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Attorneys for Plaintiffs Gilead Sciences, Inc. and Emory University

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA INC., Defendants.	Civil Action No.: *Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs"), for their complaint against Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. (collectively, "Aurobindo"), hereby allege as follows:

Nature of Action

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

The Parties

2. Gilead is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 333 Lakeside Drive, Foster City, California 94404.

3. Emory is a non-profit corporation of the State of Georgia, having an office at 201 Dowman Drive, Atlanta, Georgia 30322.

4. On information and belief, defendant Aurobindo Pharma Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad—500 038, Andhra Pradesh, India. On information and belief, Aurobindo Pharma Ltd. has actual control over the activities of Aurobindo Pharma USA Inc.

5. On information and belief, defendant Aurobindo Pharma USA Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 6 Wheeling Road, Dayton, New Jersey 08810. On information and belief, Aurobindo Pharma USA Inc. is a wholly-owned subsidiary and agent of Aurobindo Pharma Ltd.

Jurisdiction and Venue

6. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338(a).

7. On information and belief, this Court has personal jurisdiction over both Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc.

8. On information and belief, Aurobindo Pharma Ltd., itself or through one of its wholly-owned subsidiaries, including but not limited to Aurobindo Pharma USA Inc., derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in New Jersey.

9. On information and belief, Aurobindo Pharma Ltd., itself or through one of its wholly-owned subsidiaries, including but not limited to Aurobindo Pharma USA Inc., manufactures pharmaceutical drug products that are sold and used throughout the United States, including in New Jersey.

10. On information and belief, Aurobindo Pharma Ltd., itself or through one of its wholly-owned subsidiaries, including but not limited to Aurobindo Pharma USA Inc., owns manufacturing facilities in New Jersey that are used to make pharmaceutical drug products.

11. On information and belief, residents of New Jersey purchase pharmaceutical drug products from Aurobindo Pharma Ltd. in New Jersey.

12. On information and belief, Aurobindo Pharma USA Inc. is registered with the State of New Jersey to do business as a foreign corporation in New Jersey.

13. On information and belief, Aurobindo Pharma USA Inc. derives substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in New Jersey.

14. On information and belief, Aurobindo Pharma USA Inc. manufactures pharmaceutical drug products that are sold and used throughout the United States, including in New Jersey.

15. On information and belief, Aurobindo Pharma USA Inc. owns manufacturing facilities in New Jersey that are used to make pharmaceutical drug products.

16. On information and belief, Aurobindo Pharma USA Inc. is registered with the State of New Jersey Department of Health as a drug wholesaler under registration number 5003120.

17. On information and belief, residents of New Jersey purchase pharmaceutical drug products from Aurobindo Pharma USA Inc. in New Jersey.

18. On information and belief, Aurobindo Pharma USA Inc.'s submission of Abbreviated New Drug Application ("ANDA") No. 90-513, discussed below, indicates Aurobindo's intention to engage in the commercial manufacture, use, sale and/or importation of products that will compete directly with Gilead's Truvada® product, which is currently being sold throughout the United States, including in New Jersey. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. will sell tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 90-513, if approved, throughout the United States, including in New Jersey.

19. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc. have previously consented to personal jurisdiction in this District.

20. In the alternative, this Court has jurisdiction over Aurobindo Pharma Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

21. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b).

Background

22. Gilead is the holder of New Drug Application ("NDA") No. 21-752, which relates to tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate. On August 2, 2004, the United States Food and Drug Administration ("FDA") approved the use of the tablets described in NDA No. 21-752 for the treatment of HIV-1 infection in adults. These tablets are prescribed and sold in the United States under the trademark Truvada®.

23. United States Patent No. 6,642,245 ("the '245 Patent," copy attached as Exhibit A), entitled "Antiviral Activity and Resolution of 2-Hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane," was duly and legally issued by the United States Patent and Trademark Office on November 4, 2003. The '245 Patent claims, *inter alia*, methods for treating HIV infection in

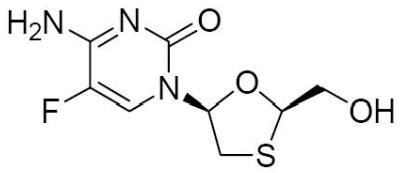
humans with emtricitabine (the active ingredient in Truvada®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Truvada®.

24. United States Patent No. 6,703,396 ("the '396 Patent," copy attached as Exhibit B), entitled "Method of Resolution and Antiviral Activity of 1,3-Oxathiolane Nucleoside Enantiomers," was duly and legally issued by the United States Patent and Trademark Office on March 9, 2004. The '396 Patent claims, *inter alia*, emtricitabine (the active ingredient in Truvada®), and is listed in the FDA Orange Book for Truvada®.

25. United States Patent No. 8,592,397 ("the '397 Patent," copy attached as Exhibit C), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on November 26, 2013. The '397 Patent claims, *inter alia*, a pharmaceutical combination tablet containing emtricitabine and tenofovir disoproxil fumarate (the two active ingredients in Truvada®) and methods for treating HIV infection in humans with the emtricitabine and tenofovir disoproxil fumarate combination. The '397 Patent is also listed in the FDA Orange Book for Truvada®.

26. United States Patent No. 8,716,264 ("the '264 Patent," copy attached as Exhibit D), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on May 6, 2014. The '264 Patent claims, *inter alia*, a pharmaceutical combination tablet containing emtricitabine and tenofovir disoproxil fumarate (the two active ingredients in Truvada®) and methods for treating HIV infection in humans with the emtricitabine and tenofovir disoproxil fumarate combination. The '264 Patent is also listed in the FDA Orange Book for Truvada®.

27. Emtricitabine is a compound that has a molecular formula of $C_8H_{10}FN_3O_3S$, and which has the following chemical structure:



28. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Truvada® label is "5-fluoro-1-[(2*R*,5*S*)-2-(hydroxymethyl)-1,3-oxathiolan-5-yl]cytosine." Two chemical names recited for emtricitabine in the '245 Patent are "(–)-β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl) -1,3-oxathiolane" and "β-L-2-hydroxymethyl-5-(5-fluorocytosin-1-yl)-1,3-oxathiolane." Two chemical names recited for emtricitabine in the '396 Patent are "(–)-cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one" and "(–)-enantiomer of cis-4-amino-5-fluoro-1-(2-hydroxymethyl-1,3-oxathiolane-5-yl)-(1H)-pyrimidin-2-one."

29. The named inventors on the '245 and '396 Patents are Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi.

30. Dennis C. Liotta, Raymond F. Schinazi, and Woo-Baeg Choi assigned the '245 and '396 Patents to Emory.

31. Pursuant to an agreement entered into between Gilead and Emory, Gilead has substantial rights in the '245 and '396 Patents, including, but not limited to, rights associated with being a licensee of the '245 and '396 Patents, and the right to sue for infringement of the '245 and '396 Patents.

32. The named inventors of the '397 and '264 Patents are Terrence C. Dahl, Mark M. Menning, and Reza Oliyai.

33. Terrence C. Dahl, Mark M. Menning, and Reza Oliyai assigned the '397 and '264 Patents to Gilead.

COUNT 1
Infringement of U.S. Patent No. 6,642,245

34. Plaintiffs repeat and reallege paragraphs 1-33 above as if set forth herein.

35. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

36. By letter dated May 27, 2016, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "May 27, 2016 Notice Letter"), Aurobindo notified Plaintiffs that it had submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '245 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 27, 2016 Notice Letter.

37. In its May 27, 2016 Notice Letter, Aurobindo notified Plaintiffs that, as a part of ANDA No. 90-513, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(III) and that it now intends to convert that into a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '245 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '245 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent

alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

38. Aurobindo alleged in its May 27, 2016 Notice Letter that Claims 1-8 and 15 of the '245 Patent are invalid and that Claims 4, 5, and 9-22 of the '245 Patent would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 90-513.

39. The May 27, 2016 Notice Letter does not allege non-infringement of Claims 1-3 and 6-8 of the '245 Patent.

40. The May 27, 2016 Notice Letter does not provide the full and detailed statement of Aurobindo's factual and legal basis to support its non-infringement and invalidity allegations as to the '245 Patent.

41. Accordingly, the May 27, 2016 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

42. By filing ANDA No. 90-513 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '245 Patent's expiration, Aurobindo has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

43. On information and belief, Aurobindo lacked a good faith basis for alleging invalidity when ANDA No. 90-513 was filed and when the Paragraph IV certification was made. Aurobindo's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '245 Patent.

44. Aurobindo's submission of ANDA No. 90-513 and service of the May 27, 2016 Notice Letter indicates a refusal to change its current course of action.

45. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will infringe one or more claims of the '245 Patent.

46. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 1 of the '245 Patent. Claim 1 recites a "method for treating HIV infection in humans comprising administering an effective amount of [emtricitabine], or its physiologically acceptable salt, optionally in a pharmaceutically acceptable carrier." On information and belief, Aurobindo will infringe Claim 1 of the '245 Patent because the product for which it seeks approval in ANDA No. 90-513 will be labeled for and used to treat HIV infection in humans with an effective amount of emtricitabine. In its May 27, 2016 Notice Letter, Aurobindo does not allege that Claim 1 would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of its proposed product that is the subject of ANDA No. 90-513. For the same reasons, on information and belief, Aurobindo will likewise infringe Claims 2, 3, 6, 7, and 8 of the '245 Patent.

47. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will be administered to human patients in an effective amount for treating HIV infection. Such administration will infringe at least one claim of the '245 Patent, as described in the preceding paragraph. On information and belief, this administration will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet this administration with knowledge that it

is in contravention of Plaintiffs' rights under the '245 Patent. Further, by filing ANDA No. 90-513 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '245 Patent.

48. The May 27, 2016 Notice Letter does not allege and does not address unenforceability of any claims of the '245 Patent. By not addressing unenforceability of any claims of the '245 Patent in its May 27, 2016 Notice Letter, Aurobindo admits that all of the claims of the '245 Patent are enforceable.

COUNT 2
Infringement of U.S. Patent No. 6,703,396

49. Plaintiffs repeat and reallege paragraphs 1-48 above as if set forth herein.

50. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

51. By letter dated May 27, 2016, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "May 27, 2016 Notice Letter"), Aurobindo notified Plaintiffs that it had submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '396 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 27, 2016 Notice Letter.

52. In its May 27, 2016 Notice Letter, Aurobindo notified Plaintiffs that, as a part of its ANDA No. 90-513, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(III) and that it now intends to convert that into a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '396 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the

best of its knowledge, that the subject patent, here the '396 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

53. Aurobindo alleged in its May 27, 2016 Notice Letter that Claims 1-7, 11, 13, 15, and 17 of the '396 Patent are invalid and that Claims 8-10, 12, 14, 16, and 18-28 would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 90-513.

54. The May 27, 2016 Notice Letter does not allege non-infringement of Claims 1-7, 11, 13, 15, and 17 of the '396 Patent.

55. The May 27, 2016 Notice Letter does not provide the full and detailed statement of Aurobindo's factual and legal basis to support its non-infringement and invalidity allegations as to the '396 Patent.

56. Accordingly, the May 27, 2016 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

57. By filing ANDA No. 90-513 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '396

Patent's expiration, Aurobindo has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

58. On information and belief, Aurobindo lacked a good faith basis for alleging invalidity when ANDA No. 90-513 was filed and when the Paragraph IV certification was made. Aurobindo's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '396 Patent.

59. Aurobindo's submission of ANDA No. 90-513 and service of the May 27, 2016 Notice Letter indicates a refusal to change its current course of action.

60. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will infringe one or more claims of the '396 Patent.

61. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 2 of the '396 Patent. Claim 2 recites "[emtricitabine] or a pharmaceutically acceptable salt, ester or salt of an ester thereof." On information and belief, Aurobindo will infringe Claim 2 of the '396 Patent because the product for which it seeks approval in ANDA No. 90-513 will contain emtricitabine as the active ingredient. In its May 27, 2016 Notice Letter, Aurobindo does not allege that Claim 2 would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of its proposed product that is the subject of ANDA No. 90-513. For the same reasons, on information and belief, Aurobindo will also infringe Claims 1, 3-7, 11, 13, 15, and 17 of the '396 Patent.

62. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No.

90-513, if approved, will infringe at least one claim of the '396 Patent, as described in the preceding paragraph. On information and belief, the manufacture of these tablets will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet the manufacture of these tablets with knowledge that it is in contravention of Plaintiffs' rights under the '396 Patent. Further, by filing ANDA No. 90-513 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '396 Patent.

63. The May 27, 2016 Notice Letter does not allege and does not address unenforceability of any claims of the '396 Patent. By not addressing unenforceability of any claims of the '396 Patent in its May 27, 2016 Notice Letter, Aurobindo admits that all of the claims of the '396 Patent are enforceable.

COUNT 3
Infringement of U.S. Patent No. 8,592,397

64. Plaintiffs repeat and reallege paragraphs 1-63 above as if set forth herein.

65. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

66. By letter dated May 27, 2016, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "May 27, 2016 Notice Letter"), Aurobindo notified Plaintiffs that it had submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '397 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 27, 2016 Notice Letter.

67. In its May 27, 2016 Notice Letter, Aurobindo notified Plaintiffs that, as a part of its ANDA No. 90-513, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(III) and that it now intends to convert that into a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '397 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '397 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . ." The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations."

68. Aurobindo alleged in its May 27, 2016 Notice Letter that Claims 1-26 of the '397 Patent are invalid.

69. Aurobindo did not allege in its May 27, 2016 Notice Letter that any claims of the '397 Patent would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 90-513.

70. The May 27, 2016 Notice Letter does not provide the full and detailed statement of Aurobindo's factual and legal basis to support its invalidity allegations as to the '397 Patent.

71. Accordingly, the May 27, 2016 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

72. By filing ANDA No. 90-513 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the '397 Patent's expiration, Aurobindo has committed an act of infringement of the '397 Patent under 35 U.S.C. § 271(e)(2).

73. On information and belief, Aurobindo lacked a good faith basis for alleging invalidity when ANDA No. 90-513 was filed and when the Paragraph IV certification was made. Aurobindo's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '397 Patent.

74. Aurobindo's submission of ANDA No. 90-513 and service of the May 27, 2016 Notice Letter indicates a refusal to change its current course of action.

75. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will infringe one or more claims of the '397 Patent.

76. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 1 of the '397 Patent. Claim 1 recites a "chemically stable fixed dose combination pharmaceutical dosage form comprising 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine; a binder selected from the group consisting of povidone, gelatin, hydroxypropyl methylcellulose, cellulose, microcrystalline cellulose, starch, and acacia; a disintegrant selected from sodium starch glycolate, crosslinked-povidone, cross-linked sodium carboxymethylcellulose, and alginic acid; and a lubricant selected from the group consisting of magnesium stearate, stearic acid, and talc; wherein said pharmaceutical dosage form exhibits less

than 10% degradation of the tenofovir disoproxil fumarate or emtricitabine after 6 months when packaged and stored with silica gel dessicant at 40° C./75% relative humidity." On information and belief, Aurobindo will infringe Claim 1 of the '397 Patent because the product for which it seeks approval in ANDA No. 90-513 will be a chemically stable, fixed-dose tablet containing 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine and at least one of each enumerated binder, disintegrant, and lubricant, or an equivalent thereof, and will exhibit less than 10% degradation of the tenofovir disoproxil fumarate or emtricitabine after six months when packaged and stored with silica gel dessicant at 40° C./75% relative humidity. In its May 27, 2016 Notice Letter, Aurobindo does not allege that Claim 1 would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of its proposed product that is the subject of ANDA No. 90-513. For the same reasons, on information and belief, Aurobindo will also infringe Claims 2-6, 14-16, and 19 of the '397 Patent.

77. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will infringe at least one claim of the '397 Patent, as described in the preceding paragraph. On information and belief, the manufacture of these tablets and use of these tablets to treat HIV infection will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet the manufacture of these tablets and use of these tablets to treat HIV infection with knowledge that it is in contravention of Plaintiffs' rights under the '397 Patent. Further, by filing ANDA No. 90-513 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '397 Patent.

78. The May 27, 2016 Notice Letter does not allege and does not address unenforceability of any claims of the '397 Patent. By not addressing unenforceability of any claims of the '397 Patent in its May 27, 2016 Notice Letter, Aurobindo admits that all of the claims of the '397 Patent are enforceable.

COUNT 4
Infringement of U.S. Patent No. 8,716,264

79. Plaintiffs repeat and reallege paragraphs 1-78 above as if set forth herein.

80. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the purpose of treating HIV infection.

81. By letter dated May 27, 2016, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "May 27, 2016 Notice Letter"), Aurobindo notified Plaintiffs that it had submitted ANDA No. 90-513 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate prior to the expiration of the '264 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 27, 2016 Notice Letter.

82. In its May 27, 2016 Notice Letter, Aurobindo notified Plaintiffs that, as a part of its ANDA No. 90-513, it had filed a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(III) and that it now intends to convert that into a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV") with respect to the '264 Patent. Paragraph IV requires, *inter alia*, certification by the ANDA applicant, in its opinion and to the best of its knowledge, that the subject patent, here the '264 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . .

. .” The statute (21 U.S.C. § 355(j)(2)(B)(iv)(II)) also requires a Paragraph IV Notice Letter to “include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed.” The FDA Rules and Regulations (21 C.F.R. § 314.95(c)(6)) further require that the detailed statement include “(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed” and “(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegations.”

83. Aurobindo alleged in its May 27, 2016 Notice Letter that Claims 1-38 of the ’264 Patent are invalid.

84. Aurobindo did not allege in its May 27, 2016 Notice Letter that any claims of the ’264 Patent would not be infringed by the commercial manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 90-513.

85. The May 27, 2016 Notice Letter does not provide the full and detailed statement of Aurobindo’s factual and legal basis to support its invalidity allegations as to the ’264 Patent.

86. Accordingly, the May 27, 2016 Notice Letter fails to comply with the law, as specified in 21 U.S.C. § 355(j) and FDA rules and regulations, as specified in 21 C.F.R. § 314.95.

87. By filing ANDA No. 90-513 under 21 U.S.C. § 355(j) for the purposes of obtaining approval to engage in the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate before the ’264 Patent’s expiration, Aurobindo has committed an act of infringement of the ’264 Patent under 35 U.S.C. § 271(e)(2).

88. On information and belief, Aurobindo lacked a good faith basis for alleging invalidity when ANDA No. 90-513 was filed and when the Paragraph IV certification was made.

Aurobindo's ANDA and Paragraph IV certification is a wholly unjustified infringement of the '264 Patent.

89. Aurobindo's submission of ANDA No. 90-513 and service of the May 27, 2016 Notice Letter indicates a refusal to change its current course of action.

90. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will infringe one or more claims of the '264 Patent.

91. On information and belief, Aurobindo will directly or indirectly infringe at least Claim 1 of the '264 Patent. Claim 1 recites a "chemically stable fixed-dose combination comprising 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine wherein the combination exhibits less than 10% degradation of tenofovir disoproxil fumarate and emtricitabine after six months at 40° C./75% relative humidity when packaged and stored with silica gel dessicant at 40° C./70% relative humidity."[1] On information and belief, Aurobindo will infringe Claim 1 of the '264 Patent because the product for which it seeks approval in ANDA No. 90-513 will be a chemically stable, fixed-dose tablet containing 300 mg of tenofovir disoproxil fumarate and 200 mg of emtricitabine and will exhibit less than 10% degradation of tenofovir disoproxil fumarate and emtricitabine after six months at 40° C./75% relative humidity when packaged and stored with silica gel dessicant at 40° C./70% relative humidity. In its May 27, 2016 Notice Letter, Aurobindo does not allege that Claim 1 would not be infringed by the commercial manufacture, use, sale, offer for sale and/or importation of its proposed product that is the subject of ANDA No.

[1] Claim 1 contains a clear typographical error in stating "70% relative humidity" in the last clause rather than "75% relative humidity." Plaintiff Gilead will request that the Court correct this error.

90-513. For the same reasons, on information and belief, Aurobindo will also infringe at least Claims 1-3, 9, 16, 17, 33, and 34 of the '264 Patent.

92. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Aurobindo seeks approval in ANDA No. 90-513, if approved, will infringe at least one claim of the '264 Patent, as described in the preceding paragraph. On information and belief, the manufacture of these tablets and use of these tablets to treat HIV infection will occur at Aurobindo's active behest and with its intent, knowledge and encouragement. On information and belief, Aurobindo will actively encourage, aid and abet the manufacture of these tablets and use of these tablets to treat HIV infection with knowledge that it is in contravention of Plaintiffs' rights under the '264 Patent. Further, by filing ANDA No. 90-513 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '264 Patent.

93. The May 27, 2016 Notice Letter does not allege and does not address unenforceability of any claims of the '264 Patent. By not addressing unenforceability of any claims of the '264 Patent in its May 27, 2016 Notice Letter, Aurobindo admits that all of the claims of the '264 Patent are enforceable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Aurobindo's ANDA No. 90-513 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the '245 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(b) A judgment declaring that the effective date of any approval of Aurobindo's ANDA No. 90-513 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a

date which is not earlier than the expiration of the ’396 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(c) A judgment declaring that the effective date of any approval of Aurobindo’s ANDA No. 90-513 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the ’397 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(d) A judgment declaring that the effective date of any approval of Aurobindo’s ANDA No. 90-513 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) be a date which is not earlier than the expiration of the ’264 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(e) A judgment declaring that the ’245 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

(f) A judgment declaring that the ’396 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

(g) A judgment declaring that the ’397 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

(h) A judgment declaring that the ’264 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

(i) A permanent injunction against any infringement of the ’245 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(j) A permanent injunction against any infringement of the ’396 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(k) A permanent injunction against any infringement of the ’397 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(l) A permanent injunction against any infringement of the ’264 Patent by Aurobindo, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(m) A judgment that Aurobindo’s conduct is exceptional in this case;

(n) An award of reasonable attorney fees pursuant to 35 U.S.C. § 285;

(o) To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the ’245 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(p) To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the ’396 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(q) To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the ’397 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(r) To the extent that Aurobindo has committed any acts with respect to the subject matter claimed in the ’264 Patent, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts, which should be trebled pursuant to 35 U.S.C. § 284;

(s) Costs and expenses in this action; and

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

Dated: July 8, 2016

Respectfully submitted,

s/ Liza M. Walsh
Liza M. Walsh

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