

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

GILEAD SCIENCES, INC.	)	
	)	
Plaintiff	)	
	)	
v.	)	C.A. No. 22-cv-00615 (MN)
	)	
LUPIN LTD., LAURUS LABS LIMITED, AND	)	
CIPLA LIMITED,	)	
Defendants.	)	
_____	)	

**LAURUS LABS LIMITED’S ANSWER AND AFFIRMATIVE DEFENSES TO FOURTH  
AMENDED COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Laurus Labs Limited (“Laurus”), by and through its attorneys, responds to the numbered paragraphs of the Fourth Amended Complaint filed by Plaintiff Gilead Sciences, Inc. (“Gilead” or “Plaintiff”), 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”).

**ANSWER:** Laurus admits that this action purports to be an action for patent infringement arising under the laws of the United States of America. Laurus denies any patent infringement as alleged by Plaintiff.

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, 10,548,846, and 11,744,802

(collectively, “the Patents-In-Suit”). Gilead attaches a true and accurate copy of each of the Patents-In-Suit as Exhibits A–C and E.<sup>1</sup>

**ANSWER:** Laurus admits that it seeks FDA approval to market the products that are the subject of the ANDA it filed under Section 505(j) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(j), before the expiration of the recited patents. Laurus admits that what purports to be copies of the Patents-In-Suit are attached to the Fourth Amended Complaint as Exhibits A-C and E.

### **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.

**ANSWER:** Laurus lacks sufficient information or knowledge to admit or deny the allegations in this paragraph and therefore denies the same.

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

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<sup>1</sup> Gilead previously asserted U.S. Patent No. 9,682,084, which was attached to Gilead’s First Amended Complaint as Exhibit D. *See* D.I. 66. Gilead’s claims asserting infringement of the ’084 patent have since been dismissed. *See* D.I. 166. To avoid confusion, Gilead designated the newly asserted U.S. Patent No. 11,744,802 as Ex. E to its Second Amended Complaint. D.I. 170. The Second and Third Amended Complaints have no Exhibit D, and this Fourth Amended Complaint likewise has no Exhibit D.

eighteen treatments in the other areas described above. And, Gilead has seven HIV treatments at Phase 2 or later in clinical development.

**ANSWER:** Laurus admits that Gilead sells TAF-containing pharmaceuticals under the registered trademark Biktarvy® in this District and throughout the United States. Laurus otherwise lacks sufficient information or knowledge to admit or deny the balance of the allegations and rhetoric set forth in this paragraph and therefore denies the same.

***Defendant Lupin***

Paragraphs 5 through 7 relate solely to Defendant Lupin. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

***Defendant Laurus***

8. 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 500 034, India.

**ANSWER:** Admitted.

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.

**ANSWER:** Laurus admits that a part of its business relates to the manufacturing and sale of generic pharmaceutical products that are bioequivalent to branded pharmaceutical products, but denies that such generic products are copies of branded products.

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.

**ANSWER:** Laurus admits that it prepared and filed ANDA No. 217037, and that this ANDA seeks approval to manufacture, import, market, offer to sell, and/or sell a generic version of Gilead’s Biktarvy® product. Laurus denies the remaining allegations of paragraph 10 as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

*Defendant Cipla*

Paragraphs 11 through 13 relate solely to Defendant Cipla. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

**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).

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest subject matter jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest subject matter jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

***Defendant Lupin***

Paragraphs 16 through 21 relate solely to Defendant Lupin. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

***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.<sup>2</sup> On information and belief, Laurus derives substantial revenue from the sale of these products in Delaware and has availed itself of the privilege of conducting business within Delaware.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

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<sup>2</sup> See Laurus Labs “Products,” <https://www.laurusgenerics.us/#productpg> (highlighting their numerous generic products, including HIV products) (last accessed Dec. 11, 2023).

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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

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, D.I. 393 (D. Del. Nov. 15, 2021); *Genentech, Inc. et al. v. Laurus Labs Ltd. et al.*, No. 19-104, D.I. 12 (D. Del. Mar. 7, 2019); *Boehringer Ingelheim Pharms. Inc. et al. v. Laurus Labs Ltd. et al.*, No. 18-1758, D.I. 13 (D. Del. Jan. 11, 2019).

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest personal jurisdiction in this Court solely for purposes of the claims asserted against Laurus in this case.

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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, Laurus does not contest that this venue is proper in this Court solely for purposes of the claims asserted against Laurus in this case.

*Defendant Cipla*

Paragraphs 28 through 33 relate solely to Defendant Cipla. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

**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 bicitgravir 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®.

**ANSWER:** Admitted.

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

**ANSWER:** Admitted.

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 associated with resistance to the individual components of Biktarvy®.

**ANSWER:** Laurus admits that the Biktarvy® label speaks for itself, but otherwise lacks information to admit or deny the underlying safety and efficacy findings made by the FDA to support said label claims, and therefore denies the balance of the allegations in this paragraph as phrased.

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).

**ANSWER:** Admitted.

38. The Orange Book lists patents that the NDA holder asserts cover the approved drug product. The four Patents-In-Suit (the '342, '067, '846 and '802 patents) are listed in the Orange Book in association with Biktarvy®. At least one claim of each of these patents covers Biktarvy® and/or components thereof.

**ANSWER:** Admitted that the Patents-In-Suit are listed in the Orange Book in association with Biktarvy®. Laurus lacks sufficient information or knowledge to admit or deny whether at least one claim of each of the Patents-In-Suit covers Biktarvy® and/or components thereof and therefore denies the same.

#### **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.

**ANSWER:** Laurus admits that a copy of the '342 patent is attached to the Fourth Amended Complaint as Exhibit A. Laurus admits that Exhibit A recites the title, issue date, and assignee as alleged. Laurus denies the '342 patent was duly and legally issued, or that it is valid.

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

**ANSWER:** Laurus admits that USPTO assignment records identify Gilead Sciences, Inc. as the assignee of 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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent a response is required, denied.

42. On August 20, 2019, the United States Patent and Trademark Office issued U.S. Patent No. 10,385,067, 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.

**ANSWER:** Laurus admits that a copy of the '067 patent is attached to the Fourth Amended Complaint as Exhibit B. Laurus admits that Exhibit B recites the title and issue date as alleged. Laurus denies the '067 patent was duly and legally issued, or that it is valid.

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

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of 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. Bictegrovir is a compound of Formula II.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent a response is required, denied.

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.

**ANSWER:** Laurus admits that a copy of the ’846 patent is attached to the Fourth Amended Complaint as Exhibit C. Laurus admits that Exhibit C recites the title and issue date as alleged. Laurus denies the ’846 patent was duly and legally issued, or that it is valid.

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

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of 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 emtricitabine, or its associated salts, wherein the tablet has a total weight less than 1000 mg. Bictegrovir is a compound of Formula I. Biktarvy® is a multilayer tablet as described in the ’846 patent claims.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent a response is required, denied.

48. On September 5, 2023, the United States Patent and Trademark Office issued U.S. Patent No. 11,744,802, titled “Therapeutic Compositions for the Treatment of Human Immunodeficiency Virus.” The ’802 patent is attached hereto as Exhibit E.

**ANSWER:** Laurus admits that a copy of the ’802 patent is attached to the Fourth Amended Complaint as Exhibit E. Laurus admits that Exhibit E recites the title and issue date as alleged. Laurus denies the ’802 patent was duly and legally issued, or that it is valid.

49. Plaintiff Gilead Sciences, Inc. is the assignee of the ’802 patent and holds title to the ’802 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the ’802 patent.

50. The ’802 patent claims, among other things, a tablet comprising 50 mg of a compound of Formula I [bictegravir] or a pharmaceutically acceptable salt thereof, 25 mg of tenofovir alafenamide or a pharmaceutically acceptable salt thereof, and 200 mg of emtricitabine or a pharmaceutically acceptable salt thereof.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent a response is required, denied.

**ACTS GIVING RISE TO THE [FOURTH AMENDED] COMPLAINT**

***Defendant Lupin’s Acts***

Paragraphs 51 through 67 relate solely to Defendant Lupin. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

***Defendant Laurus’s Acts***

68. On information and belief, Laurus submitted its ANDA to the FDA under Section 505(j) of the FDCA, 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 four Patents-In-Suit. The FDA assigned Laurus ANDA No. 217037.

**ANSWER:** Laurus admits that it submitted its ANDA No. 217037 to the FDA seeking approval by the FDA of its ANDA product. Laurus admits that the FDA assigned Laurus ANDA number 217037. Laurus denies the remaining allegations of this paragraph as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

69. 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 the '342, '067, and '846 patents.

**ANSWER:** Laurus admits that it sent a notice letter dated March 30, 2022 to Gilead that included a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '342, '067, and '846 patents.

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

**ANSWER:** Admitted.

71. On information and belief, Laurus sent a letter dated November 20, 2023 to Gilead ("Laurus's Second Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Laurus's Second Notice Letter includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '802 patent.

**ANSWER:** Admitted.

72. Gilead received Laurus's Second Notice Letter on or about November 21, 2023.

**ANSWER:** Admitted.

73. 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.

**ANSWER:** Laurus admits that it has represented to the FDA that its ANDA product has the same active ingredients as Biktarvy®, in the same dosage forms and strengths, and is bioequivalent to Biktarvy®, otherwise denied.

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

**ANSWER:** Admitted.

75. 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 emtricitabine (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.

**ANSWER:** Admitted.

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

**ANSWER:** Laurus admits that it submitted its ANDA to the FDA seeking approval of its ANDA product for the indications set forth in its currently proposed labeling. Laurus denies the remaining allegations of this paragraph as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

77. 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 bictegavir.

**ANSWER:** Laurus admits that its ANDA application seeks approval for its ANDA product for the indications set forth in its currently proposed labeling. Laurus otherwise denies the remaining allegations in this paragraph, as it has no way to know what, at the time of the anticipated ANDA approval, will be included in its label.

78. Under 21 U.S.C. § 355(j)(2)(B)(iv), Laurus's Notice Letter and Laurus's Second 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."

**ANSWER:** Admitted.

79. Laurus's Notice Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '342, '067, and '846 patent are invalid and that the '067 and '846 patents are not infringed.

**ANSWER:** Admitted.

80. 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.

**ANSWER:** Admitted.

81. Laurus's Second Notice Letter contends, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II), that the '802 patent is invalid.

**ANSWER:** Admitted.

82. Laurus's Second Notice Letter does not state that Laurus's B/F/TAF ANDA Product or its use will not infringe all claims of the '802 patent, if valid.

**ANSWER:** Admitted.

83. Laurus had actual and constructive notice of the Patents-In-Suit prior to the filing of ANDA No. 217037.

**ANSWER:** Admitted.

84. This action was 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).

**ANSWER:** Admitted.

***Defendant Cipla's Acts***

Paragraphs 85 through 101 relate solely to Defendant Lupin. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

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

102. Following the filing of the initial Complaint in this Action, Gilead has received through the discovery process copies of each Defendant's ANDA or portions thereof.

**ANSWER:** Admitted.

**COUNTS I-VIII AGAINST DEFENDANT LUPIN**

Paragraphs 103 through 180 relate solely to Defendant Lupin. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

**COUNTS IX-XVI AGAINST DEFENDANT LAURUS**

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

181. Gilead incorporates all preceding paragraphs of this [Fourth Amended] Complaint as if fully set forth herein.

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

182. 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.

**ANSWER:** Laurus admits that filing its ANDA with a Paragraph IV certification to the '342 patent is a technical act of infringement solely for jurisdictional purposes under 35 U.S.C. § 271(e). Laurus otherwise denies the balance of the allegations of this paragraph.

183. 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.

**ANSWER:** Denied.

184. 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.

**ANSWER:** Admitted.

185. 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.

**ANSWER:** Denied.

186. Gilead holds title to the '342 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '342 patent.

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

**ANSWER:** Denied.

188. 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.

**ANSWER:** Denied.

189. 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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, denied.

**Count X: Declaratory Judgment of Infringement of the '342 Patent  
by Laurus's B/F/TAF ANDA Product**

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

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

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

**ANSWER:** Admitted.

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

**ANSWER:** Admitted.

193. 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.

**ANSWER:** Laurus admits that it submitted ANDA No. 217037 to the FDA seeking approval by the FDA of its ANDA product. Laurus denies the remaining allegations of this paragraph as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

194. 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.

**ANSWER:** Denied.

195. 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.

**ANSWER:** Denied.

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

**ANSWER:** Denied.

197. 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.

**ANSWER:** Admitted.

198. Gilead holds title to the '342 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '342 patent.

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

**ANSWER:** Denied.

200. 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.

**ANSWER:** Denied.

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

201. Gilead incorporates all preceding paragraphs of this [Fourth Amended] Complaint as if fully set forth herein.

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

202. 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.

**ANSWER:** Laurus admits that filing its ANDA with a Paragraph IV certification to the '067 patent is a technical act of infringement solely for jurisdictional purposes under 35 U.S.C. § 271(e). Laurus otherwise denies the balance of the allegations of this paragraph.

203. 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.

**ANSWER:** Denied.

204. On information and belief, for example, Laurus's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegrovir—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.

**ANSWER:** Denied.

205. 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 patent claims.

**ANSWER:** Denied.

206. Gilead holds title to the '067 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '067 patent.

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

**ANSWER:** Denied.

208. 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.

**ANSWER:** Denied.

209. 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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, denied.

**Count XII: Declaratory Judgment of Infringement of the '067 Patent  
by Laurus's B/F/TAF ANDA Product**

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

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

211. Laurus has actual knowledge of the '067 patent.

**ANSWER:** Admitted.

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

**ANSWER:** Admitted.

213. 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.

**ANSWER:** Laurus admits that it submitted ANDA No. 217037 to the FDA seeking approval by the FDA of its ANDA product. Laurus denies the remaining allegations of this paragraph as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

214. 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.

**ANSWER:** Denied.

215. 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.

**ANSWER:** Denied.

216. On information and belief, for example, Laurus's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegavir—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.

**ANSWER:** Laurus admits Laurus's B/F/TAF ANDA Product contains a crystalline, polymorphic form of bictegavir that, upon FDA approval, may be used to treat an HIV infection in a human in need thereof. Otherwise denied.

217. 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 patent claims.

**ANSWER:** Denied.

218. Gilead holds title to the '067 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '067 patent.

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

**ANSWER:** Denied.

220. 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.

**ANSWER:** Denied.

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

221. Gilead incorporates all preceding paragraphs of this [Fourth Amended] Complaint as if fully set forth herein.

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

222. 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.

**ANSWER:** Laurus admits that filing its ANDA with a Paragraph IV certification to the '846 patent is a technical act of infringement for solely jurisdictional purposes under 35 U.S.C. § 271(e). Laurus otherwise denies the balance of the allegations of this paragraph.

223. 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.

**ANSWER:** Denied.

224. 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 bicitegravir (as 52.5 mg of bicitegravir 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.

**ANSWER:** Denied.

225. On information and belief, Laurus's B/F/TAF ANDA Product separates the bicitegravir 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.

**ANSWER:** Denied.

226. Gilead holds title to the '846 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '846 patent.

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

**ANSWER:** Denied.

228. 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.

**ANSWER:** Denied.

229. 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.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, denied.

**Count XIV: Declaratory Judgment of Infringement of the '846 Patent  
by Laurus's B/F/TAF ANDA Product**

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

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

231. Laurus has actual knowledge of the '846 patent.

**ANSWER:** Admitted.

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

**ANSWER:** Admitted.

233. Laurus has submitted ANDA No. 217037 for a generic version of Gilead's Biktarvy<sup>®</sup> 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.

**ANSWER:** Laurus admits that it submitted ANDA No. 217037 to the FDA seeking approval by the FDA of its ANDA product. Laurus denies the remaining allegations of this paragraph as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

234. 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.

**ANSWER:** Denied.

235. 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.

**ANSWER:** Denied.

236. 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 bicitgravir (as 52.5 mg of bicitgravir 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.

**ANSWER:** Denied.

237. On information and belief, Laurus's B/F/TAF ANDA Product separates the bicitgravir 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.

**ANSWER:** Denied.

238. Gilead holds title to the '846 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '846 patent.

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

**ANSWER:** Denied.

240. 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.

**ANSWER:** Denied.

**Count XV: Infringement of the '802 Patent under 35 U.S.C. § 271(e)(2) by Laurus's  
B/F/TAF ANDA Product**

241. Gilead incorporates all preceding paragraphs of this [Fourth Amended] Complaint as if fully set forth herein.

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

242. Under 35 U.S.C. § 271(e)(2), Laurus has committed an act of infringement of the '802 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 '802 patent.

**ANSWER:** Laurus admits that filing its ANDA with a Paragraph IV certification to the '802 patent is a technical act of infringement for solely jurisdictional purposes under 35 U.S.C. § 271(e). Laurus otherwise denies the balance of the allegations of this paragraph.

243. 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 '802 patent would infringe, contribute to the infringement of, and/or induce infringement of at least claim 1 of the '802 patent.

**ANSWER:** Denied.

244. On information and belief, for example, Laurus's B/F/TAF ANDA Product is a tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium, which is a pharmaceutically acceptable salt of bictegravir), 25 mg of tenofovir alafenamide (as 28 mg of tenofovir alafenamide fumarate, which is a pharmaceutically acceptable salt of tenofovir alafenamide), and 200 mg of emtricitabine, and thus falls within the scope of at least claim 1 of the '802 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

245. Gilead holds title to the '802 patent.

**ANSWER:** Laurus admits that USPTO assignment records identifies Gilead Sciences, Inc. as the assignee of the '802 patent.

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

**ANSWER:** Denied.

247. Gilead will be substantially and irreparably harmed if Laurus is not enjoined from infringing or actively inducing or contributing to the infringement of the '802 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

248. 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 '802 patent and any additional periods of exclusivity.

**ANSWER:** This paragraph contains legal conclusions to which no response is required. To the extent an answer is required, denied.

**Count XVI: Declaratory Judgment of Infringement of the '802 Patent under  
35 U.S.C. § 271(e)(2) by Laurus's B/F/TAF ANDA Product**

249. Gilead incorporates all preceding paragraphs of this [Fourth Amended] Complaint as if fully set forth herein.

**ANSWER:** Laurus incorporates its responses to each of the preceding paragraphs as if fully set forth herein.

250. Laurus has actual knowledge of the '802 patent.

**ANSWER:** Admitted.

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

**ANSWER:** Admitted.

252. 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 '802 patent.

**ANSWER:** Laurus admits that it submitted ANDA No. 217037 to the FDA seeking approval by the FDA of its ANDA product. Laurus denies the remaining allegations of this paragraph as phrased, and affirmatively states that it will decide whether to market its product in the United States upon FDA approval.

253. 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 directly infringe at least claim 1 of the '802 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

254. 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 directly infringe one or more claims of the '802 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.

**ANSWER:** Denied.

255. On information and belief, for example, Laurus's B/F/TAF ANDA Product is a tablet comprising 50 mg of the compound of bictegravir (as 52.5 mg of bictegravir sodium, which is a pharmaceutically acceptable salt of bictegravir), 25 mg of tenofovir alafenamide (as 28 mg of

tenofovir alafenamide fumarate, which is a pharmaceutically acceptable salt of tenofovir alafenamide), and 200 mg of emtricitabine, and thus falls within the scope of at least claim 1 of the '802 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

256. On information and belief, Laurus's B/F/TAF ANDA Product performs substantially the same function, in substantially the same way, to achieve substantially the same result as the claims of the '802 patent. Moreover, there are insubstantial differences between Laurus's B/F/TAF ANDA Product and the '802 patent claims.

**ANSWER:** Denied.

257. Gilead holds title to the '802 patent.

**ANSWER:** Laurus admits that USPTO assignment records identify Gilead Sciences, Inc. as the assignee of the '802 patent.

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

**ANSWER:** Denied.

259. 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 '802 patent, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

#### **COUNTS XVII-XXIV AGAINST DEFENDANT CIPLA**

Paragraphs 260 through 338 relate solely to Defendant Cipla. Laurus has insufficient information to either deny or admit the allegations contained therein and therefore denies the same.

## **RESPONSE TO REQUEST FOR RELIEF**

Laurus denies that Plaintiff is entitled to any of the relief requested by the Fourth Amended Complaint, or to any other relief whatsoever.

## **AFFIRMATIVE DEFENSES**

In further response to the Fourth Amended Complaint, and as additional defenses thereto, Laurus asserts the following affirmative defenses without prejudice to any denial in its Answer and without admission to any allegation in the Fourth Amended Complaint, unless otherwise explicitly admitted above. Laurus reserves the right to assert additional defenses in view of further information and/or analysis.

### **FIRST SEPARATE DEFENSE**

#### **(Non-Infringement)**

The manufacture, use, sale, offer for sale, or importation of Laurus's ANDA products have not, do not and will not infringe any valid and enforceable claim of the Patents-In-Suit asserted against Laurus herein, either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

### **SECOND SEPARATE DEFENSE**

#### **(Invalidity)**

Based on at least the factual and legal bases set forth in the Notice Letter that is the subject of the allegations of paragraph 69 and 71 of the Fourth Amended Complaint, the claims of the Patents-In-Suit asserted against Laurus is invalid for failure to comply with one or more of the provisions of the United States Code, including but not limited to, 35 U.S.C. §§ 102, 103, 112, as well as the doctrine of obviousness-type double patenting.

### **THIRD SEPARATE DEFENSE**

#### **(Lack of Irreparable Harm)**

Plaintiff has planned for, and in fact anticipated, the filing of several ANDA applications with the FDA for the approval of generic forms of its Biktarvy® products for many years. Accordingly, should Laurus's ANDA products be approved and should those products further be sold in the United States market, Plaintiff would not be irreparably harmed as a result of such anticipated competition. Further, should such sales occur, there are adequate remedies at law available, assuming for the sake of argument that such sales are found to be infringing any patent in suit, and should said patents be deemed valid. Moreover, considering the balance of hardships between the parties, and the public interest in fostering the prompt introduction of generic pharmaceuticals to the market, the equitable remedy of a permanent injunction is not warranted in any event.

### **FOURTH SEPARATE DEFENSE**

#### **(Failure To State A Claim)**

The Fourth Amended Complaint is subject to dismissal for failure to state a claim upon which relief may be granted.

### **FIFTH SEPARATE DEFENSE**

#### **(Other Defenses)**

Defendant reserves all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent laws and any additional defenses or counterclaims that discovery may reveal including that Plaintiff has failed to aver any facts supporting the conclusion that this is an exceptional case and an award of attorney's fees under 35 U.S.C. § 285 is warranted.

**PRAYER FOR RELIEF**

**WHEREFORE**, Laurus respectfully requests the Court to enter judgment against Plaintiff to include:

- (a) Dismissing the Fourth Amended Complaint with prejudice;
- (b) Finding that Laurus's submission of its ANDAs seeking FDA approval to market its ANDA products will not directly, indirectly, contributorily, and/or by inducement infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-In-Suit under 35 U.S.C. § 271;
- (c) Finding that the claims of the Patents-In-Suit are invalid for failure to comply with one or more provisions of the United States Code, including but not limited to 35 U.S.C. §§ 102, 103 and/or 112 as well as any non-statutory judicially created doctrine;
- (d) Finding in Laurus's favor on any or all of the affirmative defenses set forth herein;  
and
- (e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Laurus its attorneys' fees, costs and expenses.

*[Signature Page Immediately Follows]*

Dated: March 27, 2024

/s/ James S. Green, Jr.

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