0883 (D. Del.); *LEO Pharma A/S et al. v. Actavis Labs. UT, Inc.*, No. 17-1752 (D. Del.); *Prostrakan, Inc. et al. v. Actavis Labs. UT, Inc.*, No. 16-0015 (D. Del.); *Shionogi Inc. et al. v. Actavis Labs. UT, Inc.*, No. 16-0606 (D. Del.); *Indivior Inc. et al. v. Actavis Labs. UT, Inc.*, No. 18-0497 (D. Del.).

20. Upon information and belief, Actavis holds a current and valid Delaware "Wholesale" pharmacy drug registration under License No. A4-0001263 (expires September 30, 2018).

21. Upon information and belief, Actavis participated in the preparation, development, and filing of ANDA Nos. 208893 and 206202, and their underlying subject matter, with the intent to market, sell, and/or distribute Actavis's ANDA Products to the residents of the State of Delaware. Plaintiff's cause of action arose from Actavis's contact with the State of Delaware.

MINIVELLE®

22. Plaintiff Noven Pharmaceuticals, Inc. is the holder of New Drug Application ("NDA") No. 203752 for the manufacture and sale of estradiol transdermal system, 0.025 mg/day, 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day, and sells the product in the United States under the registered trademark Minivelle®.

23. The FDA approved NDA No. 203752 for the 0.0375 mg/day, 0.05 mg/day, 0.075 mg/day, and 0.1 mg/day dosage strengths on October 29, 2012, and the 0.025 mg/day dosage strength on September 23, 2014.

24. Plaintiff Noven Pharmaceuticals, Inc. sells and distributes Minivelle® throughout the United States pursuant to NDA No. 203752.

25. Minivelle® is indicated for the treatment of moderate to severe vasomotor symptoms (also known as "hot flashes") due to menopause and for the prevention of post-menopausal osteoporosis. A copy of the September 23, 2014 Minivelle® Label is attached as Exhibit A.

PATENTS-IN-SUIT

26. The '900 patent, entitled "Transdermal Estrogen Device and Delivery" was duly and legally issued by the United States Patent and Trademark Office on August 15, 2017. Noven is the owner of all right, title, and interest in and to the '900 patent by assignment and therefore

has the full right to sue and recover for the infringement thereof. A certified copy of the '900 patent is attached as Exhibit B.

27. Pursuant to FFD&C Act § 505(b)(1) (21 U.S.C. § 355(b)(1)) and corresponding FDA regulations, Noven has submitted information concerning the '900 patent to the FDA in connection with NDA No. 203752, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '900 patent has been listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering Minivelle® and methods for using it.

28. Claim 1 of the '900 patent is directed, *inter alia*, to a method for administering estradiol, comprising applying to the skin or mucosa of a subject in need thereof a monolithic transdermal drug delivery system consisting of (i) a backing layer and (ii) a single adhesive polymer matrix layer defining an active surface area and comprising an adhesive polymer matrix comprising estradiol as the only drug, wherein the polymer matrix has a coat weight of greater than about 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm^2/day, based on the active surface area.

29. The approved Minivelle® product labeling instructs medical personnel and/or patients to perform the steps of the claimed method of the '900 patent.

30. The use of Minivelle® in accordance with its approved product labeling by medical personnel and/or patients necessarily results in the performance of each of the claimed method steps of the '900 patent.

31. The ’310 patent, entitled “Transdermal Estrogen Device and Delivery” was duly and legally issued by the United States Patent and Trademark Office on August 8, 2017. Noven is the owner of all right, title, and interest in and to the ’310 patent by assignment and therefore has the full right to sue and recover for the infringement thereof. A certified copy of the ’310 patent is attached as Exhibit C.

32. Pursuant to FFD&C Act § 505(b)(1) (21 U.S.C. § 355(b)(1)) and corresponding FDA regulations, Noven has submitted information concerning the ’310 patent to the FDA in connection with NDA No. 203752, identifying it as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” The ’310 patent has been listed in the FDA’s Orange Book as covering Minivelle® and methods for using it.

33. Claim 1 of the ’310 patent is directed, *inter alia*, to a monolithic transdermal drug delivery system for estradiol, consisting of (i) a backing layer, (ii) a single adhesive polymer matrix layer defining an active surface area and, optionally, (iii) a release liner, wherein the single adhesive polymer matrix layer comprises an adhesive polymer matrix comprising estradiol as the only drug, wherein the adhesive polymer matrix layer has a coat weight of greater than about 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from about 0.0125 to about 0.05 mg/cm^2/day, based on the active surface area.

34. The Minivelle® product and its approved labeling describe a product that embodies at least one claim of the ’310 patent.

35. The ’419 patent, entitled “Transdermal Estrogen Device and Delivery” was duly and legally issued by the United States Patent and Trademark Office on December 5, 2017. Noven is the owner of all right, title, and interest in and to the ’419 patent by assignment and

therefore has the full right to sue and recover for the infringement thereof. A certified copy of the '419 patent is attached as Exhibit D.

36. Pursuant to FFD&C Act § 505(b)(1) (21 U.S.C. § 355(b)(1)) and corresponding FDA regulations, Noven has submitted information concerning the '419 patent to the FDA in connection with NDA No. 203752, identifying it as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." The '419 patent has been listed in the FDA's Orange Book as covering Minivelle® and methods for using it.

37. Claim 1 of the '419 patent is directed, *inter alia*, to a monolithic transdermal drug delivery system for estradiol, consisting of (i) a backing layer, (ii) a single adhesive polymer matrix layer defining an active surface area and, optionally, (iii) a release liner, wherein the single adhesive polymer matrix layer comprises an adhesive polymer matrix comprising estradiol as the only drug, wherein the adhesive polymer matrix layer has a coat weight of greater than 10 mg/cm^2 and includes greater than 0.156 mg/cm^2 estradiol, and the system achieves an estradiol flux of from 0.0125 to about 0.05 $mg/cm^2/day$, based on the active surface area.

38. The Minivelle® product and its approved labeling describe a product that embodies at least one claim of the '419 patent.

ACTAVIS'S ANDA PRODUCTS

39. Upon information and belief, pursuant to FFD&C Act § 505(j) (21 U.S.C. 355(j)), Actavis submitted ANDA Nos. 208893 and 206202 to the FDA seeking approval in each to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Actavis's ANDA Products within the United States prior to the expiration of the '900, '310, and '419 patents.

40. Upon information and belief, Actavis's ANDA Nos. 208893 and 206202 each identified Noven's Minivelle® product and each included a written certification, as required by the FFD&C Act § 505(j)(2)(A)(vii)(IV) (21 U.S.C. § 355(j)(2)(A)(vii)(IV)) (the "Paragraph IV certification"), alleging that the claims of the '900, '310, and '419 patents are invalid or otherwise will not be infringed by Actavis's ANDA Products.

41. On or about February 27, 2018, Noven received a letter from Actavis purporting to be a written notice that Actavis had filed ANDA Nos. 208893 and 206202 seeking approval to market Actavis's ANDA Products prior to the expiration of the '900, '310, and '419 patents, pursuant to FFD&C Act § 505(j)(2)(B)(iv) (21 U.S.C. § 355(j)(2)(B)(iv)) (the "Paragraph IV notice letter"). The Paragraph IV notice letter included notice of Actavis's allegations that the '900, '310, and '419 patents are not valid, unenforceable, or will not be infringed by Actavis's ANDA Products.

42. Actavis's submission of ANDA No. 208893, including the Paragraph IV certification, to the FDA constituted infringement of the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2).

43. Actavis's submission of ANDA No. 206202, including the Paragraph IV certification, to the FDA constituted infringement of the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2).

44. Actavis's anticipated commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's ANDA Products upon approval and before expiration of the '900, '310, and '419 patents will infringe at least claim 1 of the '900 patent, at least claim 1 of the '310 patent, and at least claim 1 of the '419 under 35 U.S.C. § 271(a), (b), and/or (c).

COUNT I – INFRINGEMENT OF U.S. PATENT NO. 9,730,900 BY ACTAVIS'S 208893 ANDA PRODUCT

45. Paragraphs 1-44 are incorporated by reference as though fully set forth herein.

46. Administration of Noven's Minivelle® Estradiol Transdermal System according to the approved Minivelle® product labeling satisfies at least claim 1 of the '900 patent.

47. Upon information and belief, Actavis's 208893 ANDA Product has the same use as Minivelle®, at least because Actavis's ANDA No. 208893 refers to and relies upon Plaintiff's NDA No. 203752 for Minivelle®.

48. Upon information and belief, the proposed product labeling for Actavis's 208893 ANDA Product is substantially the same as the approved product labeling for Minivelle®.

49. Upon information and belief, Actavis's 208893 ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Minivelle®.

50. Upon information and belief, Actavis's 208893 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '900 patent.

51. Actavis's submission of ANDA No. 208893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 208893 ANDA Product prior to the expiration of the '900 patent constitutes infringement of at least claim 1 of the '900 patent under 35 U.S.C. § 271(e)(2).

52. Upon information and belief, Actavis will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Actavis's 208893 ANDA Product in the United States upon the FDA's approval of ANDA No. 208893.

53. Upon information and belief, Actavis will infringe at least claim 1 of the ’900 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the ’900 patent, with knowledge of said patent and said infringement, upon the FDA’s approval of ANDA No. 208893.

54. Upon information and belief, the proposed product labeling for Actavis’s 208893 ANDA Product will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the ’900 patent.

55. Upon information and belief, the use of Actavis’s 208893 ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the ’900 patent.

56. Upon information and belief, Actavis specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Actavis knows infringe at least claim 1 of the ’900 patent.

57. Upon information and belief, Actavis will infringe at least claim 1 of the ’900 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis’s 208893 ANDA Product in the United States, with knowledge of the ’900 patent and that there is no substantial non-infringing use of Actavis’s 208893 ANDA Product, upon the FDA’s approval of ANDA No. 208893.

58. Upon information and belief, Actavis knows that Actavis’s 208893 ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the ’900 patent.

59. Actavis's 208893 ANDA Product constitutes a material part of the invention covered by the claims of the '900 patent.

60. 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 Actavis's infringement of the '900 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

61. Upon information and belief, Actavis was aware of the '900 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (21 U.S.C. § 355) and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '900 patent.

COUNT II – INFRINGEMENT OF U.S. PATENT NO. 9,724,310 BY ACTAVIS'S 208893 ANDA PRODUCT

62. Paragraphs 1-61 are incorporated by reference as though fully set forth herein.

63. Noven's Minivelle® Estradiol Transdermal System satisfies at least claim 1 of the '310 patent.

64. Upon information and belief, Actavis's 208893 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '310 patent.

65. Actavis's submission of ANDA No. 208893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 208893 ANDA Product prior to the expiration of the '310 patent constitutes infringement of at least claim 1 of the '310 patent under 35 U.S.C. § 271(e)(2).

66. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing

Actavis's 208893 ANDA Product in the United States upon the FDA's approval of ANDA No. 208893.

67. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '310 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 208893.

68. Upon information and belief, the use of Actavis's 208893 ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '310 patent.

69. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 208893 ANDA Product in the United States, with knowledge of the '310 patent and that there is no substantial non-infringing use of Actavis's 208893 ANDA Product, upon the FDA's approval of ANDA No. 208893.

70. Upon information and belief, Actavis knows that Actavis's 208893 ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '310 patent.

71. Actavis's 208893 ANDA Product constitutes a material part of the invention covered by the claims of the '310 patent.

72. 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 Actavis's infringement of the '310 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

73. Upon information and belief, Actavis was aware of the '310 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (21 U.S.C. § 355) and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '310 patent.

COUNT III – INFRINGEMENT OF U.S. PATENT NO. 9,833,419 BY ACTAVIS'S 208893 ANDA PRODUCT

74. Paragraphs 1-73 are incorporated by reference as though fully set forth herein.

75. Noven's Minivelle® Estradiol Transdermal System satisfies at least claim 1 of the '419 patent.

76. Upon information and belief, Actavis's 208893 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '419 patent.

77. Actavis's submission of ANDA No. 208893 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 208893 ANDA Product prior to the expiration of the '419 patent constitutes infringement of at least claim 1 of the '419 patent under 35 U.S.C. § 271(e)(2).

78. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Actavis's 208893 ANDA Product in the United States upon the FDA's approval of ANDA No. 208893.

79. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct

infringement of the ’419 patent, with knowledge of said patent and said infringement, upon the FDA’s approval of ANDA No. 208893.

80. Upon information and belief, the use of Actavis’s 208893 ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the ’419 patent.

81. Upon information and belief, Actavis will infringe at least claim 1 of the ’419 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis’s 208893 ANDA Product in the United States, with knowledge of the ’419 patent and that there is no substantial non-infringing use of Actavis’s 208893 ANDA Product, upon the FDA’s approval of ANDA No. 208893.

82. Upon information and belief, Actavis knows that Actavis’s 208893 ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the ’419 patent.

83. Actavis’s 208893 ANDA Product constitutes a material part of the invention covered by the claims of the ’419 patent.

84. 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 Actavis’s infringement of the ’419 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

85. Upon information and belief, Actavis was aware of the ’419 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (21 U.S.C. § 355) and 21 C.F.R. § 314.95, and acted

without a reasonable basis for a good faith belief that it would not be liable for infringing the '419 patent.

COUNT IV – INFRINGEMENT OF U.S. PATENT NO. 9,730,900 BY ACTAVIS'S 206202 ANDA PRODUCT

86. Paragraphs 1-85 are incorporated by reference as though fully set forth herein.

87. Administration of Noven's Minivelle® Estradiol Transdermal System according to the approved Minivelle® product labeling satisfies at least claim 1 of the '900 patent.

88. Upon information and belief, Actavis's 206202 ANDA Product has the same use as Minivelle®, at least because Actavis's ANDA No. 206202 refers to and relies upon Plaintiff's NDA No. 203752 for Minivelle®.

89. Upon information and belief, the proposed product labeling for Actavis's 206202 ANDA Product is substantially the same as the approved product labeling for Minivelle®.

90. Upon information and belief, Actavis's 206202 ANDA Product, if approved by the FDA, will be administered by medical personnel and/or patients in the same manner as Minivelle®.

91. Upon information and belief, Actavis's 206202 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '900 patent.

92. Actavis's submission of ANDA No. 206202 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 206202 ANDA Product prior to the expiration of the '900 patent constitutes infringement of at least claim 1 of the '900 patent under 35 U.S.C. § 271(e)(2).

93. Upon information and belief, Actavis will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing

Actavis's 206202 ANDA Product in the United States upon the FDA's approval of ANDA No. 206202.

94. Upon information and belief, Actavis will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '900 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206202.

95. Upon information and belief, the proposed product labeling for Actavis's 206202 ANDA will instruct medical personnel and/or patients to perform the steps of at least claim 1 of the '900 patent.

96. Upon information and belief, the use of Actavis's 206202 ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '900 patent.

97. Upon information and belief, Actavis specifically intends to cause others, specifically for example, medical personnel and/or patients, to perform acts that Actavis knows infringe at least claim 1 of the '900 patent.

98. Upon information and belief, Actavis will infringe at least claim 1 of the '900 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 206202 ANDA Product in the United States, with knowledge of the '900 patent and that there is no substantial non-infringing use of Actavis's 206202 ANDA Product, upon the FDA's approval of ANDA No. 206202.

99. Upon information and belief, Actavis knows that Actavis's 206202 ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '900 patent.

100. Actavis's 206202 ANDA Product constitutes a material part of the invention covered by the claims of the '900 patent.

101. 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 Actavis's infringement of the '900 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

102. Upon information and belief, Actavis was aware of the '900 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (21 U.S.C. § 355) and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '900 patent.

COUNT V – INFRINGEMENT OF U.S. PATENT NO. 9,724,310 BY ACTAVIS'S 206202 ANDA PRODUCT

103. Paragraphs 1-102 are incorporated by reference as though fully set forth herein.

104. Noven's Minivelle® Estradiol Transdermal System satisfies at least claim 1 of the '310 patent.

105. Upon information and belief, Actavis's 206202 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '310 patent.

106. Actavis's submission of ANDA No. 206202 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's

206202 ANDA Product prior to the expiration of the '310 patent constitutes infringement of at least claim 1 of the '310 patent under 35 U.S.C. § 271(e)(2).

107. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing Actavis's 206202 ANDA Product in the United States upon the FDA's approval of ANDA No. 206202.

108. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '310 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206202.

109. Upon information and belief, the use of Actavis's 206202 ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '310 patent.

110. Upon information and belief, Actavis will infringe at least claim 1 of the '310 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 206202 ANDA Product in the United States, with knowledge of the '310 patent and that there is no substantial non-infringing use of Actavis's 206202 ANDA Product, upon the FDA's approval of ANDA No. 206202.

111. Upon information and belief, Actavis knows that Actavis's 206202 ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '310 patent.

112. Actavis's 206202 ANDA Product constitutes a material part of the invention covered by the claims of the '310 patent.

113. 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 Actavis's infringement of the '310 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

114. Upon information and belief, Actavis was aware of the '310 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (21 U.S.C. § 355) and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '310 patent.

COUNT VI – INFRINGEMENT OF U.S. PATENT NO. 9,833,419 BY ACTAVIS'S 206202 ANDA PRODUCT

115. Paragraphs 1-114 are incorporated by reference as though fully set forth herein.

116. Noven's Minivelle® Estradiol Transdermal System satisfies at least claim 1 of the '419 patent.

117. Upon information and belief, Actavis's 206202 ANDA Product, or the use or manufacture thereof, is covered by at least claim 1 of the '419 patent.

118. Actavis's submission of ANDA No. 206202 and its Paragraph IV certification seeking FDA approval to commercially manufacture, use, sell, offer to sell, or import Actavis's 206202 ANDA Product prior to the expiration of the '419 patent constitutes infringement of at least claim 1 of the '419 patent under 35 U.S.C. § 271(e)(2).

119. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(a) by making, using, selling, offering to sell, or importing

Actavis's 206202 ANDA Product in the United States upon the FDA's approval of ANDA No. 206202.

120. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(b) by intentionally encouraging, aiding, and abetting acts of direct infringement of the '419 patent, with knowledge of said patent and said infringement, upon the FDA's approval of ANDA No. 206202.

121. Upon information and belief, the use of Actavis's 206202 ANDA Product, if approved and when administered by medical personnel and/or patients, in accordance with the proposed labeling, will induce medical personnel and/or patients to infringe at least claim 1 of the '419 patent.

122. Upon information and belief, Actavis will infringe at least claim 1 of the '419 patent under 35 U.S.C. § 271(c) by selling and offering to sell Actavis's 206202 ANDA Product in the United States, with knowledge of the '419 patent and that there is no substantial non-infringing use of Actavis's 206202 ANDA Product, upon the FDA's approval of ANDA No. 206202.

123. Upon information and belief, Actavis knows that Actavis's 206202 ANDA Product and its proposed labeling, if approved, will be specifically made or adapted for use in infringing one or more claims of the '419 patent.

124. Actavis's 206202 ANDA Product constitutes a material part of the invention covered by the claims of the '419 patent.

125. 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 Actavis's infringement of the '419 patent is not enjoined. Further, Noven does not have an adequate remedy at law.

126. Upon information and belief, Actavis was aware of the '419 patent prior to Actavis submitting its Paragraph IV certification, as well as the statutory provisions and regulations set forth in FFD&C Act § 505 (21 U.S.C. § 355) and 21 C.F.R. § 314.95, and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '419 patent.

PRAYER FOR RELIEF

WHEREFORE, Noven respectfully prays for:

A. A judgment that Actavis has infringed the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 208893 to the FDA;

B. A judgment that Actavis has infringed the '900, '310, and '419 patents under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206202 to the FDA;

C. A judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's 208893 ANDA Product before the expiration of the '900, '310, and '419 patents will constitute acts of infringement of the '900, '310, and '419 patents by Actavis;

D. A judgment that the commercial manufacture, use, sale, offer for sale, and/or importation of Actavis's 206202 ANDA Product before the expiration of the '900, '310, and '419 patents will constitute acts of infringement of the '900, '310, and '419 patents by Actavis;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 208893 shall be no earlier than the dates on which the '900, '310, and '419 patents expire, including any patent term and regulatory extensions;

F. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 206202 shall be no earlier than the dates on which the ’900, ’310, and ’419 patents expire, including any patent term and regulatory extensions;

G. An injunction under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283, permanently enjoining Actavis, its officers, agents, servants employees, licensees, representatives, attorneys, and all other persons acting or attempting to act in active concert in participation with it or acting on its 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 the ’900, ’310, and ’419 patents;

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

I. 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

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

ASHBY & GEDDES

/s/ Andrew C. Mayo

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John G. Day (#2403)
Andrew C. Mayo (#5207)
500 Delaware Avenue, 8th Floor
P.O. Box 1150
Wilmington, DE 19899
(302) 654-1888
jday@ashbygeddes.com
amayo@ashbygeddes.com

Attorneys for Noven Pharmaceuticals, Inc.

Of Counsel:

Liane M. Peterson
Ryan A. Schmid
FOLEY & LARDNER LLP
Washington Harbour
3000 K Street, N.W., Suite 600
Washington, DC 20007-5109
(202) 945-6116

Steven J. Rizzi
Ramy E. Hanna
Jayita Guhaniyogi, Ph.D.
FOLEY & LARDNER LLP
90 Park Avenue
New York, NY 10016
(212) 682-7474

R. Jan Pirozzolo-Mellowes
FOLEY & LARDNER LLP
777 East Wisconsin Avenue
Milwaukee, WI 53202-5306
(414) 297-2400

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