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.:

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. 79-188, 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 Emtriva® 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 capsules containing 200 mg of

emtricitabine for the use for which Aurobindo seeks approval in ANDA No. 79-188, 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

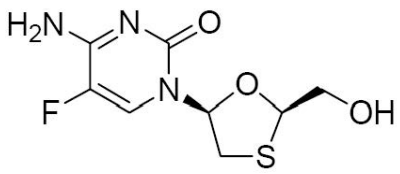
22. Gilead is the holder of New Drug Application ("NDA") No. 21-500, which relates to capsules containing 200 mg of emtricitabine. On July 2, 2003, the United States Food and Drug Administration ("FDA") approved the use of the capsules described in NDA No. 21-500 for the treatment of HIV-1 infection in adults. These capsules are prescribed and sold in the United States under the trademark Emtriva®.

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 Emtriva®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Emtriva®.

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 Emtriva®), and is listed in the FDA Orange Book for Emtriva®.

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



26. Emtricitabine can be referred to by any of several chemical names. The chemical name given to emtricitabine in the Emtriva® 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."

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

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

29. 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.

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

30. Plaintiffs repeat and reallege paragraphs 1-29 above as if set forth herein.

31. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 79-188 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of capsules containing 200 mg of emtricitabine for the purpose of treating HIV infection.

32. By letter dated May 11, 2016 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "May 11, 2016 Notice Letter"), Aurobindo notified Plaintiffs that it had submitted ANDA No. 79-188 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of capsules containing 200 mg of emtricitabine prior to the expiration of the '245 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 11, 2016 Notice Letter.

33. In its May 11, 2016 Notice Letter, Aurobindo notified Plaintiffs that, as a part of ANDA No. 79-188, 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."

34. Aurobindo alleged in its May 11, 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. 79-188.

35. The May 11, 2016 Notice Letter does not allege non-infringement of Claims 1-3 and 6-8 of the '245 Patent.

36. The May 11, 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.

37. Accordingly, the May 11, 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.

38. By filing ANDA No. 79-188 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 capsules containing 200 mg of emtricitabine 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).

39. On information and belief, Aurobindo lacked a good faith basis for alleging invalidity when ANDA No. 79-188 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.

40. Aurobindo's submission of ANDA No. 79-188 and service of the May 11, 2016 Notice Letter indicates a refusal to change its current course of action.

41. On information and belief, the commercial manufacture, use, sale and/or importation of capsules containing 200 mg of emtricitabine for which Aurobindo seeks approval in ANDA No. 79-188, if approved, will infringe one or more claims of the '245 Patent.

42. 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. 79-188 will be labeled for and used to treat HIV infection in humans with an effective amount of emtricitabine. In its May 11, 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. 79-188. For the same reasons, on information and belief, Aurobindo will likewise infringe Claims 2, 3, 6, 7, and 8 of the '245 Patent.

43. On information and belief, the capsules containing 200 mg of emtricitabine for the use for which Aurobindo seeks approval in ANDA No. 79-188, 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. 79-188 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '245 Patent.

44. The May 11, 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 11, 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

45. Plaintiffs repeat and reallege paragraphs 1-29 above as if set forth herein.

46. On information and belief, Aurobindo submitted or caused to be submitted ANDA No. 79-188 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of capsules containing 200 mg of emtricitabine for the purpose of treating HIV infection.

47. By letter dated May 11, 2016 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the "May 11, 2016 Notice Letter"), Aurobindo notified Plaintiffs that it had submitted ANDA No. 79-188 to the FDA seeking approval to engage in the commercial manufacture, use, sale and/or importation of capsules containing 200 mg of emtricitabine prior to the expiration of the '396 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the May 11, 2016 Notice Letter.

48. In its May 11, 2016 Notice Letter, Aurobindo notified Plaintiffs that, as a part of its ANDA No. 79-188, 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."

49. Aurobindo alleged in its May 11, 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. 79-188.

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

51. The May 11, 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.

52. Accordingly, the May 11, 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.

53. By filing ANDA No. 79-188 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 capsules containing 200 mg of emtricitabine 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).

54. On information and belief, Aurobindo lacked a good faith basis for alleging invalidity when ANDA No. 79-188 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.

55. Aurobindo's submission of ANDA No. 79-188 and service of the May 11, 2016 Notice Letter indicates a refusal to change its current course of action.

56. On information and belief, the commercial manufacture, use, sale and/or importation of capsules containing 200 mg of emtricitabine for which Aurobindo seeks approval in ANDA No. 79-188, if approved, will infringe one or more claims of the '396 Patent.

57. 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. 79-188 will contain emtricitabine as the active ingredient. In its May 11, 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. 79-188. 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.

58. On information and belief, the capsules containing 200 mg of emtricitabine for the use for which Aurobindo seeks approval in ANDA No. 79-188, 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 capsules 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 capsules with knowledge that it is in contravention of

Plaintiffs' rights under the '396 Patent. Further, by filing ANDA No. 79-188 with a Paragraph IV certification, Aurobindo admits that it has knowledge of the '396 Patent.

59. The May 11, 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 11, 2016 Notice Letter, Aurobindo admits that all of the claims of the '396 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. 79-188 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. 79-188 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 '245 Patent remains valid and enforceable, and that one or more claims have been infringed by Aurobindo;

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

(e) 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;

(f) 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;

(g) A judgment that Aurobindo's conduct is exceptional in this case;

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

(i) 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;

(j) 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;

(k) Costs and expenses in this action; and

(l) Such other relief as this Court may deem proper.

Dated: June 23, 2016

Respectfully submitted,

/s/ Liza M. Walsh

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RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, nor are there any non-parties known to Plaintiffs that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: June 23, 2016

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RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, inter alia, injunctive relief.

Dated: June 23, 2016

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