IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	
	)	C.A. No. 22-____
LUPIN LTD., LAURUS LABS LIMITED, AND CIPLA LIMITED	)	
	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead") brings this Complaint for patent infringement against Defendants Lupin Ltd. ("Lupin"), Laurus Labs Limited ("Laurus"), and Cipla Limited ("Cipla") (collectively "Defendants") and alleges as follows:

NATURE OF ACTION

1. This is a civil action for patent infringement against Lupin, Laurus, and Cipla arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and, more particularly 35 U.S.C. §§ 271(a)-(c), (e), and 281. Defendants each filed an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA").

2. Each defendant seeks approval to market a generic version of Gilead's Biktarvy® (bictegravir ("BIC"), tenofovir alafenamide ("TAF"), emtricitabine ("FTC")) drug product prior to the expiration of U.S. Patent Nos. 9,708,342, 10,385,067, and 10,548,846 (collectively, "the Patents-In-Suit"). Gilead attaches a true and accurate copy of each of the Patents-In-Suit as Exhibits A–C.

PARTIES

Gilead

3. Plaintiff Gilead Sciences, Inc. 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.

4. Gilead is a research-based pharmaceutical company that discovers, develops, and markets transformative pharmaceutical products in areas of unmet medical need, including human immunodeficiency virus ("HIV"), hepatitis B, hepatitis C, other liver diseases, respiratory diseases, cardiovascular diseases, other virological diseases including COVID-19, and cancer. Biktarvy® is one of eleven different HIV treatments currently marketed by Gilead. Gilead markets eighteen treatments in the other areas described above. And, Gilead has seven HIV treatments at Phase 2 or later in clinical development.

Defendant Lupin

5. On information and belief, Defendant Lupin is a foreign corporation organized and existing under the laws of India, having its principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Express Highway, Santacruz (East), Mumbai, 400055, India.

6. On information and belief, Lupin, itself and through its subsidiaries, affiliates, and agents, is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market, including in this District.

7. On information and belief, Lupin prepared and filed ANDA No. 217152 ("Lupin's ANDA"), seeking approval to manufacture, import, market, offer to sell, and/or sell a generic version of Gilead's Biktarvy® product titled "bictegravir/emtricitabine/tenofovir alafenamide tablets for oral use" ("Lupin's B/F/TAF ANDA Product") in the United States, including in this District, if the FDA approves Lupin's ANDA.

Defendant Laurus

8. On information and belief, Defendant Laurus is a foreign corporation organized and existing under the laws of India, having its principal place of business at Serene Chambers, Road No. 7, Banjarahills, Hyderabad 500034, India.

9. On information and belief, Laurus, itself and through its subsidiaries, affiliates, and agents, is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market, including in this District.

10. On information and belief, Laurus prepared and filed ANDA No. 217037 ("Laurus's ANDA"), seeking approval to manufacture, import, market, offer to sell, and/or sell a generic version of Gilead's Biktarvy® product titled "bictegravir sodium/emtricitabine/ tenofovir alafenamide fumarate" ("Laurus's B/F/TAF ANDA Product") in the United States, including in this District, if the FDA approves Laurus's ANDA.

Defendant Cipla

11. On information and belief, Defendant Cipla is a foreign corporation organized and existing under the laws of India, having its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

12. On information and belief, Cipla, itself and through its subsidiaries, affiliates, and agents, is in the business of, among other things, manufacturing and selling generic copies of branded pharmaceutical products for the United States market, including in this District.

13. On information and belief, Cipla prepared and filed ANDA No. 216914 ("Cipla's ANDA"), seeking approval to manufacture, import, market, offer to sell, and/or sell a generic version of Gilead's Biktarvy® product titled "Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate, tablets, 50 mg base of Bictegravir, 200 mg of Emtricitabine and 25 mg

base of Tenofovir Alafenamide Fumarate" ("Cipla's B/F/TAF ANDA Product") in the United States, including in this District, if the FDA approves Cipla's ANDA.

JURISDICTION AND VENUE

14. This action arises under the patent laws of the United States of America, 35 U.S.C § 100 *et seq.*, including § 271(a)–(c), (e)(2) and 28 U.S.C. §§ 2201 and 2202. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

15. This Court has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and justiciable case or controversy exists between Gilead and Defendants such that the Court may entertain Gilead's request for declaratory relief consistent with Article III of the United States Constitution, and that actual and justiciable case or controversy requires a declaration of rights by this Court.

Defendant Lupin

16. This Court has personal jurisdiction over Lupin because of its systematic and continuous contacts with this jurisdiction. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin 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 United States, including in Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin received its first ANDA approval in 2003 and has received more than 250 FDA approvals to currently market and sell 180 generic pharmaceutical products throughout the United States, including in Delaware.[1] On information and belief, Lupin derives substantial revenue from the sale

[1] *See* Lupin "Our Products—Generic Medicines," https://www.lupin.com/our-products/generics/ (last accessed May 9, 2022).

of these products in Delaware and has availed itself of the privilege of conducting business within Delaware.

17. On information and belief, Lupin markets and distributes its pharmaceutical products in the United States and Delaware through subsidiaries, agents, and/or affiliates, including Lupin Pharmaceuticals, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware. On information and belief, Lupin Pharmaceuticals, Inc. is or will be the labeler for Lupin's B/F/TAF ANDA Product. On information and belief, Lupin, through Lupin Pharmaceuticals, Inc., is licensed to sell generic pharmaceutical products in the State of Delaware, pursuant to 24. Del. C. § 2540.

18. This Court has personal jurisdiction because Lupin has filed its ANDA seeking approval from the FDA to market and sell Lupin's B/F/TAF ANDA Product throughout the United States, including in Delaware. On information and belief, Lupin intends to commercially manufacture, use, offer to sell, and sell Lupin's B/F/TAF ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Lupin's B/F/TAF ANDA Product, Lupin's B/F/TAF ANDA Product would be marketed, distributed, offered for sale, and sold in Delaware, and/or prescribed by physicians practicing in Delaware and dispensed by pharmacies located in Delaware, all of which would have a substantial effect on Delaware. By filing its ANDA, Lupin has made clear that it intends to use its distribution channels to direct sales of Lupin's B/F/TAF ANDA Product into Delaware.

19. Further, this Court has personal jurisdiction over Lupin because Lupin has been sued in this District and has not challenged personal jurisdiction, and, in some cases, Lupin has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g.*, *Gilead Scis. Inc. v. Apotex, Inc. et al.*, No. 20-189-MN, D.I. 20 (D. Del. Apr. 13, 2020); *Forest*

Labs, LLC, et al. v. Lupin Ltd, et al., No. 14-1058, D.I. 15 (D. Del. Sept. 8, 2014); *ViiV Healthcare UK Ltd., et al. v. Lupin Ltd, et al.*, No. 14-369, D.I. 10 (D. Del. June 12, 2014); *Teijin Ltd., et al. v. Lupin Ltd, et al.*, No. 14-184, D.I. 20 (D. Del. Apr. 1, 2014). 1, 2014). 1, 2014). 1, 2014).

20. Alternatively, Lupin is subject to jurisdiction in the United States, and specifically in Delaware, under Fed. R. Civ. P. 4(k)(2). Gilead's claims arise under federal law and Lupin is a foreign company not subject to personal jurisdiction in the courts of any particular state and has sufficient contacts with the United States as a whole—including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States—such that this Court's exercise of jurisdiction over Lupin satisfies due process.

21. Venue is proper in this judicial district under 28 U.S.C. § 1391(c) for at least the reasons set forth above. Lupin is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's jurisdiction, including this District.

Defendant Laurus

22. This Court has personal jurisdiction over Laurus because of its systematic and continuous contacts with this jurisdiction. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Laurus 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 United States, including in Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Laurus markets and sells generic pharmaceutical products throughout the United States, including in Delaware.[2] On information and belief, Laurus derives substantial revenue from the sale of these

[2] *See* Laurus Labs "Products," https://www.laurusgenerics.us/#productpg (highlighting their numerous generic products, including HIV products) (last accessed May 9, 2022).

products in Delaware and has availed itself of the privilege of conducting business within Delaware.

23. On information and belief, Laurus markets and distributes its pharmaceutical products in the United States and in Delaware through its subsidiaries, agents, and/or affiliates, including Laurus Generics, Inc., a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware. On information and belief, Laurus Generics, Inc. has been the labeler for Laurus products.

24. This Court has personal jurisdiction because Laurus has filed its ANDA seeking approval from the FDA to market and sell Laurus's B/F/TAF ANDA Product throughout the United States, including in Delaware. On information and belief, Laurus intends to commercially manufacture, use, offer to sell, and sell Laurus's B/F/TAF ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Laurus's B/F/TAF ANDA Product, Laurus's B/F/TAF ANDA Product would be marketed, distributed, offered for sale, and sold in Delaware, and/or prescribed by physicians practicing in Delaware and dispensed by pharmacies located in Delaware, all of which would have a substantial effect on Delaware. By filing its ANDA, Laurus has made clear that it intends to use its established distribution channels to direct sales of Laurus's B/F/TAF ANDA Product into Delaware.

25. Further, this Court has personal jurisdiction over Laurus because Laurus has been sued in this District and has not challenged personal jurisdiction, and, in some cases, Laurus has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g., Gilead Scis. Inc. v. Apotex, Inc. et al.*, No. 20-189-MN, D.I. 393 (D. Del. Oct. 15, 2020); *Genentech, Inc. et al. v. Laurus Labs Ltd. et al.*, No. 19-104, D.I. 12 (D. Del. Mar. 7, 2019);

Boehringer Ingelheim Pharm. Inc. et al. v. Laurus Labs Ltd. et al., No. 18-1758, D.I. 13 (D. Del. Jan. 11, 2019).

26. Alternatively, Laurus is subject to jurisdiction in the United States, and specifically in Delaware, under Fed. R. Civ. P. 4(k)(2). Gilead's claims arise under federal law and Laurus is a foreign company not subject to personal jurisdiction in the courts of any particular state and has sufficient contacts with the United States as a whole—including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States—such that this Court's exercise of jurisdiction over Laurus satisfies due process.

27. Venue is proper in this judicial district under 28 U.S.C. § 1391(c) for at least the reasons set forth above. Laurus is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's jurisdiction, including this District.

Defendant Cipla

28. This Court has personal jurisdiction over Cipla because of its systematic and continuous contacts with this jurisdiction. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Cipla regularly and continuously transacts business within Delaware including this District, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the United States, including in Delaware. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Cipla markets and sells generic pharmaceutical products throughout the United States, including in Delaware. Cipla generics cover at least 26 therapeutic categories that include more than 150 brands and more than 11 different dosage forms.[3] On information and belief, Cipla

[3] *See* Cipla "Cipla Generics," https://www.cipla.com/our-offerings/cipla-generics (last accessed May 9, 2022).

derives substantial revenue from the sale of these products in Delaware and has availed itself of the privilege of conducting business within Delaware.

29. On information and belief, Cipla markets and distributes its pharmaceutical products in the United States and this District through subsidiaries, agents, and/or affiliates, including Cipla 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, Cipla USA, Inc. is or will be the labeler for Cipla's B/F/TAF ANDA Product.

30. This Court has personal jurisdiction because Cipla has filed its ANDA seeking approval from the FDA to market and sell Cipla's B/F/TAF ANDA Product throughout the United States, including in Delaware. On information and belief, Cipla intends to commercially manufacture, use, offer to sell, and sell Cipla's B/F/TAF ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves Cipla's B/F/TAF ANDA Product, Cipla's B/F/TAF ANDA Product would be marketed, distributed, offered for sale, and sold in Delaware, and/or prescribed by physicians practicing in Delaware and dispensed by pharmacies located in Delaware, all of which would have a substantial effect on Delaware. By filing its ANDA, Cipla has made clear that it intends to use its distribution channels to direct sales of Cipla's B/F/TAF ANDA Product into Delaware.

31. Further, this Court has personal jurisdiction over Cipla because Cipla has been sued in this District and has not challenged personal jurisdiction, and, in some cases, Cipla has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g., Gilead Scis. Inc. v. Apotex, Inc. et al.*, No. 20-189-MN, D.I. 392 (D. Del. Oct. 15, 2021); *Biogen Int'l GmbH et al. v. Cipla Ltd. et al.*, No. 17-cv851, D.I. 10 (D. Del. Oct. 16, 2017)*; Onyx Therapeutics, Inc. v. Cipla Ltd.*, No. 16- 988, D.I. 12 (D. Del. Jan. 13, 2017). On information and

belief, Cipla has also availed itself of the legal protections of the State of Delaware by having filed suit in this jurisdiction. *See, e.g., Cipla Ltd. et al. v. Amgen Inc.*, No. 19- 44, D.I. 1 (D. Del. Jan. 8, 2019)*; Cipla Ltd. v. Sunovion Pharm. Inc.*, No. 15- 424, D.I. 1 (D. Del. May 26, 2015).

32. Alternatively, Cipla is subject to jurisdiction in the United States, and specifically in Delaware, under Fed. R. Civ. P. 4(k)(2). Gilead's claims arise under federal law and Cipla is a foreign company not subject to personal jurisdiction in the courts of any particular state and has sufficient contacts with the United States as a whole—including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States—such that this Court's exercise of jurisdiction over Cipla satisfies due process.

33. Venue is proper in this judicial district under 28 U.S.C. § 1391(c) for at least the reasons set forth above. Cipla is a foreign corporation and may be sued in any judicial district in the United States in which it is subject to the court's jurisdiction, including this District.

BIKTARVY®

34. Gilead is the holder of approved New Drug Application ("NDA") No. 210251 for fixed-dose tablets that contain 50 mg of BIC (equivalent to 52.5 mg of bictegravir sodium), 200 mg of FTC, and 25 mg of TAF (equivalent to 28 mg of tenofovir alafenamide fumarate), which is sold under the brand name Biktarvy®.

35. Biktarvy® was initially approved by the FDA on February 7, 2018.

36. Biktarvy®—in the dosages described above—is indicated as a complete regimen for the treatment of HIV-1 infection in adults and pediatric patients weighing at least 25 kg who have no antiretroviral treatment history or to replace the current antiviral regimen in those who are virologically suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral

regimen with no history of treatment failure and no known substitutions associations with resistance to the individual components of Biktarvy®.

37. Biktarvy® is included in the FDA's list of "Approved Drug Products with Therapeutic Equivalence Evaluations," also known as the "Orange Book." Approved drugs in the Orange Book may be used as the basis of an applicant's ANDA to obtain approval of the generic drug product under the provisions of 21 U.S.C. § 355(j).

38. The Orange Book lists patents that the NDA holder asserts cover the approved drug product. The Patents-In-Suit are listed in the Orange Book in association with Biktarvy®. At least one claim of each of the Patents-In-Suit covers Biktarvy® and/or components thereof.

PATENTS-IN-SUIT

39. On July 18, 2017, the United States Patent and Trademark Office issued U.S. Patent No. 9,708,342, titled "Sodium (2R,5S,13AR)-7,9-dioxo-10-((2,4,6-trifluorobenzyl)carbamoyl)-2,3,4,5,7,9,13,13A-octahydro-2,5-methanopyrido[1',2':4,5]pyrazino[2,1-B][1,3]oxazepin-8-olate." The '342 patent is attached hereto as Exhibit A.

40. Plaintiff Gilead Sciences, Inc. is the assignee of the '342 patent and holds title to the '342 patent.

41. The '342 patent claims, among other things, a compound of Formula II, including crystalline and polymorphic forms of that compound as well as pharmaceutical compositions containing a compound of Formula II. Bictegravir is a compound of Formula II and the '342 patent claims sodium salt, crystalline, and polymorphic forms of bictegravir.

42. On August 20, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,285,067, titled "Sodium (2R,5S,13AR)-7,9-dioxo-10-((2,4,6-trifluorobenzyl)carbamoyl)-2,3,4,5,7,9,13,13A-octahydro-2,5-

methanopyrido[1',2':4,5]pyrazino[2,1-B][1,3]oxazepin-8-olate." The '067 patent is attached hereto as Exhibit B.

43. Plaintiff Gilead Sciences, Inc. is the assignee of the '067 patent and holds title to the '067 patent.

44. The '067 patent claims, among other things, a method for treating an HIV infection in a human in need thereof by administering a therapeutically effective amount of a crystalline and polymorphic form of a compound of Formula II. The '067 patent also claims a method for treating an HIV infection in a human by administering a pharmaceutical composition that includes a crystalline and polymorphic form of a compound of Formula II. Bictegravir is a compound of Formula II.

45. On February 4, 2020, the United States Patent and Trademark Office issued U.S. Patent No. 10,548,846, titled "Therapeutic compositions for treatment of human immunodeficiency virus." The '846 patent is attached hereto as Exhibit C.

46. Plaintiff Gilead Sciences, Inc. is the assignee of the '846 patent and holds title to the '846 patent.

47. The '846 patent claims, among other things, a multilayer tablet comprising 50 mg of the compound of Formula I, or its associated salts, 25 mg of tenofovir alafenamide, or its associated salts, and 200 mg of embtricitabine, or its associated salts, wherein the tablet has a total weight less than 1000 mg. Bictegravir is a compound of Formula I. Biktarvy® is a multilayer tablet as described in the '846 patent claims.

ACTS GIVING RISE TO THE COMPLAINT

Defendant Lupin's Acts

48. On information and belief, Lupin submitted its ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FFDCA"), seeking the FDA's approval to

engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Lupin's B/F/TAF ANDA Product before the expiration of all three Patents-In-Suit. On information and belief, the FDA assigned Lupin ANDA No. 217152.

49. On information and belief, Lupin sent a letter dated March 25, 2022 to Gilead ("Lupin's Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Lupin's Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to all three Patents-In-Suit.

50. Gilead received Lupin's Notice Letter on or about March 28, 2022.

51. By filing its ANDA, Lupin has represented to the FDA and to Gilead that its B/F/TAF ANDA Product has the same active ingredients as Biktarvy®, including bictegravir; has the same dosage forms and strengths as Biktarvy®; and is bioequivalent to Biktarvy®. *See* Lupin's Notice Letter ¶¶ I, IV, V.

52. Lupin's B/F/TAF ANDA Product contains EQ 50 mg bictegravir, 200 mg emtricitabine, and EQ 25 mg tenofovir alafenamide.

53. On information and belief, Lupin's proposed label for its B/F/TAF ANDA Product will refer to the product as a three-drug combination of bictegravir (BIC), a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and embtricitabine (FTC) and tenofovir alafenamide (TAF), HIV-1 nucleoside reverse transcriptase inhibitors (NRTIs). On further information and belief, Lupin's proposed label will describe the fixed-dose combination tablets as containing 50 mg of BIC (equivalent to 52.5 mg of bictegravir sodium), 200 mg of FTC, and 25 mg of TAF (equivalent to 28 mg of tenofovir alafenamide fumarate). The proposed name of Lupin's B/F/TAF ANDA Product is bictegravir/emtricitabine/tenofovir alafenamide tablets for oral use. Lupin's Notice Letter ¶ IV.

54. On information and belief, Lupin is seeking approval to market its B/F/TAF ANDA Product for the same indications as Biktarvy®.

55. On information and belief, Lupin's proposed label for its B/F/TAF ANDA Product will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving Biktarvy® and bictegravir.

56. Under 21 U.S.C. § 355(j)(2)(B)(iv), Lupin's Notice Letter shall contain "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."

57. Lupin's Notice Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that all three Patents-In-Suit are invalid and that the '067 and '842 patents are not infringed.

58. Lupin's Notice Letter does not state that Lupin's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

59. On information and belief, Lupin had actual and constructive notice of the Patents-In-Suit prior to the filing of ANDA No. 217152.

60. This action is being filed before the expiration of 45 days from the date Gilead received Lupin's Notice Letter, which triggers a stay of FDA approval of Lupin's ANDA under 21 U.S.C. § 355(j)(5)(B)(iii).

Defendant Laurus's Acts

61. On information and belief, Laurus submitted its ANDA to the FDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Laurus's B/F/TAF ANDA Product before the expiration of all three Patents-In-Suit. On information and belief, the FDA assigned Laurus ANDA No. 217037.

62. On information and belief, Laurus sent a letter dated March 30, 2022 to Gilead ("Laurus's Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Laurus's Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to all three Patents-In-Suit.

63. Gilead received Laurus's Notice Letter on or about March 31, 2022.

64. By filing its ANDA and sending its Notice Letter, Laurus has represented to the FDA and to Gilead that its B/F/TAF ANDA Product has the same active ingredients as Biktarvy®, including bictegravir; has the same dosage forms and strengths as Biktarvy®; and is bioequivalent to Biktarvy®. *See* Laurus's Notice Letter ¶¶ I, IV, V.

65. Laurus's B/F/TAF ANDA Product contains "bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate" "EQ 50 mg base/200 mg/EQ 25 mg base."

66. On information and belief, Laurus's proposed label for its B/F/TAF ANDA Product will refer to the product as a three-drug combination of bictegravir (BIC), a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and embtricitabine (FTC) and tenofovir alafenamide (TAF), HIV-1 nucleoside reverse transcriptase inhibitors (NRTIs). On further information and belief, Laurus's proposed label will describe the fixed-dose combination tablets as containing 50 mg of BIC (equivalent to 52.5 mg of bictegravir sodium), 200 mg of FTC, and 25 mg of TAF (equivalent to 28 mg of tenofovir alafenamide fumarate). The proposed name of Laurus's B/F/TAF ANDA Product is bictegravir sodium/emtricitabine/tenofovir alafenamide fumarate. Laurus's Notice Letter ¶ IV.

67. On information and belief, Laurus is seeking approval to market its B/F/TAF ANDA Product for the same indications as Biktarvy®.

68. On information and belief, Laurus's proposed label for its B/F/TAF ANDA Product will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving Biktarvy® and bictegravir.

69. Under 21 U.S.C. § 355(j)(2)(B)(iv), Laurus's Notice Letter shall contain "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."

70. Laurus's Notice Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that all three Patents-In-Suit are invalid and that the '067 and '842 patents are not infringed.

71. Laurus's Notice Letter does not state that Laurus's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

72. On information and belief, Laurus had actual and constructive notice of the Patents-In-Suit prior to the filing of ANDA No. 217037.

73. This action is being filed before the expiration of 45 days from the date Gilead received Laurus's Notice Letter, which triggers a stay of FDA approval of Laurus's ANDA under 21 U.S.C. § 355(j)(5)(B)(iii).

Defendant Cipla's Acts

74. On information and belief, Cipla submitted its ANDA to the FDA under Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of Cipla's B/F/TAF ANDA Product before the expiration of all three Patents-In-Suit. On information and belief, the FDA assigned Cipla ANDA No. 216914.

75. On information and belief, Cipla sent a letter dated March 31, 2022 to Gilead ("Cipla's Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Cipla's

Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to all three Patents-In-Suit.

76. Gilead received Cipla's Notice Letter on or about April 1, 2022.

77. By filing its ANDA and sending its Notice Letter, Cipla has represented to the FDA and to Gilead that its B/F/TAF ANDA Product has the same active ingredients as Biktarvy®, including bictegravir; has the same dosage forms and strengths as Biktarvy®; and is bioequivalent to Biktarvy®. *See* Cipla's Notice Letter ¶¶ I, IV, V.

78. Cipla's B/F/TAF ANDA Product contains 50 mg base of Bictegravir, 200 mg of Emtricitabine, and 25 mg base of Tenofovir Alafenamide Fumarate as 52.45 mg of bictegravir sodium, 200 mg of emtricitabine, and 28.045 mg of tenofovir alafenamide fumarate.

79. On information and belief, Cipla's proposed label for its B/F/TAF ANDA Product will refer to the product as a three-drug combination of bictegravir (BIC), a human immunodeficiency virus type-1 (HIV-1) integrase strand transfer inhibitor (INSTI), and emtricitabine (FTC) and tenofovir alafenamide (TAF), HIV-1 nucleoside reverse transcriptase inhibitors (NRTIs). On further information and belief, Cipla's proposed label will describe the fixed-dose combination tablets as containing 50 mg of BIC (equivalent to 52.5 mg of bictegravir sodium), 200 mg of FTC, and 25 mg of TAF (equivalent to 28 mg of tenofovir alafenamide fumarate). The proposed name of Cipla's B/F/TAF ANDA Product is Bictegravir Sodium, Emtricitabine and Tenofovir Alafenamide Fumarate, tablets, 50 mg base of Bictegravir, 200 mg of Emtricitabine, and 25 mg base of Tenofovir Alafenamide Fumarate.

80. On information and belief, Cipla is seeking approval to market its B/F/TAF ANDA Product for the same indications as Biktarvy®.

81. On information and belief, Cipla's proposed label for its B/F/TAF ANDA Product will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving Biktarvy® and bictegravir.

82. Under 21 U.S.C. § 355(j)(2)(B)(iv), Cipla's Notice Letter shall contain "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."

83. Cipla's Notice Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that all three Patents-In-Suit are invalid and that the '067 and '842 patents are not infringed.

84. Cipla's Notice Letter does not state that Cipla's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

85. On information and belief, Cipla had actual and constructive notice of the Patents-In-Suit prior to the filing of ANDA No. 216914.

86. This action is being filed before the expiration of 45 days from the date Gilead received Cipla's Notice Letter, which triggers a stay of FDA approval of Cipla's ANDA under 21 U.S.C. § 355(j)(5)(B)(iii).

Gilead's Attempts to Gain Access to Each Defendant's ANDA

87. Defendants' Notice Letters each included an Offer for Confidential Access ("OCA") to their respective ANDAs on terms and conditions set forth in each Notice Letter. The OCAs requested that Gilead accept the terms of each OCA before receiving access to a portion of that Defendant's ANDA. Under 35 U.S.C. § 355(j)(5)(C)(i)(III), an OCA "shall contain such restrictions as to persons entitled access, on the use and disposition of any information access, as would apply had a protective order been entered for the purpose of protecting trade secrets and

other confidential business information." Defendants' OCAs each contained restrictions above and beyond those that would apply under a protective order.

88. Since receiving Defendants' Notice Letters, Gilead and each of the Defendants have been negotiating in good faith to reach a mutually acceptable agreement under which Defendants would provide their respective ANDA to Gilead. To date, each Defendant has refused to offer Gilead access to its ANDA under terms consistent with a protective order entered for the purpose of protecting trade secrets and other confidential business information. As a result, Gilead has been unable to access any ANDA of any Defendant.

89. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug during the pendency of litigation, as appropriate, pursuant to 21 U.S.C. § 355(c)(3)(C).

90. Gilead is not aware of any other means of obtaining information regarding Defendants' B/F/TAF ANDA Products within the 45-day period. In the absence of such information, Gilead resorts to the statutorily enacted judicial process and the aid of the discovery process to obtain such information as is required to confirm its belief, and to present to the Court evidence, that Defendants have and will infringe certain claims of the Patents-In-Suit.

COUNTS I-VI AGAINST DEFENDANT LUPIN

Count I: Infringement of the '342 Patent under 35 U.S.C. § 271(e)(2) by Lupin's B/F/TAF ANDA Product

91. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

92. Under 35 U.S.C. § 271(e)(2), Lupin has committed an act of infringement of the '342 patent by submitting ANDA No. 217152 to the FDA for the purpose of obtaining approval to

engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's B/F/TAF ANDA Product in the United States before the expiration of the '342 patent.

93. Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of its B/F/TAF ANDA Product prior to the expiration of the '342 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the '342 patent.

94. Lupin's Notice Letter does not state that Lupin's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

95. On information and belief, for example, Lupin's B/F/TAF ANDA Product contains a crystalline form of bictegravir and thus falls within the scope of the claims of the '342 patent, either literally or under the doctrine of equivalents.

96. Gilead holds title to the '342 patent.

97. Gilead has no adequate remedy at law to redress Lupin's infringement.

98. Gilead will be substantially and irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to the infringement of the '342 patent, either literally or under the doctrine of equivalents.

99. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Lupin's ANDA shall be a date which is not earlier than the current expiration date of the '342 patent and any additional periods of exclusivity.

Count II: Declaratory Judgment of Infringement of the '342 patent by Lupin's B/F/TAF ANDA Product

100. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

101. Lupin has actual knowledge of the '342 patent.

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

103. Lupin has submitted ANDA No. 217152 for a generic version of Gilead's Biktarvy® product. According to Lupin's Notice Letter, Lupin intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin's B/F/TAF ANDA Product before the expiration of the '342 patent.

104. On information and belief, Lupin's B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '342 patent, either literally or under the doctrine of equivalents.

105. On information and belief, Lupin's marketing, commercial manufacture, use, offer for sale, sale and/or importation of Lupin's B/F/TAF ANDA Product will infringe one or more claims of the '342 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents

106. Lupin's Notice Letter does not state that Lupin's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

107. Gilead holds title to the '342 patent.

108. Gilead has no adequate remedy at law to redress Lupin's infringing activities.

109. Gilead will be substantially and irreparably harmed if Lupin is not enjoined from infringing or actively inducing and/or contributing to the infringement of the '342 patent, either literally or under the doctrine of equivalents.

Count III: Infringement of the ’067 Patent under 35 U.S.C. § 271(e)(2) by Lupin’s B/F/TAF ANDA Product

110. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

111. Under 35 U.S.C. § 271(e)(2), Lupin has committed an act of infringement of the ’067 patent by submitting ANDA No. 217152 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin’s B/F/TAF ANDA Product in the United States before the expiration of the ’067 patent.

112. On information and belief, Lupin’s commercial manufacture, use, offer for sale, sale, and/or importation of its B/F/TAF ANDA Product prior to the expiration of the ’067 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the ’067 patent.

113. On information and belief, for example, Lupin’s B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir—used to treat an HIV infection in a human in need thereof—and thus falls within the scope of at least claim 1 of the ’067 patent, either literally or under the doctrine of equivalents.

114. On information and belief, Lupin’s B/F/TAF ANDA Product would infringe the claims of the ’067 patent under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the ’067 patent claims. Moreover, there are insubstantial differences between Lupin’s B/F/TAF ANDA Product and the ’067 claims.

115. Gilead holds title to the ’067 patent.

116. Gilead has no adequate remedy at law to redress Lupin’s infringement.

117. Gilead will be substantially and irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to the infringement of the ’067 patent, either literally or under the doctrine of equivalents.

118. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Lupin’s ANDA shall be a date which is not earlier than the current expiration date of the ’067 patent and any additional periods of exclusivity.

Count IV: Declaratory Judgment of Infringement of the ’067 patent by Lupin’s B/F/TAF ANDA Product

119. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

120. Lupin has actual knowledge of the ’067 patent.

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

122. Lupin has submitted ANDA No. 217152 for a generic version of Gilead’s Biktarvy® product. According to Lupin’s Notice Letter, Lupin intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s B/F/TAF ANDA Product before the expiration of the ’067 patent.

123. On information and belief, Lupin’s B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’067 patent, either literally or under the doctrine of equivalents.

124. On information and belief, Lupin’s marketing, commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s B/F/TAF ANDA Product will infringe one or more claims of the ’067 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to

infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents.

125. On information and belief, for example, Lupin's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir—used to treat an HIV infection in a human in need thereof—and thus falls within the scope of at least claim 1 of the '067 patent, either literally or under the doctrine of equivalents.

126. On information and belief, Lupin's B/F/TAF ANDA Product would infringe the claims of the '067 patent under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the '067 patent claims. Moreover, there are insubstantial differences between Lupin's B/F/TAF ANDA Product and the '067 claims.

127. Gilead holds title to the '067 patent.

128. Gilead has no adequate remedy at law to redress Lupin's infringing activities.

129. Gilead will be substantially and irreparably harmed if Lupin is not enjoined from infringing or actively inducing and/or contributing to the infringement of the '067 patent, either literally or under the doctrine of equivalents.

Count V: Infringement of the '846 Patent under 35 U.S.C. § 271(e)(2) by Lupin's B/F/TAF ANDA Product

130. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

131. Under 35 U.S.C. § 271(e)(2), Lupin has committed an act of infringement of the '846 patent by submitting ANDA No. 217152 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's B/F/TAF ANDA Product in the United States before the expiration of the '846 patent.

132. On information and belief, Lupin's commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's B/F/TAF ANDA Product prior to the expiration of the '846 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the '846 patent.

133. On information and belief, for example, Lupin's B/F/TAF ANDA Product contains a multi-layer tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium) that is separate from 25 mg of tenofovir alafenamide (as 28 mg of tenofovir alafenamide fumarate) and from 200 mg of emtricitabine, wherein the tablet has a total weight less than 1000 mg and thus falls within the scope of at least claim 1 of the '846 patent, either literally or under the doctrine of equivalents.

134. On information and belief, Lupin's B/F/TAF ANDA Product separates the bictegravir from the tenofovir alafenamide and emtricitabine and therefore performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the '846 patent. Moreover, there are insubstantial differences between Lupin's B/F/TAF ANDA Product and the '846 patent claims.

135. Gilead holds title to the '846 patent.

136. Gilead has no adequate remedy at law to redress Lupin's infringement.

137. Gilead will be substantially and irreparably harmed if Lupin is not enjoined from infringing or actively inducing or contributing to the infringement of the '846 patent, either literally or under the doctrine of equivalents.

138. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Lupin's ANDA shall be a

date which is not earlier than the current expiration date of the ’846 patent and any additional periods of exclusivity.

Count VI: Declaratory Judgment of Infringement of the ’846 patent by Lupin’s B/F/TAF ANDA Product

139. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

140. Lupin has actual knowledge of the ’846 patent.

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

142. Lupin has submitted ANDA No. 217152 for a generic version of Gilead’s Biktarvy® product. According to Lupin’s Notice Letter, Lupin intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s B/F/TAF ANDA Product before the expiration of the ’846 patent.

143. On information and belief, Lupin’s B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the ’846 patent, either literally or under the doctrine of equivalents.

144. On information and belief, Lupin’s marketing, commercial manufacture, use, offer for sale, sale and/or importation of Lupin’s B/F/TAF ANDA Product will infringe one or more claims of the ’846 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents.

145. On information and belief, for example, Lupin’s B/F/TAF ANDA Product contains a multi-layer tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium) that is separate from 25 mg of tenofovir alafenamide (as 28 mg of tenofovir alafenamide

fumarate) and from 200 mg of emtricitabine, wherein the tablet has a total weight less than 1000 mg and thus falls within the scope of at least claim 1 of the ’846 patent, either literally or under the doctrine of equivalents.

146. On information and belief, Lupin’s B/F/TAF ANDA Product separates the bictegravir from the tenofovir alafenamide and emtricitabine and therefore performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the ’846 patent. Moreover, there are insubstantial differences between Lupin’s B/F/TAF ANDA Product and the ’846 patent claims.

147. Gilead holds title to the ’846 patent.

148. Gilead has no adequate remedy at law to redress Lupin’s infringing activities.

149. Gilead will be substantially and irreparably harmed if Lupin is not enjoined from infringing or actively inducing and/or contributing to the infringement of the ’846 patent, either literally or under the doctrine of equivalents.

COUNTS VII-XII AGAINST DEFENDANT LAURUS

Count VII: Infringement of the ’342 Patent under 35 U.S.C. § 271(e)(2) by Laurus’s B/F/TAF ANDA Product

150. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

151. Under 35 U.S.C. § 271(e)(2), Laurus has committed an act of infringement of the ’342 patent by submitting ANDA No. 217037 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus’s B/F/TAF ANDA Product in the United States before the expiration of the ’342 patent.

152. Laurus's commercial manufacture, use, offer for sale, sale, and/or importation of its B/F/TAF ANDA Product prior to the expiration of the '342 patent would infringe, contribute to the infringement of, and/or induce infringement at least claim 1 of the '342 patent.

153. Laurus's Notice Letter does not state that Laurus's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

154. On information and belief, for example, Laurus's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir and thus falls within the scope of the claims of the '342 patent, either literally or under the doctrine of equivalents.

155. Gilead holds title to the '342 patent.

156. Gilead has no adequate remedy at law to redress Laurus's infringement.

157. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing or contributing to the infringement of the '342 patent, either literally or under the doctrine of equivalents.

158. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Laurus's ANDA shall be a date which is not earlier than the current expiration date of the '342 patent and any additional periods of exclusivity.

Count VIII: Declaratory Judgment of Infringement of the '342 patent by Laurus's B/F/TAF ANDA Product

159. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

160. Laurus has actual knowledge of the '342 patent.

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

162. Laurus has submitted ANDA No. 217037 for a generic version of Gilead's Biktarvy® product. According to Laurus's Notice Letter, Laurus intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Laurus's B/F/TAF ANDA Product before the expiration of the '342 patent.

163. Laurus's B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the '342 patent, either literally or under the doctrine of equivalents.

164. On information and belief, Laurus's marketing, commercial manufacture, use, offer for sale, sale and/or importation of Laurus's B/F/TAF ANDA Product will infringe one or more claims of the '342 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents.

165. On information and belief, for example, Laurus's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir and thus falls within the scope of the claims of the '342 patent, either literally or under the doctrine of equivalents.

166. Laurus's Notice Letter does not state that Laurus's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

167. Gilead holds title to the '342 patent.

168. Gilead has no adequate remedy at law to redress Laurus's infringing activities.

169. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing and/or contributing to the infringement of the '342 patent, either literally or under the doctrine of equivalents.

Count IX: Infringement of the ’067 Patent under 35 U.S.C. § 271(e)(2) by Laurus’s B/F/TAF ANDA Product

170. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

171. Under 35 U.S.C. § 271(e)(2), Laurus has committed an act of infringement of the ’067 patent by submitting ANDA No. 217037 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus’s B/F/TAF ANDA Product in the United States before the expiration of the ’067 patent.

172. On information and belief, Laurus’s commercial manufacture, use, offer for sale, sale, and/or importation of its B/F/TAF ANDA Product prior to the expiration of the ’067 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the ’067 patent.

173. On information and belief, for example, Laurus’s B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir—used to treat an HIV infection in a human in need thereof—and thus falls within the scope of the claims of the ’067 patent, either literally or under the doctrine of equivalents.

174. On information and belief, Laurus’s B/F/TAF ANDA Product would infringe the claims of the ’067 patent under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the ’067 patent claims. Moreover, there are insubstantial differences between Laurus’s B/F/TAF ANDA Product and the ’067 claims.

175. Gilead holds title to the ’067 patent.

176. Gilead has no adequate remedy at law to redress Laurus’s infringement.

177. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing or contributing to the infringement of the ’067 patent, either literally or under the doctrine of equivalents.

178. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Laurus’s ANDA shall be a date which is not earlier than the current expiration date of the ’067 patent and any additional periods of exclusivity.

Count X: Declaratory Judgment of Infringement of the ’067 patent by Laurus’s B/F/TAF ANDA Product

179. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

180. Laurus has actual knowledge of the ’067 patent.

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

182. Laurus has submitted ANDA No. 217037 for a generic version of Gilead’s Biktarvy® product. According to Laurus’s Notice Letter, Laurus intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Laurus’s B/F/TAF ANDA Product before the expiration of the ’067 patent.

183. On information and belief, Laurus’s B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the ’067 patent, either literally or under the doctrine of equivalents.

184. On information and belief, Laurus’s marketing, commercial manufacture, use, offer for sale, sale and/or importation of Laurus’s B/F/TAF ANDA Product will infringe one or more claims of the ’067 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to

infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents.

185. On information and belief, for example, Laurus's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir—used to treat an HIV infection in a human in need thereof—and thus falls within the scope of the claims of the '067 patent, either literally or under the doctrine of equivalents.

186. On information and belief, Laurus's B/F/TAF ANDA Product would infringe the claims of the '067 patent under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the '067 patent claims. Moreover, there are insubstantial differences between Laurus's B/F/TAF ANDA Product and the '067 claims.

187. Gilead holds title to the '067 patent.

188. Gilead has no adequate remedy at law to redress Laurus's infringing activities.

189. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing and/or contributing to the infringement of the '067 patent, either literally or under the doctrine of equivalents.

Count XI: Infringement of the '846 Patent under 35 U.S.C. § 271(e)(2) by Laurus's B/F/TAF ANDA Product

190. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

191. Under 35 U.S.C. § 271(e)(2), Laurus has committed an act of infringement of the '846 patent by submitting ANDA No. 217037 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Laurus's B/F/TAF ANDA Product in the United States before the expiration of the '846 patent.

192. On information and belief, Laurus's commercial manufacture, use, offer for sale, sale, and/or importation of Laurus's B/F/TAF ANDA Product prior to the expiration of the '846 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the '846 patent.

193. On information and belief, for example, Laurus's B/F/TAF ANDA Product contains a multi-layer tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium) that is separate from 25 mg of tenofovir alafenamide (as 28 mg of tenofovir alafenamide fumarate) and 200 mg of emtricitabine, wherein the tablet has a total weight less than 1000 mg and thus falls within the scope of at least claim 1 of the '846 patent, either literally or under the doctrine of equivalents.

194. On information and belief, Laurus's B/F/TAF ANDA Product separates the bictegravir from the tenofovir alafenamide and emtricitabine and therefore performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the '846 patent. Moreover, there are insubstantial differences between Laurus's B/F/TAF ANDA Product and the '846 patent claims.

195. Gilead holds title to the '846 patent.

196. Gilead has no adequate remedy at law to redress Laurus's infringement.

197. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing or contributing to the infringement of the '846 patent, either literally or under the doctrine of equivalents.

198. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Laurus's ANDA shall be

a date which is not earlier than the current expiration date of the ’846 patent and any additional periods of exclusivity.

Count XII: Declaratory Judgment of Infringement of the ’846 patent by Laurus’s B/F/TAF ANDA Product

199. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

200. Laurus has actual knowledge of the ’846 patent.

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

202. Laurus has submitted ANDA No. 217037 for a generic version of Gilead’s Biktarvy® product. According to Laurus’s Notice Letter, Laurus intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Laurus’s B/F/TAF ANDA Product before the expiration of the ’846 patent.

203. On information and belief Laurus’s B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the ’846 patent, either literally or under the doctrine of equivalents.

204. On information and belief, Laurus’s marketing, commercial manufacture, use, offer for sale, sale and/or importation of Laurus’s B/F/TAF ANDA Product will infringe one or more claims of the ’846 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents.

205. On information and belief, for example, Laurus’s B/F/TAF ANDA Product contains a multi-layer tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium) that is separate from 25 mg of tenofovir alafenamide (as 28 mg of tenofovir

alafenamide fumarate) and 200 mg of emtricitabine, wherein the tablet has a total weight less than 1000 mg and thus falls within the scope of at least claim 1 of the ’846 patent, either literally or under the doctrine of equivalents.

206. On information and belief, Laurus’s B/F/TAF ANDA Product separates the bictegravir from the tenofovir alafenamide and emtricitabine and therefore performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the ’846 patent. Moreover, there are insubstantial differences between Laurus’s B/F/TAF ANDA Product and the ’846 patent claims.

207. Gilead holds title to the ’846 patent.

208. Gilead has no adequate remedy at law to redress Laurus’s infringing activities.

209. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing and/or contributing to the infringement of the ’846 patent, either literally or under the doctrine of equivalents.

COUNTS XIII-XVIII AGAINST DEFENDANT CIPLA

Count XIII: Infringement of the ’342 Patent under 35 U.S.C. § 271(e)(2) by Cipla’s B/F/TAF ANDA Product

210. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

211. Under 35 U.S.C. § 271(e)(2), Cipla has committed an act of infringement of the ’342 patent by submitting ANDA No. 216914 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s B/F/TAF ANDA Product in the United States before the expiration of the ’342 patent.

212. Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of its B/F/TAF ANDA Product prior to the expiration of the '342 patent would infringe, contribute to the infringement of, and/or induce infringement at least claim 1 of the '342 patent.

213. Cipla's Notice Letter does not state that Cipla's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

214. On information and belief, for example, Cipla's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir and thus falls within the scope of the claims of the '342 patent, either literally or under the doctrine of equivalents.

215. Gilead holds title to the '342 patent.

216. Gilead has no adequate remedy at law to redress Cipla's infringement.

217. Gilead will be substantially and irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to the infringement of the '342 patent, either literally or under the doctrine of equivalents.

218. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Cipla's ANDA shall be a date which is not earlier than the current expiration date of the '342 patent and any additional periods of exclusivity.

Count XIV: Declaratory Judgment of Infringement of the '342 patent by Cipla's B/F/TAF ANDA Product

219. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

220. Cipla has actual knowledge of the '342 patent.

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

222. Cipla has submitted ANDA No. 216914 for a generic version of Gilead's Biktarvy® product. According to Cipla's Notice Letter, Cipla intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Cipla's B/F/TAF ANDA Product before the expiration of the '342 patent.

223. Cipla's B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the '342 patent, either literally or under the doctrine of equivalents.

224. On information and belief, Cipla's marketing, commercial manufacture, use, offer for sale, sale and/or importation of Cipla's B/F/TAF ANDA Product will infringe one or more claims of the '342 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents

225. On information and belief, for example, Cipla's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir and thus falls within the scope of the claims of the '342 patent, either literally or under the doctrine of equivalents.

226. Cipla's Notice Letter does not state that Cipla's B/F/TAF ANDA Product or its use will not infringe all claims of the '342 patent, if valid.

227. Gilead holds title to the '342 patent.

228. Gilead has no adequate remedy at law to redress Cipla's infringing activities.

229. Gilead will be substantially and irreparably harmed if Cipla is not enjoined from infringing or actively inducing and/or contributing to the infringement of the '342 patent, either literally or under the doctrine of equivalents.

Count XV: Infringement of the ’067 Patent under 35 U.S.C. § 271(e)(2) by Cipla’s B/F/TAF ANDA Product

230. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

231. Under 35 U.S.C. § 271(e)(2), Cipla has committed an act of infringement of the ’067 patent by submitting ANDA No. 216914 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s B/F/TAF ANDA Product in the United States before the expiration of the ’067 patent.

232. On information and belief, Cipla’s commercial manufacture, use, offer for sale, sale, and/or importation of its B/F/TAF ANDA Product prior to the expiration of the ’067 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the ’067 patent.

233. On information and belief, for example, Cipla’s B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir—used to treat an HIV infection in a human in need thereof—and thus falls within the scope of the claims of the ’067 patent, either literally or under the doctrine of equivalents.

234. On information and belief, Cipla’s B/F/TAF ANDA Product would infringe the claims of the ’067 patent under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the ’067 patent claims. Moreover, there are insubstantial differences between Cipla’s B/F/TAF ANDA Product and the ’067 claims.

235. Gilead holds title to the ’067 patent.

236. Gilead has no adequate remedy at law to redress Cipla’s infringement.

237. Gilead will be substantially and irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to the infringement of the ’067 patent, either literally or under the doctrine of equivalents.

238. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Cipla’s ANDA shall be a date which is not earlier than the current expiration date of the ’067 patent and any additional periods of exclusivity.

Count XVI: Declaratory Judgment of Infringement of the ’067 patent by Cipla’s B/F/TAF ANDA Product

239. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

240. Cipla has actual knowledge of the ’067 patent.

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

242. Cipla has submitted ANDA No. 216914 for a generic version of Gilead’s Biktarvy® product. According to Cipla’s Notice Letter, Cipla intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Cipla’s B/F/TAF ANDA Product before the expiration of the ’067 patent.

243. On information and belief, Cipla’s B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the ’067 patent, either literally or under the doctrine of equivalents.

244. On information and belief, Cipla’s marketing, commercial manufacture, use, offer for sale, sale and/or importation of Cipla’s B/F/TAF ANDA Product will infringe one or more claims of the ’067 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to

infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents.

245. On information and belief, for example, Cipla's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegravir—used to treat an HIV infection in a human in need thereof—and thus falls within the scope of the claims of the '067 patent, either literally or under the doctrine of equivalents.

246. On information and belief, Cipla's B/F/TAF ANDA Product would infringe the claims of the '067 patent under the doctrine of equivalents because it performs substantially the same function, in substantially the same way, to achieve substantially the same result as the '067 patent claims. Moreover, there are insubstantial differences between Cipla's B/F/TAF ANDA Product and the '067 claims.

247. Gilead holds title to the '067 patent.

248. Gilead has no adequate remedy at law to redress Cipla's infringing activities.

249. Gilead will be substantially and irreparably harmed if Cipla is not enjoined from infringing or actively inducing and/or contributing to the infringement of the '067 patent, either literally or under the doctrine of equivalents.

Count XVII: Infringement of the '846 Patent under 35 U.S.C. § 271(e)(2) by Cipla's B/F/TAF ANDA Product

250. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

251. Under 35 U.S.C. § 271(e)(2), Cipla has committed an act of infringement of the '846 patent by submitting ANDA No. 216914 to the FDA for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's B/F/TAF ANDA Product in the United States before the expiration of the '846 patent.

252. On information and belief, Cipla's commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's B/F/TAF ANDA Product prior to the expiration of the '846 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the '846 patent.

253. On information and belief, for example, Cipla's B/F/TAF ANDA Product contains a multi-layer tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium) that is separate from 25 mg of tenofovir alafenamide (as 28 mg of tenofovir alafenamide fumarate) and 200 mg of emtricitabine, wherein the tablet has a total weight less than 1000 mg and thus falls within the scope of at least claim 1 of the '846 patent, either literally or under the doctrine of equivalents.

254. On information and belief, Cipla's B/F/TAF ANDA Product separates the bictegravir from the tenofovir alafenamide and emtricitabine and therefore performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the '846 patent. Moreover, there are insubstantial differences between Cipla's B/F/TAF ANDA Product and the '846 patent claims.

255. Gilead holds title to the '846 patent.

256. Gilead has no adequate remedy at law to redress Cipla's infringement.

257. Gilead will be substantially and irreparably harmed if Cipla is not enjoined from infringing or actively inducing or contributing to the infringement of the '846 patent, either literally or under the doctrine of equivalents.

258. Gilead respectfully requests the relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of any approval relating to Cipla's ANDA shall be a

date which is not earlier than the current expiration date of the ’846 patent and any additional periods of exclusivity.

Count XVIII: Declaratory Judgment of Infringement of the ’846 patent by Cipla’s B/F/TAF ANDA Product

259. Gilead incorporates all preceding paragraphs of this Complaint as if fully set forth herein.

260. Cipla has actual knowledge of the ’846 patent.

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

262. Cipla has submitted ANDA No. 216914 for a generic version of Gilead’s Biktarvy® product. According to Cipla’s Notice Letter, Cipla intends to engage in the commercial manufacture, use, offer for sale, sale and/or importation of Cipla’s B/F/TAF ANDA Product before the expiration of the ’846 patent.

263. On information and belief Cipla’s B/F/TAF ANDA Product, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least claim 1 of the ’846 patent, either literally or under the doctrine of equivalents.

264. On information and belief, Cipla’s marketing, commercial manufacture, use, offer for sale, sale and/or importation of Cipla’s B/F/TAF ANDA Product will infringe one or more claims of the ’846 patent under 35 U.S.C. § 271(a), or actively induce and/or contribute to infringement by others under 35 U.S.C. § 271(b) and (c), either literally or under the doctrine of equivalents

265. On information and belief, for example, Cipla’s B/F/TAF ANDA Product contains a multi-layer tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium) that is separate from 25 mg of tenofovir alafenamide (as 28 mg of tenofovir alafenamide fumarate) and 200 mg of emtricitabine, wherein the tablet has a total weight less than 1000 mg

and thus falls within the scope of at least claim 1 of the ’846 patent, either literally or under the doctrine of equivalents.

266. On information and belief, Cipla’s B/F/TAF ANDA Product separates the bictegravir from the tenofovir alafenamide and emtricitabine and therefore performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the ’846 patent. Moreover, there are insubstantial differences between Cipla’s B/F/TAF ANDA Product and the ’846 patent claims.

267. Gilead holds title to the ’846 patent.

268. Gilead has no adequate remedy at law to redress Cipla’s infringing activities.

269. Gilead will be substantially and irreparably harmed if Cipla is not enjoined from infringing or actively inducing and/or contributing to the infringement of the ’846 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Gilead respectfully requests the following relief:

A. a judgment that each Defendant has infringed the ’342 patent, the ’067 patent, and/or the ’846 patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents;

B. a judgment pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of Defendants’ ANDAs under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is not earlier than the day after the expiration of the Patents-In-Suit, including any applicable exclusivity period to which Gilead becomes entitled;

C. a judgment declaring that the commercial manufacture, use, offer for sale, sale and/or importation of Defendants’ B/F/TAF ANDA Products would constitute infringement of the

Patents-In-Suit, or induce or contribute to such conduct, pursuant to 35 U.S.C. § 271(a), (b) and/or (c), either literally or under the doctrine of equivalents, and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

D. a judgment permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any of Defendants' B/F/TAF ANDA Products until the day after the expiration of the Patents-In-Suit, including any applicable exclusivity period to which Gilead becomes entitled, and from otherwise infringing one or more claims of the Patents-In-Suit, either literally or under the doctrine of equivalents;

E. damages or other monetary relief under 35 U.S.C. § 271(a), (b), (c), and (e)(4)(c) and/or 35 U.S.C. § 284, including costs, fees, pre- and post-judgment interest, to Gilead if Defendants engage in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of any of Defendants' B/F/TAF ANDA Products prior to the latest expiration date of the Patents-In-Suit, including any applicable exclusivity period to which Gilead becomes entitled;

F. an order that this case is exceptional;

G. an award of Gilead's costs, expenses, reasonable attorneys' fees and such other relief as the Court deems just and proper pursuant to 35 U.S.C. § 285; and

H. any such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Defendant Gilead Sciences, Inc.

OF COUNSEL:
J. Scott McBride
Rebecca T. Horwitz
Matthew R. Ford
BARTLIT BECK LLP
54 West Hubbard Street, Suite 300
Chicago, IL 60654
(312) 494-4400

Taylor J.S. Kelson
BARTLIT BECK LLP
1801 Wewatta Street, Suite 1200
Denver, CO 80202
(303) 592-3100

May 9, 2022