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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIVUS, INC., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD.,** **Defendants.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT** **(Filed Electronically)**

Plaintiff VIVUS, Inc. ("VIVUS"), by its undersigned attorneys, for its Complaint against defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. (collectively, "Teva") 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 Teva'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"), 8,580,299 (the "'299 patent"), 8,895,057 (the "'057 patent"), and 8,895,058 (the "'058 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 Teva Pharmaceuticals USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

4. On information and belief, defendant Teva Pharmaceutical Industries Ltd. is an Israeli corporation having a principal place of business at 5 Basel Street, Petah Tikva 49131, Israel.

5. On information and belief, defendant Teva Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of defendant Teva Pharmaceutical Industries Ltd.

6. On information and belief, defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. manufacture and/or distribute generic drugs for sale and use throughout the United States, including in this Judicial District. On information and belief, defendants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries Ltd. also prepare and/or aid in the preparation and submission of ANDAs to the FDA.

7. On information and belief, the acts of Teva Pharmaceuticals USA, 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, Teva Pharmaceutical Industries Ltd.

Jurisdiction and Venue

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

9. This Court has personal jurisdiction over Teva Pharmaceuticals USA, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Pharmaceuticals USA, Inc. is registered to do business in the State of New Jersey under entity ID No. 0100250184. In addition, on information and belief, Teva Pharmaceuticals USA, Inc. has appointed a registered agent for service of process in New Jersey (Corporate Creations Network Inc., 811 Church Road #105, Cherry Hill, NJ 08002).

10. On information and belief, Teva Pharmaceuticals USA, Inc. holds licenses in the State of New Jersey as a "wholesaler" and "manufacturer and wholesaler" of drugs, with License Nos. 5003436 and 5000583, respectively. On information and belief, Teva Pharmaceuticals USA, Inc. employs people throughout the State of New Jersey, including at least the following two locations: 8 Gloria Ln, Fairfield, NJ 07004 and 400 Chestnut Ridge Rd, Woodcliff Lake, NJ 07677. On information and belief, Teva Pharmaceuticals USA, Inc. 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, Teva Pharmaceuticals USA, Inc. has customers in the State of New Jersey.

11. On information and belief, Teva Pharmaceuticals USA, Inc. has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following cases: *Amarin Pharma, Inc., et al. v. Teva Pharmaceuticals USA, Inc.*, No. 14-3558, *Boehringer Ingelheim Pharma GmBH & Co. KG, et al. v. Teva Pharmaceuticals USA,*

Inc., et al., No. 14-7811, *Helsinn Healthcare S.A., et al., v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-6341, *Novo Nordisk Inc., et al., v. Teva Pharmaceuticals USA, Inc.*, No. 14-4248, *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-5878, *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, No. 14-5498. Further, on information and belief, Teva Pharmaceuticals USA, Inc. has purposefully availed itself of the benefits of this forum by filing counterclaims in each of those actions. Additionally, on information and belief, Teva Pharmaceuticals USA, Inc. has availed itself of this forum by bringing civil actions for patent infringement in this forum in at least the following cases: *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672, *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 15-472.

12. This Court has personal jurisdiction over Teva Pharmaceutical Industries Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva Pharmaceutical Industries Ltd. 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, Teva Pharmaceutical Industries Ltd. has customers in the State of New Jersey.

13. On information and belief, Teva Pharmaceutical Industries Ltd. has been sued for patent infringement in this District and did not contest personal jurisdiction in this District in at least the following case: *Boehringer Ingelheim Pharma GmBH & Co. KG, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 14-7811. Further, on information and belief, Teva Pharmaceutical Industries Ltd. has purposefully availed itself of the benefits of this forum by filing counterclaims in that action. Additionally, on information and belief, Teva Pharmaceutical

Industries Ltd. has availed itself of the benefits of this forum by bringing civil actions for patent infringement in this forum. *See, e.g., Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, No. 14-5672, *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 15-472.

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

The Patent-In-Suit

15. 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.

16. 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.

17. 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.

18. 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.

19. 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.

20. 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.

21. On November 25, 2014, the USPTO duly and lawfully issued the '057 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 '057 patent is attached hereto as Exhibit G.

22. On November 25, 2014, the USPTO duly and lawfully issued the '058 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 '058 patent is attached hereto as Exhibit H.

The QSYMIA® Drug Products

23. 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.

24. 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

25. Pursuant to Section 505 of the FFDCA, Teva filed ANDA No. 208175 ("Teva's 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 ("Teva's Proposed Product"), before the patents-in-suit expire.

26. On information and belief, in connection with the filing of its ANDA as described in the preceding paragraph, Teva 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) ("Teva's 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 Teva's ANDA.

27. No earlier than March 4, 2015, Teva sent written notice of its Paragraph IV Certification to VIVUS ("Teva's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Teva's 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 Teva's ANDA. Teva's Notice Letter also informed VIVUS that Teva seeks approval to market Teva's Proposed Product before the patents-in-suit expire.

Count I: Infringement of the '890 Patent

28. Plaintiff repeats and realleges the allegations of paragraphs 1-27 as though fully set forth herein.

29. Teva's 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).

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

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

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

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

34. VIVUS will be substantially and irreparably damaged and harmed if Teva’s infringement of the ’890 patent is not enjoined.

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

36. 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

37. Plaintiff repeats and realleges the allegations of paragraphs 1-36 as though fully set forth herein.

38. Teva’s 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).

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

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

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

42. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will contributorily infringe the ’818 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva’s Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva’s Proposed Product is especially adapted for a use that infringes the ’818 patent and that there is no substantial non-infringing use for Teva’s Proposed Product.

43. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '818 patent is not enjoined.

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

45. 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

46. Plaintiff repeats and realleges the allegations of paragraphs 1-45 as though fully set forth herein.

47. Teva's 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).

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

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

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

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

52. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '256 patent is not enjoined.

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

54. 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

55. Plaintiff repeats and realleges the allegations of paragraphs 1-54 as though fully set forth herein.

56. Teva's 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).

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

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

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

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

61. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '776 patent is not enjoined.

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

63. 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

64. Plaintiff repeats and realleges the allegations of paragraphs 1-63 as though fully set forth herein.

65. Teva's 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).

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

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

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

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

70. VIVUS will be substantially and irreparably damaged and harmed if Teva’s infringement of the ’298 patent is not enjoined.

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

72. 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

73. Plaintiff repeats and realleges the allegations of paragraphs 1-72 as though fully set forth herein.

74. Teva’s 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).

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

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

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

78. Unless enjoined by this Court, upon FDA approval of Teva’s ANDA, Teva will contributorily infringe the ’299 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva’s Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva’s Proposed Product is especially adapted for a use that infringes the ’299 patent and that there is no substantial non-infringing use for Teva’s Proposed Product.

79. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '299 patent is not enjoined.

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

81. 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 VII: Infringement of the '057 Patent

82. Plaintiff repeats and realleges the allegations of paragraphs 1-81 as though fully set forth herein.

83. Teva's 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 '057 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

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

85. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '057 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

86. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '057 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '057 patent and knowledge that its acts are encouraging infringement.

87. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '057 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '057 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

88. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '057 patent is not enjoined.

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

90. 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 VIII: Infringement of the '058 Patent

91. Plaintiff repeats and realleges the allegations of paragraphs 1-90 as though fully set forth herein.

92. Teva's 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 '058 patent, constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

93. There is a justiciable controversy between the parties hereto as to the infringement of the '058 patent.

94. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will infringe the '058 patent under 35 U.S.C. § 271(a) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States.

95. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will induce infringement of the '058 patent under 35 U.S.C. § 271(b) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, upon FDA approval of Teva's ANDA, Teva will intentionally encourage acts of direct infringement with knowledge of the '058 patent and knowledge that its acts are encouraging infringement.

96. Unless enjoined by this Court, upon FDA approval of Teva's ANDA, Teva will contributorily infringe the '058 patent under 35 U.S.C. § 271(c) by making, using, offering to sell, importing, and/or selling Teva's Proposed Product in the United States. On information and belief, Teva has had and continues to have knowledge that Teva's Proposed Product is especially adapted for a use that infringes the '058 patent and that there is no substantial non-infringing use for Teva's Proposed Product.

97. VIVUS will be substantially and irreparably damaged and harmed if Teva's infringement of the '058 patent is not enjoined.

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

99. 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 that Teva has infringed the patents-in-suit by submitting ANDA No. 208175;

(B) A Judgment that Teva has infringed, and that Teva's making, using, selling, offering to sell, or importing Teva's 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. 208175 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 Teva 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 Teva's 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, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Teva, 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 Teva's Proposed Product will directly infringe, induce and/or contribute to infringement of the patents-in-suit;

(G) To the extent that Teva has committed any acts of infringement 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), a judgment awarding Plaintiff VIVUS damages for such acts, together with interest;

(H) If Teva engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Teva's 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: April 15, 2015

By: s/ Charles M. Lizza

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