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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIVUS, INC., **Plaintiff,** **v.** **ACTAVIS LABORATORIES FL, INC., ACTAVIS, INC., and ACTAVIS PLC,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff VIVUS, Inc. ("VIVUS"), by its undersigned attorneys, for its Complaint against defendant Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis plc (collectively, "Actavis") alleges as follows:

Nature of the Action

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq.*, arising from Actavis Laboratories FL, Inc.'s filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market generic versions of VIVUS' QSYMIA® drug products prior to the expiration of United States Patent Nos. 7,056,890 (the "'890 patent"), 7,553,818 (the "'818 patent"), 7,659,256 (the "'256 patent"), 7,674,776 (the "'776

patent"), 8,580,298 (the "'298 patent"), and 8,580,299 (the "'299 patent") owned by VIVUS (collectively, "the patents-in-suit").

The Parties

2. Plaintiff VIVUS is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 351 E. Evelyn Avenue, Mountain View, California 94041.

3. On information and belief, defendant Actavis Laboratories FL, Inc. is a corporation organized and existing under the laws of the State of Florida, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. On information and belief, Actavis Laboratories FL, Inc. develops numerous generic drugs for sale and use throughout the United States, including in this judicial district.

5. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

6. On information and belief, defendant Actavis Laboratories FL, Inc. is a wholly-owned subsidiary of defendant Actavis, Inc.

7. On information and belief, defendant Actavis plc is a corporation organized and existing under the laws of Ireland, having a principal place of business at 1 Grand Canal Square, Docklands, Dublin 2, Ireland.

8. On information and belief, defendant Actavis, Inc. is a wholly-owned subsidiary of defendant Actavis plc.

9. On information and belief, the acts of Actavis Laboratories FL, Inc. complained of herein were done at the direction of, with the authorization of, or with the cooperation, participation, or assistance of, or at least in part for the benefit of, Actavis, Inc. and Actavis plc.

10. Actavis Laboratories FL, Inc., Actavis, Inc., and Actavis plc are referred to hereinafter, collectively, as "Actavis."

Jurisdiction and Venue

11. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

12. This Court has personal jurisdiction over Actavis by virtue of, *inter alia,* its systematic and continuous contacts with the State of New Jersey. On information and belief, Actavis has its principal place of business in Parsippany, New Jersey, conducts business in this District, and purposefully avails itself of this forum by, among other things, making, shipping, using, offering to sell or selling, or causing others to use, offer to sell, or sell, pharmaceutical products in the State of New Jersey and deriving revenue from such activities. Also, on information and belief, Actavis has customers in the State of New Jersey.

13. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400(b).

The Patent-In-Suit

14. On June 6, 2006, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '890 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '890 patent is attached hereto as Exhibit A.

15. On June 30, 2009, the USPTO duly and lawfully issued the '818 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '818 patent is attached hereto as Exhibit B.

16. On February 9, 2010, the USPTO duly and lawfully issued the '256 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '256 patent is attached hereto as Exhibit C.

17. On March 9, 2010, the USPTO duly and lawfully issued the '776 patent, entitled "Combination therapy for effecting weight loss and treating obesity" to VIVUS as assignee of the inventor Thomas Najarian. A copy of the '776 patent is attached hereto as Exhibit D.

18. On November 12, 2013, the USPTO duly and lawfully issued the '298 patent, entitled "Low dose topiramate/phentermine composition and methods of use thereof" to VIVUS as assignee of the inventors Thomas Najarian, Peter Y. Tam and Leland F. Wilson. A copy of the '298 patent is attached hereto as Exhibit E.

19. On November 12, 2013, the USPTO duly and lawfully issued the '299 patent, entitled "Escalating dosing regimen for effecting weight loss and treating obesity" to VIVUS as assignee of the inventors Thomas Najarian, Peter Y. Tam and Leland F. Wilson. A copy of the '299 patent is attached hereto as Exhibit F.

The QSYMIA® Drug Products

20. VIVUS holds an approved New Drug Application ("NDA") under Section 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), for phentermine and topiramate extended-release capsules (NDA No. 022580), which it sells under the trade name QSYMIA®. The claims of the patents-in-suit cover, *inter alia*, pharmaceutical compositions containing combinations of phentermine and topiramate, and methods of use and administration of combinations of phentermine and topiramate. VIVUS owns the patents-in-suit.

21. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit are listed in the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), with respect to QSYMIA®.

Acts Giving Rise to This Suit

22. Pursuant to Section 505 of the FFDCA, Actavis filed ANDA No. 204982 ("Actavis' ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale or importation of 15/92 mg, 11.25/69 mg, 7.5/46 mg, and 3.75/23 mg capsules containing as the active pharmaceutical ingredients, phentermine and topiramate extended-release ("Actavis' Proposed Product"), before the patents-in-suit expire.

23. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Actavis has provided a written certification to the FDA, as called for by Section 505 of the FFDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Actavis' Paragraph IV Certification"), alleging that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis' ANDA.

24. No earlier than May 6, 2014, VIVUS received written notice of Actavis' Paragraph IV Certification ("Actavis' Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Actavis' Notice Letter alleged that the claims of the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the activities described in Actavis' ANDA. Actavis' Notice Letter also informed VIVUS that Actavis seeks approval to market Actavis' Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '890 Patent

25. Plaintiff repeats and realleges the allegations of paragraphs 1-24 as though fully set forth herein.

26. Actavis' submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '890 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

27. There is a justiciable controversy between the parties hereto as to the infringement of the '890 patent.

28. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will infringe the '890 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States.

29. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will induce infringement of the '890 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, upon FDA approval of Actavis' ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '890 patent and knowledge that its acts are encouraging infringement.

30. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will contributorily infringe the '890 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis' Proposed Product is especially adapted for a use that infringes the '890 patent and that there is no substantial non-infringing use for Actavis' Proposed Product.

31. VIVUS will be substantially and irreparably damaged and harmed if Actavis' infringement of the '890 patent is not enjoined.

32. VIVUS does not have an adequate remedy at law.

33. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count II: Infringement of the '818 Patent

34. Plaintiff repeats and realleges the allegations of paragraphs 1-33 as though fully set forth herein.

35. Actavis' submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '818 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

36. There is a justiciable controversy between the parties hereto as to the infringement of the '818 patent.

37. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will infringe the '818 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States.

38. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will induce infringement of the '818 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, upon FDA approval of Actavis' ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '818 patent and knowledge that its acts are encouraging infringement.

39. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will contributorily infringe the '818 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information

and belief, Actavis has had and continues to have knowledge that Actavis' Proposed Product is especially adapted for a use that infringes the '818 patent and that there is no substantial non-infringing use for Actavis' Proposed Product.

40. VIVUS will be substantially and irreparably damaged and harmed if Actavis' infringement of the '818 patent is not enjoined.

41. VIVUS does not have an adequate remedy at law.

42. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count III: Infringement of the '256 Patent

43. Plaintiff repeats and realleges the allegations of paragraphs 1-42 as though fully set forth herein.

44. Actavis' submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '256 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

45. There is a justiciable controversy between the parties hereto as to the infringement of the '256 patent.

46. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will infringe the '256 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States.

47. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will induce infringement of the '256 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, upon FDA approval of Actavis' ANDA, Actavis will intentionally encourage acts of

direct infringement with knowledge of the '256 patent and knowledge that its acts are encouraging infringement.

48. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will contributorily infringe the '256 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis' Proposed Product is especially adapted for a use that infringes the '256 patent and that there is no substantial non-infringing use for Actavis' Proposed Product.

49. VIVUS will be substantially and irreparably damaged and harmed if Actavis' infringement of the '256 patent is not enjoined.

50. VIVUS does not have an adequate remedy at law.

51. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count IV: Infringement of the '776 Patent

52. Plaintiff repeats and realleges the allegations of paragraphs 1-51 as though fully set forth herein.

53. Actavis' submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '776 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

54. There is a justiciable controversy between the parties hereto as to the infringement of the '776 patent.

55. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will infringe the '776 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States.

56. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will induce infringement of the '776 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, upon FDA approval of Actavis' ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '776 patent and knowledge that its acts are encouraging infringement.

57. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will contributorily infringe the '776 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis' Proposed Product is especially adapted for a use that infringes the '776 patent and that there is no substantial non-infringing use for Actavis' Proposed Product.

58. VIVUS will be substantially and irreparably damaged and harmed if Actavis' infringement of the '776 patent is not enjoined.

59. VIVUS does not have an adequate remedy at law.

60. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count V: Infringement of the '298 Patent

61. Plaintiff repeats and realleges the allegations of paragraphs 1-60 as though fully set forth herein.

62. Actavis' submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '298 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

63. There is a justiciable controversy between the parties hereto as to the infringement of the '298 patent.

64. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will infringe the '298 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States.

65. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will induce infringement of the '298 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, upon FDA approval of Actavis' ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '298 patent and knowledge that its acts are encouraging infringement.

66. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will contributorily infringe the '298 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, Actavis has had and continues to have knowledge that Actavis' Proposed Product is especially adapted for a use that infringes the '298 patent and that there is no substantial non-infringing use for Actavis' Proposed Product.

67. VIVUS will be substantially and irreparably damaged and harmed if Actavis' infringement of the '298 patent is not enjoined.

68. VIVUS does not have an adequate remedy at law.

69. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

Count VI: Infringement of the '299 Patent

70. Plaintiff repeats and realleges the allegations of paragraphs 1-69 as though fully set forth herein.

71. Actavis' submission of its ANDA to obtain approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of phentermine and topiramate extended-release capsules, prior to the expiration of the '299 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

72. There is a justiciable controversy between the parties hereto as to the infringement of the '299 patent.

73. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will infringe the '299 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States.

74. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will induce infringement of the '299 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information and belief, upon FDA approval of Actavis' ANDA, Actavis will intentionally encourage acts of direct infringement with knowledge of the '299 patent and knowledge that its acts are encouraging infringement.

75. Unless enjoined by this Court, upon FDA approval of Actavis' ANDA, Actavis will contributorily infringe the '299 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Actavis' Proposed Product in the United States. On information

and belief, Actavis has had and continues to have knowledge that Actavis' Proposed Product is especially adapted for a use that infringes the '299 patent and that there is no substantial non-infringing use for Actavis' Proposed Product.

76. VIVUS will be substantially and irreparably damaged and harmed if Actavis' infringement of the '299 patent is not enjoined.

77. VIVUS does not have an adequate remedy at law.

78. This case is an exceptional one, and VIVUS is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff VIVUS respectfully requests the following relief:

(A) A Judgment be entered that Actavis has infringed the patents-in-suit by submitting ANDA No. 204982;

(B) A Judgment be entered that Actavis has infringed, and that Actavis' making, using, selling, offering to sell, or importing Actavis' Proposed Product will infringe one or more claims of the patents-in-suit;

(C) An Order that the effective date of FDA approval of ANDA No. 204982 be a date which is not earlier than the later of the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(D) Preliminary and permanent injunctions enjoining Actavis and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from making, using, selling, offering to sell, or importing Actavis' Proposed Product until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(E) A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Actavis, its officers, agents, attorneys and employees, and those acting

in privity or concert with them, from practicing any methods as claimed in the patents-in-suit, or from actively inducing or contributing to the infringement of any claim of the patents-in-suit, until after the expiration of the patents-in-suit, or any later expiration of exclusivity to which Plaintiff is or becomes entitled;

(F) A Declaration that the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis' Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Actavis has committed any acts with respect to the compositions and methods claimed in the patents-in-suit, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), that Plaintiff VIVUS be awarded damages for such acts;

(H) If Actavis engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Actavis' Proposed Product prior to the expiration of the patents-in-suit, a Judgment awarding damages to Plaintiff VIVUS resulting from such infringement, together with interest;

(I) Attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285;

(J) Costs and expenses in this action; and

(K) Such further and other relief as this Court may deem just and proper.

Dated: June 12, 2014

By: s/ Charles M. Lizza

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, 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: June 12, 2014

By: s/ Charles M. Lizza

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