IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC. and EMORY UNIVERSITY, Plaintiffs, v. LAURUS LABS LTD. and LAURUS GENERICS INC., Defendants.	C.A. No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. ("Gilead") and Emory University ("Emory") (collectively, "Plaintiffs"), for their complaint against Defendants Laurus Labs Ltd. ("Laurus Labs") and Laurus Generics Inc. ("Laurus Generics") (Laurus Labs and Laurus Generics are referred to collectively as "Laurus"), 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 Laurus Generics is a Delaware corporation, having a principal place of business at 400 Connell Drive, Suite 5200, Berkeley Heights, NJ 07922

and is an agent or affiliate of Defendant Laurus Labs and is acting as the agent of Laurus Labs with respect to Abbreviated New Drug Application ("ANDA") No. 212114.

5. On information and belief, Defendant Laurus Labs is an Indian corporation, having a principal place of business at Plot No:21, JN Pharma City, Parawada, Visakhapatnam 531021, AP, India.

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 Laurus Generics and Laurus Labs.

8. On information and belief, Laurus Labs and Laurus Generics are generic pharmaceutical companies in the business of marketing and distributing generic drug products, and derive substantial revenue from selling various pharmaceutical drug products and doing business throughout the United States, including in Delaware.

9. On information and belief, Laurus Labs and Laurus Generics, themselves or through their wholly-owned subsidiaries or affiliates, manufacture pharmaceutical drug products that are sold and used throughout the United States, including in Delaware.

10. On information and belief, residents of Delaware purchase pharmaceutical drug products from Laurus in Delaware.

11. On information and belief, Laurus Generics is a corporation registered with the Delaware Department of State, Division of Corporations, under file number 6504207.

12. On information and belief, Laurus Generics maintains a registered agent for service of process in Delaware, Intertrust Corporate Services Delaware Ltd., 200 Bellevue Parkway, Suite 210, Wilmington, Delaware 19809.

13. On information and belief, this Court has jurisdiction over Laurus Labs because Laurus Generics is a Delaware corporation and is the subsidiary and agent of Laurus Labs. On information and belief, Laurus Generics is acting as the agent of Laurus Labs with respect to ANDA No. 212114. On information and belief, Laurus Labs and Laurus Generics are working in concert for purposes of developing, formulating, manufacturing, marketing, selling, and importing drug products throughout the United States, including Delaware, and Delaware would be a destination of Laurus Labs' products. On information and belief, Laurus Labs manufactures a generic version of another Gilead product, Viread® (tenofovir disoproxil fumarate) for Laurus Generics.

14. In the alternative, this Court has jurisdiction over Laurus Labs because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met. This Court has jurisdiction over Laurus Labs because, *inter alia*, this action arises from actions of Laurus Labs directed toward Delaware, and because Laurus Labs has purposely availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. On information and belief, Laurus Labs regularly and continuously transacts business within the State of Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. On information and belief, Laurus Labs derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

15. On information and belief, Laurus' submission of ANDA No. 212114, discussed below, indicates Laurus' 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 Delaware. On information and belief, Laurus will sell tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, if approved, throughout the United States, including in Delaware.

16. Venue is proper in this District under 28 U.S.C. § 1391(b), (c), (d), and 28 U.S.C. § 1400(b). Specifically, venue is proper in Delaware because Laurus Generics is incorporated in Delaware.

Background

17. 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®.

18. 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 (one of the active ingredients in Truvada®), and is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for Truvada®.

19. 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 (one of the active ingredients in Truvada®), and is listed in the FDA Orange Book for Truvada®.

20. 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®.

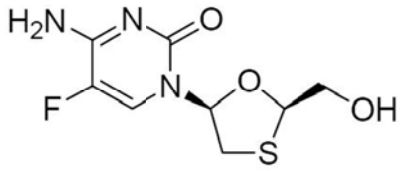
21. United States Patent No. 8,716,264 ("the '264 Patent," copy attached as Exhibit D), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on May 6, 2014. The '264 Patent claims, *inter alia*, a pharmaceutical 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®.

22. United States Patent No. 9,457,036 ("the '036 Patent," copy attached as Exhibit E), entitled "Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on October 4, 2016. The '036 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 '036 Patent is also listed in the FDA Orange Book for Truvada®.

23. United States Patent No. 9,744,181 ("the '181 Patent," copy attached as Exhibit F), entitled Compositions and Methods for Combination Antiviral Therapy," was duly and legally issued by the United States Patent and Trademark Office on August 29, 2017. The '181 Patent claims, *inter alia*, a fixed-dose 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 '181 Patent is also listed in the FDA Orange Book for Truvada®.

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



25. 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."

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

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

28. 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.

29. The named inventors on the ’397, ’264, ’036, and ’181 Patents are Terrence C. Dahl, Mark M. Menning, and Reza Oliyai.

30. Terrence C. Dahl, Mark M. Menning and Reza Oliyai assigned the ’397, ’264, ’036, and ’181 Patents to Gilead.

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

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

32. On information and belief, Laurus submitted or caused to be submitted ANDA No. 212114 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 tenofovir disoproxil fumarate for the purpose of treating HIV infection.

33. By letter dated September 24, 2018, pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) (the “September 24, 2018 Notice Letter”), Laurus notified Plaintiffs that it had submitted ANDA No. 212114 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 tenofovir disoproxil

fumarate prior to the expiration of the '245 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the September 24, 2018 Notice Letter.

34. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that, as a part of ANDA No. 212114, it had filed 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."

35. Laurus alleged in its September 24, 2018 Notice Letter that all claims of the '245 Patent are invalid and that no claims 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. 212114.

36. By filing ANDA No. 212114 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 tenofovir disoproxil fumarate before the '245

Patent's expiration, Laurus has committed an act of infringement of the '245 Patent under 35 U.S.C. § 271(e)(2).

37. Laurus' submission of ANDA No. 212114 and service of the September 24, 2018 Notice Letter indicates a refusal to change its current course of action.

38. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe one or more claims of the '245 Patent.

39. On information and belief, Laurus 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, Laurus will infringe Claim 1 of the '245 Patent because the product for which it seeks approval in ANDA No. 212114 will be labeled for and used to treat HIV infection in humans with an effective amount of emtricitabine. In its September 24, 2018 Notice Letter, Laurus 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. 212114. For the same reasons, on information and belief, Laurus will likewise infringe Claims 2, 4, 6, 7 and 8 of the '245 Patent.

40. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, 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 Laurus'

active behest and with its intent, knowledge, and encouragement. On information and belief, Laurus 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. 212114 with a Paragraph IV certification, Laurus admits that it has knowledge of the '245 Patent.

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

41. Plaintiffs repeat and reallege paragraphs 1-40 above as if set forth herein.

42. On information and belief, Laurus submitted or caused to be submitted ANDA No. 212114 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 tenofovir disoproxil fumarate for the purpose of treating HIV infection.

43. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that it had submitted ANDA No. 212114 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 tenofovir disoproxil fumarate prior to the expiration of the '396 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the September 24, 2018 Notice Letter.

44. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that, as a part of its ANDA No. 212114, it had filed a Paragraph IV certification 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 . . . ."

45. Laurus alleged in its September 24, 2018 Notice Letter that Claims 1-9 and 11-28 of the '396 Patent are invalid and that Claims 7-10 would not be infringed by the commercial

manufacture, use, sale and/or importation of its proposed product that is the subject of ANDA No. 212114.

46. The September 24, 2018 Notice Letter does not allege non-infringement of Claims 1-6 and 11-28 of the '396 Patent.

47. By filing ANDA No. 212114 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 tenofovir disoproxil fumarate before the '396 Patent's expiration, Laurus has committed an act of infringement of the '396 Patent under 35 U.S.C. § 271(e)(2).

48. Laurus' submission of ANDA No. 212114 and service of the September 24, 2018 Notice Letter indicates a refusal to change its current course of action.

49. On information and belief, the commercial manufacture, use, sale and/or importation of tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe one or more claims of the '396 Patent.

50. On information and belief, Laurus 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, Laurus will infringe Claim 2 of the '396 Patent because the product for which it seeks approval in ANDA No. 212114 will contain emtricitabine as the active ingredient. In its September 24, 2018 Notice Letter, Laurus 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. 212114. For the same

reasons, on information and belief, Laurus will also infringe at least Claims 1, 3-7, 11-16, 22, and 23 of the '396 Patent.

51. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, 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 Laurus' active behest and with its intent, knowledge, and encouragement. On information and belief, Laurus 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. 212114 with a Paragraph IV certification, Laurus admits that it has knowledge of the '396 Patent.

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

52. Plaintiffs repeat and reallege paragraphs 1-51 above as if set forth herein.

53. On information and belief, Laurus submitted or caused to be submitted ANDA No. 212114 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 tenofovir disoproxil fumarate for the purpose of treating HIV infection.

54. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that it had submitted ANDA No. 212114 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 tenofovir disoproxil fumarate prior to the expiration of the '397 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the September 24, 2018 Notice Letter.

55. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that, as a part of ANDA No. 212114, it had filed a Paragraph IV certification 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 . . . ."

56. Laurus alleged in its September 24, 2018 Notice Letter that Claims 1-6, 14-16, 19-22, and 24-26 of the '397 Patent are invalid and that Claims 7-13, 17-18, and 23 would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 212114.

57. Laurus did not allege in its September 24, 2018 Notice Letter that Claims 1-6, 14-16, 19-22, and 24-26 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. 212114.

58. By filing ANDA No. 212114 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 tenofovir disoproxil fumarate before the '397 Patent's expiration, Laurus has committed an act of infringement of the '397 Patent under 35 U.S.C. § 271(e)(2).

59. Laurus' submission of ANDA No. 212114 and service of the September 24, 2018 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 tenofovir disoproxil

fumarate for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe one or more claims of the ’397 Patent.

61. On information and belief, Laurus 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, Laurus will infringe Claim 1 of the ’397 Patent because the product for which it seeks approval in ANDA No. 091055 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 September 24, 2018 Notice Letter, Laurus 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. 212114. For the same reasons, on information and belief, Laurus will also infringe at least Claims 2-6, 14-16, 19-22, and 24-26 of the ’397 Patent.

62. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, 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 Laurus' active behest and with its intent, knowledge, and encouragement. On information and belief, Laurus 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 Gilead's rights under the '397 Patent. Further, by filing ANDA No. 212114 with a Paragraph IV certification, Laurus admits that it has knowledge of the '397 Patent.

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

63. Plaintiffs repeat and reallege paragraphs 1-62 above as if set forth herein.

64. On information and belief, Laurus submitted or caused to be submitted ANDA No. 212114 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 tenofovir disoproxil fumarate for the purpose of treating HIV infection.

65. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that it had submitted ANDA No. 212114 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 tenofovir disoproxil fumarate prior to the expiration of the '264 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the September 24, 2018 Notice Letter.

66. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that, as a part of its ANDA No. 212114, it had filed a Paragraph IV certification 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 . . . ."

67. Laurus alleged in its September 24, 2018 Notice Letter that Claims 1-17, 25, and 33-35 of the '264 Patent are invalid and that Claims 18-24, 26-32, and 36-38 would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 212114.

68. The September 24, 2018 Notice Letter does not allege non-infringement of Claims 1-17, 25, and 33-35 of the '264 Patent.

69. By filing ANDA No. 212114 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, Laurus has committed an act of infringement of the '264 Patent under 35 U.S.C. § 271(e)(2).

70. Laurus' submission of ANDA No. 212114 and service of the September 24, 2018 Notice Letter indicates a refusal to change its current course of action.

71. 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 Laurus seeks approval in ANDA No. 212114, if approved, will infringe one or more claims of the '264 Patent.

72. On information and belief, Laurus 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, Laurus will infringe Claim 1 of the '264 Patent because the product for which it seeks approval in ANDA No. 212114 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 September 24, 2018 Notice Letter, Laurus 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. 212114. For the same reasons, on information and belief, Laurus will also infringe at least Claims 2-17, 25, and 33-35 of the '264 Patent.

73. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg of tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, 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 Laurus' active behest and with its intent, knowledge, and encouragement. On information and belief, Laurus 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 Gilead's rights under the '264 Patent. Further, by filing ANDA No. 212114 with a Paragraph IV certification, Laurus admits that it has knowledge of the '264 Patent.

[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.

COUNT 5
Infringement of U.S. Patent No. 9,457,036

74. Plaintiffs repeat and reallege paragraphs 1-73 above as if set forth herein.

75. On information and belief, Laurus submitted or caused to be submitted ANDA No. 212114 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 tenofovir disoproxil fumarate for the purpose of treating HIV infection.

76. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that it had submitted ANDA No. 212114 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 tenofovir disoproxil fumarate prior to the expiration of the ’036 Patent. This complaint has been filed within 45 days of Plaintiffs’ receipt of the September 24, 2018 Notice Letter.

77. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that, as a part of ANDA No. 212114, it had filed a Paragraph IV certification with respect to the ’036 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 ’036 Patent, “is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . .”

78. Laurus alleged in its September 24, 2018 Notice Letter that Claims 1-4, 12-14, and 16 of the ’036 Patent are invalid and that Claims 5-11 and 15 would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 212114.

79. Laurus did not allege in its September 24, 2018 Notice Letter that claims 1-4, 12-14, or 16 of the '036 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. 212114.

80. By filing ANDA No. 212114 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 tenofovir disoproxil fumarate before the '036 Patent's expiration, Laurus has committed an act of infringement of the '036 Patent under 35 U.S.C. § 271(e)(2).

81. Laurus' submission of ANDA No. 212114 and service of the September 24, 2018 Notice Letter indicates a refusal to change its current course of action.

82. On information and belief, the commercial manufacture, use, sale, and/or importation of tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe one or more claims of the '036 Patent.

83. On information and belief, Laurus will directly or indirectly infringe at least Claim 1 of the '036 Patent. Claim 1 recites a "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 equal to or less than 5% 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; and wherein said pharmaceutical dosage form is a tablet." On information and belief, Laurus will infringe Claim 1 of the '036 Patent because the product for which it seeks approval in ANDA No. 212114 will be a 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 equal to or less than 5% 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 September 24, 2018 Notice Letter, Laurus 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. 212114. For the same reasons, on information and belief, Laurus will also infringe at least Claims 2-4, 12-14, and 16 of the '036 Patent.

84. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe at least one claim of the '036 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 Laurus' active behest and with its intent, knowledge, and encouragement. On information and belief, Laurus 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 Gilead's rights under the '036 Patent. Further, by filing ANDA No. 212114 with a Paragraph IV certification, Laurus admits that it has knowledge of the '036 Patent.

COUNT 6
Infringement of U.S. Patent No. 9,744,181

85. Plaintiffs repeat and reallege paragraphs 1-84 above as if set forth herein.

86. On information and belief, Laurus submitted or caused to be submitted ANDA No. 212114 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 tenofovir disoproxil fumarate for the purpose of treating HIV infection.

87. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that it had submitted ANDA No. 212114 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 tenofovir disoproxil fumarate prior to the expiration of the '181 Patent. This complaint has been filed within 45 days of Plaintiffs' receipt of the September 24, 2018 Notice Letter.

88. In its September 24, 2018 Notice Letter, Laurus notified Plaintiffs that, as a part of ANDA No. 212114, it had filed a Paragraph IV certification with respect to the '181 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 '036 Patent, "is invalid or will not be infringed by the manufacture, use or sale of the new drug for which the application is submitted . . . ."

89. Laurus alleged in its September 24, 2018 Notice Letter that Claims 1-5, 7, 11, 13-17, 25, and 29 of the '181 Patent are invalid and that Claims 6, 8-10, 12, 18-24, 26-28, and 30 would not be infringed by the commercial manufacture, use, sale, and/or importation of its proposed product that is the subject of ANDA No. 212114.

90. Laurus did not allege in its September 24, 2018 Notice Letter that claims 1-5, 7, 11, 13-17, 25, or 29 of the '181 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. 212114.

91. By filing ANDA No. 212114 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 tenofovir disoproxil fumarate before the '181 Patent's expiration, Laurus has committed an act of infringement of the '181 Patent under 35 U.S.C. § 271(e)(2).

92. Laurus' submission of ANDA No. 212114 and service of the September 24, 2018 Notice Letter indicates a refusal to change its current course of action.

93. On information and belief, the commercial manufacture, use, sale, and/or importation of tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe one or more claims of the '181 Patent.

94. On information and belief, Laurus will directly or indirectly infringe at least Claim 1 of the '181 Patent. Claim 1 recites a "fixed dose combination comprising 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine wherein the combination exhibits equal to or less than 5% degradation of the tenofovir disoproxil fumarate and emtricitabine after six months at 40° C./75% relative humidity when packaged and stored with silica gel dessicant, and wherein the fixed-dose combination is a tablet." On information and belief, Laurus will infringe Claim 1 of the '181 Patent because the product for which it seeks approval in ANDA No. 212114 will be a fixed-dose tablet containing 300 mg tenofovir disoproxil fumarate and 200 mg emtricitabine and will exhibit equal to or less than 5% degradation of the tenofovir disoproxil fumarate and emtricitabine after six months when packaged and stored with silica gel dessicant at 40° C./75% relative humidity. In its September 24, 2018 Notice Letter, Laurus 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. 212114. For the same reasons, on information and belief, Laurus will also infringe at least Claims 1-5, 7, 11, 13-17, 25, and 29 of the '181 Patent.

95. On information and belief, the tablets containing 200 mg of emtricitabine and 300 mg tenofovir disoproxil fumarate for the use for which Laurus seeks approval in ANDA No. 212114, if approved, will infringe at least one claim of the '181 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 Laurus' active behest and with its intent, knowledge, and encouragement. On information and belief, Laurus 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 Gilead's rights under the '181 Patent. Further, by filing ANDA No. 212114 with a Paragraph IV certification, Laurus admits that it has knowledge of the '181 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that the effective date of any approval of Laurus' ANDA No. 212114 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 Laurus' ANDA No. 212114 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 Laurus' ANDA No. 212114 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 Laurus’ ANDA No. 212114 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 effective date of any approval of Laurus’ ANDA No. 212114 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 ’036 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

(f) A judgment declaring that the effective date of any approval of Laurus’ ANDA No. 212114 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 ’181 Patent or any later date of exclusivity to which Plaintiffs are or become entitled;

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

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

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

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

(k) A judgment declaring that the ’036 Patent remains valid and enforceable, and that one or more claims have been infringed by Laurus;

(l) A judgment declaring that the ’181 Patent remains valid and enforceable, and that one or more claims have been infringed by Laurus;

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

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

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

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

(q) A permanent injunction against any infringement of the ’036 Patent by Laurus, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(r) A permanent injunction against any infringement of the ’181 Patent by Laurus, their officers, agents, attorneys and employees, and those acting in privity or contract with them;

(s) To the extent that Laurus 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;

(t) To the extent that Laurus 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;

(u) To the extent that Laurus 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;

(v) To the extent that Laurus 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;

(w) To the extent that Laurus has committed any acts with respect to the subject matter claimed in the '036 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;

(x) To the extent that Laurus has committed any acts with respect to the subject matter claimed in the '181 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;

(y) Costs and expenses in this action; and

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

Dated: November 6, 2018

Respectfully submitted,

FARNAN LLP

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