IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
AUROBINDO PHARMA LTD. and AUROBINDO PHARMA USA, INC.,	)	
	)	
	)	
Defendants.	)	

PLAINTIFF GILEAD SCIENCES, INC.'S
COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead"), by its undersigned attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the U.S., Title 35, United States Code, against Defendants Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. (collectively, "Aurobindo" or "Defendants"). This action arises out of Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA").

2. Defendants seek approval to market a generic copy of Gilead's highly successful product, LETAIRIS®, containing 5 mg or 10 mg of ambrisentan, an endothelin receptor antagonist, prior to the expiration of U.S. Patent No. 8,377,933 (the "'933 patent"); U.S. Patent No. 9,474,752 (the "'752 patent"); and U.S. Patent No. 9,549,926 (the "'926 patent") (collectively, the "Patents-In-Suit"). Gilead attaches hereto true and accurate copies of each of the Patents-In-Suit as Exhibits A-C.

PARTIES

3. Plaintiff Gilead Sciences, Inc. is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

4. Gilead is a research-based pharmaceutical company that invents, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for human immunodeficiency virus, hepatitis B virus, hepatitis C virus, hepatitis delta virus, liver diseases, serious cardiovascular and respiratory diseases, and cancer. Gilead's portfolio of products includes treatments for pulmonary arterial hypertension ("PAH") using ambrisentan alone or in combination with tadalafil. Gilead is the owner of the Patents-In-Suit.

5. On information and belief, Aurobindo Pharma Ltd. is a foreign corporation organized and existing under the laws of India, having its principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha Ranga Reddy District, Hyderabad – 500 032, Telangana, India. On information and belief, Aurobindo Pharma Ltd. is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market and/or manufacturing active pharmaceutical ingredients for generic copies of branded pharmaceutical products for the U.S. market.

6. On information and belief, Aurobindo Pharma USA, Inc. is a corporation organized under the laws of Delaware, having its principal place of business at 279 Princeton Highstown Road, East Windsor, NJ 08520. On information and belief, Aurobindo Pharma USA, Inc. is in the business of, among other things, marketing, distributing, and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Aurobindo Pharma USA,

Inc. is a wholly-owned subsidiary of and an authorized U.S. agent of Defendant Aurobindo Pharma Ltd.

7. On information and belief, Aurobindo prepared and submitted to the FDA ANDA No. 216531 (the "LETAIRIS ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Gilead's LETAIRIS product ("Defendants' LETAIRIS ANDA Product" or the "LETAIRIS ANDA Product") in the U.S., including in this District. On information and belief, Aurobindo is the holder of the LETAIRIS ANDA.

8. On information and belief, Aurobindo Pharma Ltd. will manufacture the LETAIRIS ANDA Product for Aurobindo Pharma USA, Inc., which will market and distribute it. On information and belief, the acts of Aurobindo Pharma Ltd. complained of herein were done with the cooperation, participation, and assistance of Aurobindo Pharma USA, Inc.

9. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. collaborate with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of the LETAIRIS ANDA Product for the U.S. market, including the market in the State of Delaware.

10. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. intend to act collaboratively to commercially manufacture, import, market, distribute, offer for sale, and/or sell the LETAIRIS ANDA Product, in the event that the FDA approves the LETAIRIS ANDA.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the U.S., 35 U.S.C. §§ 100 *et seq.*, including §§ 271(e)(2) and 271(b). This Court has jurisdiction over this action under 28 U.S.C. §§ 1331 and 1338(a).

12. The Court also has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable controversy exists between Gilead and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the Patents-In-Suit.

13. On information and belief, this Court has personal jurisdiction over Aurobindo Pharma USA, Inc., *inter alia*, because Aurobindo Pharma USA, Inc. is incorporated in Delaware.

14. On information and belief, Aurobindo Pharma USA, Inc. has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being subject to the jurisdiction of the court in the District of Delaware.

15. On information and belief, Aurobindo Pharma USA, Inc., directly and/or through its parent company Aurobindo Pharma Ltd., markets, distributes, and/or sells generic pharmaceutical products throughout the U.S., including in this District.

16. On information and belief, Aurobindo Pharma USA, Inc. derives substantial revenue from selling generic pharmaceutical products throughout the U.S., including in this District, directly and/or through its parent company Aurobindo Pharma Ltd.

17. On information and belief, Aurobindo Pharma USA, Inc., directly and/or through its parent company Aurobindo Pharma Ltd., has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers, and/or distributors in this District.

18. On information and belief, this Court has personal jurisdiction over Aurobindo Pharma Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates,

Aurobindo Pharma Ltd. regularly and continuously transacts business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the U.S., including Delaware. Specifically, on information and belief, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because, *inter alia*, it: (1) intends to market, sell, and/or distribute the LETAIRIS ANDA Product to residents of Delaware; (2) has continuous and systemic contacts with the State of Delaware and regularly conducts business in the State of Delaware, either directly or through one or more of its affiliates, agents, and/or alter egos; (3) exercises control over Defendant Aurobindo Pharma USA, Inc.; (4) operates through its wholly-owned subsidiary Aurobindo Pharma USA, Inc., which is incorporated in Delaware; (5) makes its generic pharmaceutical products available in Delaware; (6) maintains a broad distributorship network within Delaware; and (7) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

19. On information and belief, Aurobindo Pharma Ltd. has been and is engaging in activities directed toward infringement of the Patents-In-Suit by, among other things, preparing and submitting to the FDA the LETAIRIS ANDA, and acting in concert with Aurobindo Pharma USA, Inc. in the preparation and submission of the LETAIRIS ANDA seeking FDA approval to market the LETAIRIS ANDA Product throughout the U.S., including in Delaware, before expiration of the Patents-In-Suit.

20. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Aurobindo Pharma Ltd. has received more than 700 FDA approvals to market and sell pharmaceutical products throughout the U.S., including in Delaware. On information and belief, Aurobindo Pharma Ltd. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

21. On information and belief, Aurobindo Pharma Ltd. markets and distributes its pharmaceutical products through subsidiaries, agents, and/or affiliates, including Aurobindo Pharma USA, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware. On information and belief, Aurobindo Pharma Ltd., through Aurobindo Pharma USA, Inc., is licensed to sell generic pharmaceutical products in the State of Delaware, pursuant to 24 Del. C. § 2540.

22. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. operate and act in concert as an integrated, unitary business. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. work in concert with respect to the manufacturing, marketing, sale, and/or distribution of generic pharmaceutical products throughout the U.S., including in Delaware.

23. This Court also has personal jurisdiction because Aurobindo Pharma Ltd. has submitted an ANDA for a generic copy of Gilead's LETAIRIS product, seeking approval from the FDA to market and sell the LETAIRIS ANDA Product throughout the U.S., including in Delaware. On information and belief, Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc. intend to commercially manufacture, import, use, offer for sale, and/or sell the LETAIRIS ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves the LETAIRIS ANDA, the LETAIRIS ANDA Product would, among other things, be marketed, distributed, and/or sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By submitting Defendants' ANDA, Aurobindo Pharma Ltd. has made clear that it intends to use its distribution channels to direct sales of the LETAIRIS ANDA Product into Delaware.

24. Further, this Court has personal jurisdiction over Aurobindo Pharma Ltd. because it has previously been sued in this District and has not challenged personal jurisdiction, and Aurobindo Pharma Ltd. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g.*, *Amgen Inc., et al., v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 21-662, D.I. 14 (D. Del. June 10, 2021); *Acadia Pharmaceuticals Inc., et al., v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 20-985, D.I. 10 (D. Del. Sept. 1, 2020); *Kissei Pharmaceutical Co., Ltd., et al., v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 17-1161, D.I. 12 (D. Del. Sept. 13, 2017); *Allergan, Inc., et al., v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 17-1290, D.I. 9 (D. Del. Oct. 10, 2017); *Astellas Pharma Inc., et al., v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 16-942, D.I. 16 (D. Del. Dec. 19, 2016); *Astrazeneca Pharms. LP, et al., v. Aurobindo Pharma Ltd., et al.*, Civil Action No. 07-810, D.I. 12 (D. Del. July 18, 2014).

25. Alternatively, this Court may exercise personal jurisdiction over Aurobindo Pharma Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Aurobindo Pharma Ltd. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Aurobindo Pharma Ltd. has sufficient contacts with the U.S. as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the U.S., such that this Court's exercise of jurisdiction over Aurobindo Pharma Ltd. satisfies due process.

26. Venue is proper in this Court for Aurobindo Pharma USA, Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Aurobindo Pharma USA, Inc. is incorporated in this District.

27. Venue is proper in this Court for Aurobindo Pharma Ltd. under 28 U.S.C. § 1391(c)(3) because Aurobindo Pharma Ltd. is a foreign corporation and may be sued in any

judicial district in the U.S. in which it is subject to the court's personal jurisdiction, including in this District.

PATENTS-IN-SUIT

28. On February 19, 2013, the U.S. Patent and Trademark Office duly and legally issued the '933 patent, titled, "Method for Treating a Pulmonary Hypertension Condition." A true and correct copy of the '933 patent is attached hereto as Exhibit A. The claims of the '933 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '933 patent.

29. On October 25, 2016, the U.S. Patent and Trademark Office duly and legally issued the '752 patent, titled, "Method for Treating a Pulmonary Hypertension Condition." A true and correct copy of the '752 patent is attached hereto as Exhibit B. The claims of the '752 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '752 patent.

30. On January 24, 2017, the U.S. Patent and Trademark Office duly and legally issued the '926 patent, titled, "Compositions and Methods for Treating Pulmonary Hypertension." A true and correct copy of the '926 patent is attached hereto as Exhibit C. The claims of the '926 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '926 patent.

ACTS GIVING RISE TO THIS ACTION

LETAIRIS

31. Gilead holds approved NDA No. 22081 for tablets containing 5 mg or 10 mg of ambrisentan. The tablets are indicated for the treatment of PAH either alone or in combination with tadalafil.

32. Gilead markets the tablets approved under NDA No. 22081 in the U.S. under the registered trademark LETAIRIS. The FDA's publication *Approved Drug Products with*

Therapeutic Equivalence Evaluations (commonly known as the "Orange Book") lists the Patents-In-Suit for LETAIRIS.

33. At least one claim of each of the Patents-In-Suit covers an approved method of using LETAIRIS.

34. Defendants submitted to the FDA an ANDA listing LETAIRIS as the reference listed drug.

Defendants' Acts Regarding LETAIRIS

35. On information and belief, Defendants submitted to the FDA the LETAIRIS ANDA under Section 505(j) of the FDCA, seeking the FDA's approval to engage in the commercial manufacture, use, offer for sale, and sale and/or importation of the LETAIRIS ANDA Product before the expiration of the Patents-In-Suit. On information and belief, the FDA assigned the ANDA number 216531.

36. On information and belief, Defendants sent a letter dated October 26, 2021 to Gilead (the "LETAIRIS Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The LETAIRIS Notice Letter states that the LETAIRIS ANDA includes a certification pursuant to 21 U.S.C. §§ 355(j)(1) and (2)(A) with respect to each of the Patents-In-Suit.

37. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH would infringe one or more claims of the Patents-in-Suit.

38. Gilead received the LETAIRIS Notice Letter on or about October 28, 2021.

39. This action is being commenced before the expiration of 45 days from the date Gilead received the LETAIRIS Notice Letter, which triggers a stay of FDA approval of the LETAIRIS ANDA pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

40. By submitting their LETAIRIS ANDA, Defendants have represented to the FDA that their LETAIRIS ANDA Product has the same active ingredients as LETAIRIS; has the same dosage forms and strengths as LETAIRIS; and is bioequivalent to LETAIRIS.

41. On information and belief, Defendants are seeking approval to market their LETAIRIS ANDA Product for the same approved indications as LETAIRIS.

42. On information and belief, Defendants' proposed label for their LETAIRIS ANDA Product (the "Defendants' Proposed Label") will refer to the product as, *inter alia*, a 5 mg or 10 mg tablet of ambrisentan, indicated as treatment for PAH alone or in combination with tadalafil.

43. On information and belief, the Defendants' Proposed Label will instruct physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil for the treatment of PAH.

44. On information and belief, the Defendants' Proposed Label will contain data relating to the treatment of patients with PAH, obtained from clinical studies involving LETAIRIS in combination with tadalafil.

COUNTS I-VI FOR PATENT INFRINGEMENT

Count I: Infringement of the '933 Patent under 35 U.S.C. § 271(e)(2) by the LETAIRIS ANDA Product

45. Gilead realleges the foregoing paragraphs as if fully set forth herein.

46. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants have committed an act of infringement of the '933 patent by submitting to the FDA the LETAIRIS ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the LETAIRIS ANDA

Product in the U.S., and/or importation of said product into the U.S., prior to the expiration of the '933 patent.

47. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the LETAIRIS ANDA Product prior to the expiration of the '933 patent, and their inducement of physicians and healthcare providers to administer the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH, would constitute infringement of at least one of the claims of the '933 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

48. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH would infringe claims 1-11 of the '933 patent.

49. The commercial manufacture, use, offer for sale, sale and/or importation of the LETAIRIS ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

50. Unless Defendants are enjoined from infringing the '933 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count II: Declaratory Judgment of Infringement of the '933 Patent under 35 U.S.C. § 271(b) by the LETAIRIS ANDA Product

51. Gilead realleges the foregoing paragraphs as if fully set forth herein.

52. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

53. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

54. Defendants have submitted to the FDA an ANDA for a generic copy of Gilead's LETAIRIS pharmaceutical product. According to the LETAIRIS Notice Letter, Defendants intend to manufacture, use, offer for sale and/or sell the LETAIRIS ANDA Product within the U.S., and/or import it into the U.S.

55. Although the FDA has not approved the LETAIRIS ANDA, Defendants have made, and will continue to make, substantial preparation in the U.S. to manufacture, use, offer to sell, sell and/or import the LETAIRIS ANDA Product.

56. Defendants' actions indicate that they do not intend to change their course of conduct.

57. On information and belief, upon FDA approval of the LETAIRIS ANDA, Defendants will actively induce the infringement of one or more claims of the '933 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, by making, using, offering to sell, and/or selling the LETAIRIS ANDA Product in the U.S. and/or importing said product into the U.S., and/or encouraging or instructing physicians and healthcare providers to administer the product to patients in combination with tadalafil for the treatment of PAH, under 35 U.S.C. § 271(b) unless enjoined by the Court.

58. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH would infringe claims 1-11 of the '933 patent.

59. Defendants have actual knowledge of the '933 patent.

60. On information and belief, Defendants became aware of the '933 patent no later than the filing of their LETAIRIS ANDA.

61. On information and belief, Defendants' efforts to make, use, offer for sale, sell, and/or import the LETAIRIS ANDA Product have been made and will be made with full knowledge of the '933 patent and without a reasonable basis for believing that they would not be liable for actively inducing infringement of the '933 patent. On information and belief, this knowledge is reflected through, among other things, the LETAIRIS Notice Letter, which does not contest infringement of claims 1-11 of the '933 patent.

62. On information and belief, the LETAIRIS ANDA Product, if FDA-approved, will be commercially manufactured, used, offered for sale, and/or sold by Defendants in the U.S., and/or imported into the U.S. by Defendants.

63. On information and belief, the Defendants' Proposed Label will include directions and instructions for physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in accordance with the methods described and claimed in the '933 patent.

64. On information and belief, physicians and healthcare providers will administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in the U.S. according to the directions and instructions in the Defendants' Proposed Label, and such administration will constitute direct infringement of at least one claim of the '933 patent.

65. On information and belief, Defendants will encourage physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in accordance with the methods described and claimed in the '933 patent, and Defendants know or should know that such conduct will occur.

66. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the '933 patent.

67. Through at least the foregoing actions, Defendants will actively induce the infringement of at least one claim of the '933 patent under 35 U.S.C. § 271(b).

68. Gilead is entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of the LETAIRIS ANDA Product by Defendants prior to the expiration of the '933 patent will induce the actual and direct infringement of the '933 patent.

69. The commercial manufacture, importation, use, sale, and/or offer for sale of the LETAIRIS ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

70. Unless Defendants are enjoined from infringing the '933 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count III: Infringement of the '752 Patent under 35 U.S.C. § 271(e)(2) by the LETAIRIS ANDA Product

71. Gilead realleges the foregoing paragraphs as if fully set forth herein.

72. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants have committed an act of infringement of the '752 patent by submitting to the FDA the LETAIRIS ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, and/or sale of the LETAIRIS ANDA Product in the U.S., and/or importation of said product into the U.S., prior to the expiration of the '752 patent.

73. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the LETAIRIS ANDA Product prior to the expiration of the '752 patent, and their inducement of physicians and healthcare providers to administer the LETAIRIS ANDA Product to patients in

combination with tadalafil for the treatment of PAH, would constitute infringement of at least one of the claims of the '752 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

74. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH would infringe claims 1-15 of the '752 patent.

75. The commercial manufacture, use, offer for sale, sale and/or importation of the LETAIRIS ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

76. Unless Defendants are enjoined from infringing the '752 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count IV: Declaratory Judgment of Infringement of the '752 Patent under 35 U.S.C. § 271(b) by the LETAIRIS ANDA Product

77. Gilead realleges the foregoing paragraphs as if fully set forth herein.

78. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

79. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

80. Defendants have submitted to the FDA an ANDA for a generic copy of Gilead's LETAIRIS pharmaceutical product. According to the LETAIRIS Notice Letter, Defendants intend to manufacture, use, offer for sale, and/or sell the LETAIRIS ANDA Product within the U.S., and/or import it into the U.S.

81. Although the FDA has not approved the LETAIRIS ANDA, Defendants have made, and will continue to make, substantial preparation in the U.S. to manufacture, use, offer to sell, sell and/or import the LETAIRIS ANDA Product.

82. Defendants' actions indicate that they do not intend to change their course of conduct.

83. On information and belief, upon FDA approval of the LETAIRIS ANDA, Defendants will actively induce infringement of one or more claims of the '752 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, by making, using, offering to sell, and/or selling the LETAIRIS ANDA Product in the U.S. and/or importing said product into the U.S., and/or encouraging or instructing physicians and healthcare providers to administer the product to patients in combination with tadalafil for the treatment of PAH, under 35 U.S.C. § 271(b) unless enjoined by the Court.

84. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH would infringe claims 1-15 of the '752 patent.

85. Defendants have actual knowledge of the '752 patent.

86. On information and belief, Defendants became aware of the '752 patent no later than the filing of their LETAIRIS ANDA.

87. On information and belief, Defendants' efforts to make, use, offer to sell, sell and/or import the LETAIRIS ANDA Product have been made and will be made with full knowledge of the '752 patent and without a reasonable basis for believing that they would not be liable for actively inducing infringement of the '752 patent. On information and belief, this knowledge is

reflected through, among other things, the LETAIRIS Notice Letter, which does not contest infringement of claims 1-15 of the '752 patent.

88. On information and belief, the LETAIRIS ANDA Product, if FDA-approved, will be commercially manufactured, used, offered for sale, and/or sold by Defendants in the U.S. or on their behalf, and/or imported into the U.S. by Defendants

89. On information and belief, the Defendants' Proposed Label will include directions and instructions for physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in accordance with the methods described and claimed in the '752 patent.

90. On information and belief, physicians and healthcare providers will administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in the U.S. according to the directions and instructions in the Defendants' Proposed Label, and such administration will constitute direct infringement of at least one claim of the '752 patent.

91. On information and belief, Defendants will encourage physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in accordance with the methods described and claimed in the '752 patent, and Defendants know or should know that such conduct will occur.

92. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the '752 patent.

93. Through at least the foregoing actions, Defendants will actively induce the infringement of at least one claim of the '752 patent under 35 U.S.C. § 271(b).

94. Gilead is entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of the LETAIRIS ANDA Product by Defendants prior to the expiration of the '752 patent will induce the actual and direct infringement of the '752 patent.

95. The commercial manufacture, importation, use, offer for sale and/or sale of the LETAIRIS ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

96. Unless Defendants are enjoined from infringing the '752 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count V: Infringement of the '926 Patent under 35 U.S.C. § 271(e)(2) by the LETAIRIS ANDA Product

97. Gilead realleges the foregoing paragraphs as if fully set forth herein.

98. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants have committed an act of infringement of the '926 patent by submitting to the FDA the LETAIRIS ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale and/or sale of the LETAIRIS ANDA Product in the U.S., and/or importation into the U.S., prior to the expiration of the '926 patent.

99. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the LETAIRIS ANDA Product prior to the expiration of the '926 patent, and their inducement of physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil for the treatment of PAH, would constitute infringement of at least one of the claims of the '926 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

100. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product in combination with tadalafil to patients for the treatment of PAH would infringe claims 1-6 of the '926 patent.

101. The commercial manufacture, importation, use, offer for sale and/or sale of the LETAIRIS ANDA Product in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate

102. Unless Defendants are enjoined from infringing the '926 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VI: Declaratory Judgment of Infringement of the '926 Patent under 35 U.S.C. § 271(b) by the LETAIRIS ANDA Product

103. Gilead realleges the foregoing paragraphs as if fully set forth herein.

104. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

105. There is an actual case or controversy such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the U.S. Constitution, and that actual case or controversy requires a declaration of rights by this Court.

106. Defendants have submitted to the FDA an ANDA for a generic copy of Gilead's LETAIRIS pharmaceutical product. According to the LETAIRIS Notice Letter, Defendants intend to manufacture, use, offer for sale, and/or sell the LETAIRIS ANDA Product within the U.S., and/or import it into the U.S.

107. Although the FDA has not approved the LETAIRIS ANDA, Defendants have made, and will continue to make, substantial preparation in the U.S. to manufacture, use, offer to sell, sell and/or import the LETAIRIS ANDA Product.

108. Defendants' actions indicate that they do not intend to change their course of conduct.

109. On information and belief, upon FDA approval of the LETAIRIS ANDA, Defendants will actively induce infringement of one or more claims of the '926 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, by making,

using, offering to sell, and/or selling the LETAIRIS ANDA Product in the U.S., and/or importing said product into the U.S., and/or encouraging or instructing physicians and healthcare providers to administer the product to patients in combination with tadalafil for the treatment of PAH, under 35 U.S.C. § 271(b) unless enjoined by the Court.

110. The LETAIRIS Notice Letter does not dispute that administration of the LETAIRIS ANDA Product to patients in combination with tadalafil for the treatment of PAH would infringe claims 1-6 of the '926 patent.

111. Defendants have actual knowledge of the '926 patent.

112. On information and belief, Defendants became aware of the '926 patent no later than the filing of their LETAIRIS ANDA.

113. On information and belief, Defendants' efforts to make, use, offer to sell, sell and/or import the LETAIRIS ANDA Product have been made and will be made with full knowledge of the '926 patent and without a reasonable basis for believing that they would not be liable for actively inducing infringement of the '926 patent. On information and belief, this knowledge is reflected through, among other things, the LETAIRIS Notice Letter, which does not contest infringement of claims 1-11 of the '926 patent.

114. On information and belief, the LETAIRIS ANDA Product, if FDA-approved, will be commercially manufactured, used, offered for sale, and/or sold by Defendants in the U.S. and/or imported into the U.S. by Defendants

115. On information and belief, the Defendants' Proposed Label will include directions and instructions for physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in accordance with the methods described and claimed in the '926 patent.

116. On information and belief, physicians and healthcare providers will administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in the U.S. according to the directions and instructions in the Defendants' Proposed Label, and such administration will constitute direct infringement of at least one claim of the '926 patent.

117. On information and belief, Defendants will encourage physicians and healthcare providers to administer the LETAIRIS ANDA Product in combination with tadalafil in order to treat PAH in accordance with the methods described and claimed in the '926 patent, and Defendants will know or should know that such conduct will occur.

118. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the '926 patent.

119. Through at least the foregoing actions, Defendants will actively induce the infringement of at least one claim of the '926 patent under 35 U.S.C. § 271(b).

120. Gilead is entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of the LETAIRIS ANDA Product by the Defendants prior to the expiration of the '926 patent will induce the actual and direct infringement of the '926 patent.

121. The commercial manufacture, importation, use, offer for sale and/or sale of the LETAIRIS ANDA Product in violation of Gilead's patent rights will cause harm to Plaintiff for which damages are inadequate.

122. Unless Defendants are enjoined from infringing the '926 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Gilead prays that this Court grant the following relief:

A) A judgment that Defendants have infringed the '933 patent, the '752 patent, and the '926 patent under 35 U.S.C. § 271(e)(2)(A);

B) A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the LETAIRIS ANDA shall be a date which is not earlier than the day after the latest expiration date of the '933 patent, the '752 patent, and the '926 patent, as extended by any applicable periods of exclusivity to which Gilead is or will be entitled;

C) A judgment declaring that Defendants' commercial manufacture, use, offer for sale, and sale of the LETAIRIS ANDA Product in the U.S., and/or importation into the U.S., prior to the expiration of the '933 patent, the '752 patent, and the '926 patent (including such actions by its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Defendants or acting on Defendants' behalf) will constitute infringement of the '933 patent, the '752 patent, and the '926 patent under 35 U.S.C. § 271(b) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

D) An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the U.S., and/or importing into the U.S., the LETAIRIS ANDA Product until the day after the latest expiration date of the '933 patent, the '752 patent, and the '926 patent, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled, and from otherwise infringing one or more claims of the '933 patent, the '752 patent, and the '926 patent;

E) A declaration that this case is exceptional;

F) An award of Gilead's costs, expenses, reasonable attorneys' fees and such other relief as the Court deems proper and just pursuant to 35 U.S.C. § 271(e)(4) and 35 U.S.C. § 285; and

G) Such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Jeremy A. Tigan (#5239)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@morrisnichols.com
jtigan@morrisnichols.com

Attorneys for Plaintiff
Gilead Sciences, Inc.

OF COUNSEL:

Charlotte Jacobsen
Filko Prugo
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, NY 10036-8704
(212) 596-9000

Rebecca Gentilli
ROPES & GRAY LLP
Prudential Tower
800 Boylston Street
Boston, MA 02199-3600
(617) 951-7000

December 10, 2021