IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., Plaintiff, v. APOTEX INC. and APOTEX CORP., Defendants.	)	C.A. No. 1:23-cv-0775

APOTEX'S ANSWER AND COUNTERCLAIMS TO COMPLAINT FOR PATENT INFRINGEMENT

Defendants, Apotex Inc. and Apotex Corp. (collectively, "Apotex"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiff, Gilead Sciences, Inc., ("Gilead" or "Plaintiff"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Apotex denies all allegations in Gilead's Complaint except those expressly admitted below.

NATURE OF THE ACTION

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

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that it filed Abbreviated New Drug Application ("ANDA") No. 218575 with the FDA for approval to engage in the commercial manufacture, use or sale of generic versions of cobicistat, elvitegravir, emtricitabine, and tenofovir alafenamide fumarate, 150mg; 150mg; 200mg; EQ 10mg base ("the Apotex ANDA Product"), which is a generic version of GENVOYA® oral tablets, prior to expiration of U.S. Patent Nos. 8,754,065 ("the '065 patent") and 9,296,769 ("the '769 patent") (the '065 patent and the '769

patent collectively "the Patents-in-Suit"). Apotex denies any and all remaining allegations contained in this Paragraph.

2. Apotex seeks approval to market a generic copy of Gilead's highly successful product, GENVOYA®, containing a four-drug combination of elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide, prior to the expiration of U.S. Patent Nos. 8,754,065 ("the '065 patent") and 9,296,769 ("the '769 patent") (together, the "Patents-In-Suit"). Gilead attaches hereto true and accurate copies of each of the Patents-In-Suit as Exhibits A-B.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 with the FDA for approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product, which is a generic version of GENVOYA®, prior to expiration of the Patents-In-Suit. Apotex further admits that what purports to be copies of the Patents-In-Suit were attached to the Complaint as Exhibits A and B. Apotex denies the remaining allegations in Paragraph 2.

PARTIES

Plaintiff Gilead

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

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. Apotex lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore denies the same.

4. Gilead is a research-based pharmaceutical company that invents, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for human immunodeficiency virus ("HIV"), hepatitis B virus ("HBV"), hepatitis C virus ("HCV"), hepatitis delta virus ("HDV"), liver diseases, serious cardiovascular and respiratory diseases, and cancer. Gilead's portfolio of products includes treatments for HIV using the drugs elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide. Gilead is the owner of the Patents-In-Suit.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Gilead Sciences, Inc. is listed as the assignee on the faces of the Patents-In-Suit, and in the electronic records of the United States Patent and Trademark Office ("USPTO"). Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

Defendants Apotex Inc. & Apotex Corp.

5. On information and belief, Apotex Inc. is a foreign corporation organized and existing under the laws of Canada, having its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Apotex Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. Apotex denies any and all remaining allegations contained in this Paragraph.

6. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 2400 N. Commerce Parkway Suite 400, Weston, FL 33326.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Apotex Corp. is a Delaware corporation, having a place of business at 2400 N. Commerce Parkway Suite 400, Weston, FL 33326. Apotex denies any and all remaining allegations contained in this Paragraph.

7. On information and belief, Apotex, alone and through subsidiaries, affiliates, agents, and partners, manufactures, distributes, and/or imports generic copies of branded pharmaceutical products for sale and use throughout the United States, including in this District.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies the remaining allegations of this Paragraph.

8. On information and belief, Apotex, alone and with subsidiaries, affiliates, agents, and partners, prepared and filed ANDA No. 218575 (the "GENVOYA ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Gilead's GENVOYA® product (the "GENVOYA ANDA Product") in or into the United States, including in this District, if the FDA approves the GENVOYA ANDA.

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed ANDA No. 218575 with the FDA for approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product, which is a generic version of Gilead's GENVOYA® product. Apotex denies the remaining allegations of this Paragraph.

9. On information and belief, Apotex is the holder of the GENVOYA ANDA. On information and belief, Apotex Corp. is an authorized U.S. agent of Apotex Inc., including for the GENVOYA ANDA.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it filed ANDA No. 218575 with the FDA for approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product, which is a generic version of Gilead's GENVOYA® product. Apotex denies the remaining allegations of this Paragraph.

JURISDICTION AND VENUE

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

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiff purports to bring this action under the patent laws of the United States. Apotex further admits that Plaintiff's Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiff is entitled to any relief. Apotex denies any and all remaining allegations contained in this Paragraph.

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

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that Plaintiff's Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiff is entitled to any relief. Solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

Apotex Inc.

12. On information and belief, this Court has personal jurisdiction over Apotex, Inc. by virtue of, *inter alia*, its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly or through subsidiaries, agents, and/or affiliates, Apotex Inc. 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 subsidiaries, agents, and/or affiliates, Apotex Inc. has received more than 90 FDA approvals to market and sell pharmaceutical products throughout the United States, including in Delaware. On information and belief, Apotex Inc. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

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

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

14. On information and belief, Apotex Inc. and Apotex Corp. operate and act in concert as an integrated, unitary business. On information and belief, Apotex Inc. and Apotex Corp. work in concert with respect to the manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in Delaware.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

15. This Court also has personal jurisdiction because Apotex Inc., together with Apotex Corp., has filed an ANDA for a generic copy of Gilead's GENVOYA® product, seeking approval from the FDA to market and sell the GENVOYA ANDA Product, throughout the United States,

including in Delaware. On information and belief, Apotex Inc. intends to commercially manufacture, use, and sell the GENVOYA ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves the GENVOYA ANDA, the GENVOYA ANDA Product would, among other things, be marketed, distributed, and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing the GENVOYA ANDA, Apotex Inc. has made clear that it intends to use its distribution channels to direct sales of the GENVOYA ANDA Product into Delaware.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

16. Further, this Court has personal jurisdiction over Apotex Inc. because it has previously been sued in this District and has not challenged personal jurisdiction, and Apotex Inc. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g.*, *Gilead Sciences, Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 22-1399, D.I. 25 (D. Del. Mar. 1, 2023); *Gilead Sciences, Inc. v. Apotex Inc. et al.*, Civil Action No. 20-189, D.I. 28 (D. Del. Apr. 13, 2020); *Horizon Medicines LLC et al. v. Apotex Inc. et al.*, Civil Action No. 22640, D.I. 35 (D. Del. June 28, 2022); *Galderma Laby's L.P. et al. v. Apotex Inc. et al.*, Civil Action No. 22-724, D.I. 13 (D. Del. June 23, 2022); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.*, Civil Action No. 21-1429, D.I. 14 (D. Del. Mar. 1, 2022); *Zogenix, Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 21-1533, D.I. 13 (D. Del. Jan. 3, 2022); *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.*, Civil Action No. 21-187, D.I. 6 (D. Del. Mar. 3, 2021); *Intercept Pharma., Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 20-1105, D.I. 10 (D. Del. Oct. 23, 2020); *UCB, Inc. et al. v. Annora Pharma Pvt. Ltd. et al.*, Civil Action No. 20-987, D.I. 33 (D. Del. Oct. 6, 2020); *Sanofi-Aventis U.S., LLC et al. v. Actavis LLC et al.*, Civil Action No. 20-804, D.I. 46 (D. Del. July 20, 2020); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.*, Civil Action No. 20-749, D.I. 7 (D. Del. June 26, 2020).

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

17. Alternatively, this Court may exercise personal jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Gilead's claims arise under federal law; (b) Apotex Inc. is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Apotex Inc. 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 Apotex Inc. satisfies due process.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

18. Venue is proper in this Court for Apotex Inc. under 28 U.S.C. § 1391(c)(3) because Apotex Inc. 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 personal jurisdiction, including in this District.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

Apotex Corp.

19. On information and belief, this Court has personal jurisdiction over Apotex Corp. because, *inter alia,* it is incorporated in Delaware.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

20. On information and belief, Apotex Corp. has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being subject to the jurisdiction of the court in the District of Delaware.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

21. On information and belief, Apotex Corp., directly and/or through its parent company Apotex Inc., markets, distributes, and sells generic pharmaceutical products throughout the United States, including in this District.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

22. On information and belief, Apotex Corp. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this District, directly and/or through its parent company Apotex Inc.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

23. On information and belief, this Court also has personal jurisdiction because Apotex Corp., together with Apotex Inc., has filed an ANDA for a generic copy of Gilead's GENVOYA®

product, seeking approval from the FDA to market and sell the GENVOYA ANDA Product, throughout the United States, including in Delaware. On information and belief, Apotex Corp. intends to commercially manufacture, use, and sell the GENVOYA ANDA Product upon receiving FDA approval. On information and belief, if and when the FDA approves the GENVOYA ANDA, the GENVOYA ANDA Product would, among other things, be marketed, distributed and sold in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which would have a substantial effect on Delaware. By filing the GENVOYA ANDA, Apotex Corp. has made clear that it intends to use its distribution channels to direct sales of the GENVOYA ANDA Product into Delaware.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

24. Further, this Court has personal jurisdiction over Apotex Corp. because it has previously been sued in this District and has not challenged personal jurisdiction, and Apotex Corp. has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this District. *See, e.g., Gilead Sciences, Inc. et al. v. Apotex Inc. et al.,* Civil Action No. 22-1399, D.I. 25 (D. Del. Mar. 1, 2023); *Horizon Medicines LLC et al. v. Apotex Inc. et al.,* Civil Action No. 22640, D.I. 35 (D. Del. June 28, 2022); *Galderma Laby's L.P. et al. v. Apotex Inc. et al.,* Civil Action No. 22-724, D.I. 13 (D. Del. June 23, 2022); *Bayer Healthcare LLC et al. v. Apotex Inc. et al.,* Civil Action No. 21-1429, D.I. 14 (D. Del. Mar. 1, 2022); *Zogenix, Inc. et al. v. Apotex Inc. et al.,* Civil Action No. 21-1533, D.I. 13 (D. Del. Jan. 3, 2022); *Bial-Portela & CA S.A. et al. v. Apotex Inc. et al.,* Civil Action No. 21-187, D.I. 6 (D. Del. Mar. 3, 2021); *Intercept Pharma., Inc. et al. v. Apotex Inc. et al.,* Civil Action No. 20-1105, D.I. 10 (D. Del. Oct. 23, 2020); *UCB, Inc. et al. v. Annora Pharma Pvt. Ltd. et al.,* Civil Action No. 20-987, D.I. 33 (D. Del. Oct. 6, 2020); *Sanofi-Aventis U.S., LLC et al. v. Actavis LLC et al.,* Civil Action No. 20-804, D.I. 46 (D. Del. July 20, 2020); *Merck Sharp & Dohme Corp. v. Apotex Inc. et al.,* Civil Action No. 20-749, D.I. 7 (D. Del. June 26, 2020).

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

25. Venue is proper in this Court for Apotex Corp. under 28 U.S.C. § 1400(b) because *inter alia,* Apotex Corp. is incorporated in Delaware.

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely to conserve the resources of the parties and the Court, Apotex does not contest venue in this Judicial District solely for the limited purposes of this action only. Apotex denies any and all remaining allegations contained in this Paragraph.

PATENTS-IN-SUIT

26. On June 17, 2014, the U.S. Patent and Trademark Office duly and legally issued the '065 patent, titled, "Tenofovir Alafenamide Hemifumarate." A true and correct copy of the '065 patent is attached hereto as Exhibit A. The claims of the '065 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '065 patent.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that what purports to be a copy of the '065 patent was attached to the Complaint as Exhibit A, that the patent is entitled "Tenofovir Alafenamide Hemifumarate," that it bears an issue date of June 17, 2014, and the face of the patent states that the assignee is Gilead Sciences, Inc. Apotex denies that the '065 patent was duly and legally issued and further denies any suggestion that the '065 patent is valid or enforceable. Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

27. On March 29, 2016, the U.S. Patent and Trademark Office duly and legally issued the '769 patent, titled, "Tenofovir Alafenamide Hemifumarate." A true and correct copy of the '769 patent is attached hereto as Exhibit B. The claims of the '769 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '769 patent.

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer may be required, Apotex admits that what purports to be a copy of the '769 patent was attached to the Complaint as Exhibit B that the patent is entitled "Tenofovir

Alafenamide Hemifumarate," that it bears an issue date of March 29, 2016, and the face of the patent states that the assignee is Gilead Sciences, Inc. Apotex denies that the '769 patent was duly and legally issued and further denies any suggestion that the '769 patent is valid or enforceable. Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

ACTS GIVING RISE TO THIS ACTION

GENVOYA®

28. Gilead holds approved NDA No. 207561 for tablets containing a four-drug combination of elvitegravir (EVG), a human immunodeficiency virus (HIV-1) integrase strand transfer inhibitor, cobicistat (COBI), a CYP3A inhibitor, and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors. The tablets are indicated as a complete regimen for the treatment of HIV-1 infection.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that, according to the Orange Book, the applicant holder full name for NDA 207561 for GENVOYA (cobicistat, elvitegravir, emtricitabine, and tenofovir alafenamide fumarate) oral tablets is Gilead Sciences Inc. According to its prescribing information (revised 01/2022), GENVOYA® is a four-drug combination of elvitegravir (EVG), an HIV-1 integrase strand transfer inhibitor (INSTI), cobicistat (COBI), a CYP3A inhibitor, and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors (NRTIs), and 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 antiretroviral regimen in those who are virologically-suppressed (HIV-1 RNA less than 50 copies per mL) on a stable antiretroviral regimen for at least 6 months with no history of treatment failure and no known substitutions associated with resistance to the individual components of GENVOYA. Apotex is

without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

29. Gilead markets the tablets approved under NDA No. 207561 in the United States under the registered trademark GENVOYA®. FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the Patents-In-Suit, among other patents, for GENVOYA®.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that, according to the Orange Book, the applicant holder full name for NDA 207561 for GENVOYA® (cobicistat, elvitegravir, emtricitabine, and tenofovir alafenamide) oral tablets is Gilead. The Orange Book lists the Patents-in-Suit in connection with NDA 207561 for GENVOYA®. Apotex is without sufficient knowledge or information to form a belief as to the remaining allegations of this Paragraph, and therefore denies the same.

30. At least one claim of each of the Patents-In-Suit covers GENVOYA®, or approved methods of using GENVOYA®.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the Patents-in-Suit are listed in the Orange Book in connection with GENVOYA®. Apotex denies any and all remaining allegations contained in this Paragraph.

31. Apotex submitted to FDA an ANDA listing GENVOYA® as the reference listed drug ("RLD").

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 with the FDA for approval to engage in the commercial manufacture, use or sale of the

Apotex ANDA Product prior to expiration of the Patents-in-Suit. Apotex denies any and all remaining allegations contained in this Paragraph.

Apotex's Acts Regarding GENVOYA®

32. On information and belief, Apotex, alone and with subsidiaries, affiliates, agents, and partners, submitted to FDA the GENVOYA ANDA under Section 505(j) of the FDCA, seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the GENVOYA ANDA Product before the expiration of the Patents-In-Suit. On information and belief, FDA assigned the ANDA number 218575.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 seeking approval to engage in the commercial manufacture, use or sale of Apotex's GENVOYA ANDA Product prior to the expiration of the Patents-in-Suit. Apotex denies any and all remaining allegations contained in this Paragraph.

33. On information and belief, Apotex sent a letter dated June 1, 2023 to Gilead ("Apotex's GENVOYA Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's GENVOYA Notice Letter states that the GENVOYA ANDA includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Patents-In-Suit.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it sent a notice letter to Gilead, dated June 1, 2023, which served as written notification to Gilead pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218575 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Apotex denies any and all remaining allegations contained in this Paragraph.

34. Gilead received Apotex's GENVOYA Notice Letter on or about June 2, 2023.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a notice letter to Gilead, dated June 1, 2023, which served as written notification to Gilead pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218575 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Apotex denies any and all remaining allegations contained in this Paragraph.

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

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Apotex admits that it sent a notice letter to Gilead, dated June 1, 2023, which served as written notification to Gilead pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218575 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Apotex denies any and all remaining allegations contained in this Paragraph.

36. By submitting the GENVOYA ANDA, Apotex has represented to FDA that the GENVOYA ANDA Product has the same active ingredients as GENVOYA®; has the same dosage forms and strengths as GENVOYA®; and is bioequivalent to GENVOYA®.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 seeking approval to engage in the commercial manufacture, use or sale of Apotex's GENVOYA ANDA Product prior to the expiration of the Patents-in-Suit. Apotex further admits that it sent a notice letter to Gilead, dated June 1, 2023, which served as written notification to

Gilead pursuant to U.S.C. § 355(j)(2)(B) that Apotex submitted ANDA No. 218575 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Apotex denies any and all remaining allegations contained in this Paragraph.

37. On information and belief, Apotex's proposed label for its GENVOYA ANDA Product (the "Proposed Label") will refer to the product as, *inter alia*, a four-drug combination of elvitegravir, cobicistat, emtricitabine, and tenofovir alafenamide, indicated as a complete regimen for the treatment of HIV-1 infection.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 seeking approval to engage in the commercial manufacture, use or sale of Apotex's GENVOYA ANDA Product prior to the expiration of the Patents-in-Suit. Apotex's ANDA speaks for itself. Apotex denies any and all remaining allegations contained in this Paragraph.

38. On information and belief, the Proposed Label will instruct physicians and healthcare providers to administer the GENVOYA ANDA Product for the treatment of HIV-1infection.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 seeking approval to engage in the commercial manufacture, use or sale of Apotex's GENVOYA ANDA Product prior to the expiration of the Patents-in-Suit. Apotex's ANDA speaks for itself. Apotex denies any and all remaining allegations contained in this Paragraph.

39. On information and belief, the Proposed Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving GENVOYA®.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No.

218575 seeking approval to engage in the commercial manufacture, use or sale of Apotex's GENVOYA ANDA Product prior to the expiration of the Patents-in-Suit. Apotex's ANDA speaks for itself. Apotex denies any and all remaining allegations contained in this Paragraph.

COUNTS I-IV FOR PATENT INFRINGEMENT

Count I: Infringement of the '065 Patent Under 35 U.S.C. § 271(e)(2)by the Genvoya ANDA Product

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

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 39 as if fully set forth herein.

41. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '065 patent by submitting to FDA the GENVOYA ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product in or into the United States prior to the expiration of the '065 patent.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

42. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product prior to the expiration of the '065 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '065 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

43. On information and belief, for example, the GENVOYA ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the Apotex ANDA Product contains tenofovir alafenamide hemifumarate. Apotex denies any and all remaining allegations contained in this Paragraph.

44. On information and belief, Apotex also seeks approval to market the GENVOYA ANDA Product for a use claimed in at least claim 17 of the '065 patent.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

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

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

46. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

Count II: Declaratory Judgment of Infringement of the '065 Patent Under 35 U.S.C. §§ 271(a)-(c) and/or (g) by the GENVOYA ANDA Product

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

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 46 as if fully set forth herein.

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

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

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

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

50. Apotex has submitted to FDA an ANDA for a generic version of Gilead's GENVOYA® product. According to Apotex's GENVOYA Notice Letter, Apotex intends to commercially manufacture, use, offer for sale, sell, and/or import the GENVOYA ANDA Product in or into the United States.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex's ANDA and notice letter speak for themselves. Apotex denies any and all remaining allegations contained in this Paragraph.

51. Although FDA has not approved the GENVOYA ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import the GENVOYA ANDA Product.

ANSWER: Paragraph 51 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

52. Apotex's actions indicate that it does not intend to change its course of conduct.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

53. On information and belief, upon FDA approval of the GENVOYA ANDA, Apotex will infringe one or more claims of the '065 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, by making, using, offering to sell, and/or selling the GENVOYA ANDA Product, and/or importing said product into the United States, and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

54. On information and belief, for example, the GENVOYA ANDA Product contains tenofovir alafenamide hemifumarate and thus falls within the scope of at least claim 1 of the '065 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 54 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the Apotex ANDA Product contains tenofovir alafenamide hemifumarate. Apotex denies any and all remaining allegations contained in this Paragraph.

55. On information and belief, if the GENVOYA ANDA is approved by FDA, Apotex will commercially manufacture, use, offer to sell, and/or sell the GENVOYA ANDA Product in the United States, and/or import said product into the United States.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

56. Through at least the foregoing actions, Apotex will directly infringe one or more claims of the '065 patent under 35 U.S.C. § 271(a).

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

57. On information and belief, Apotex has actual knowledge of the '065 patent.

ANSWER: Paragraph 57 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits it had knowledge of the '065 patent when it submitted ANDA No. 218575 to the FDA. Apotex denies any and all remaining allegations contained in this Paragraph.

58. On information and belief, Apotex became aware of the '065 patent no later than the filing of its GENVOYA ANDA.

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits it had knowledge of the '065 patent when it submitted ANDA No. 218575 to the FDA. Apotex denies any and all remaining allegations contained in this Paragraph.

59. On information and belief, if the GENVOYA ANDA is approved by FDA, the commercial manufacture, use, offer to sell, and/or sale of the GENVOYA ANDA Product in the United States, and/or importation of said product into the United States will directly infringe one or more claims of the '065 patent.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

60. On information and belief, if the GENVOYA ANDA is approved by the FDA, Apotex will actively induce, encourage, aid and abet the commercial manufacture, use, offer for sale, and/or sale of the GENVOYA ANDA Product in the United States, and/or importation of said product into the United States, with knowledge and specific intent that the conduct infringes the '065 patent.

ANSWER: Paragraph 60 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 seeking approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to the expiration of the Patents-in-Suit. Apotex denies any and all remaining allegations contained in this Paragraph.

61. On information and belief, the Proposed Label will include directions and instructions that instruct physicians and healthcare providers to administer the GENVOYA ANDA Product in order to treat HIV-1infection in accordance with the methods described and claimed in the ’065 patent.

ANSWER: Paragraph 61 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

62. On information and belief, at least through the Proposed Label Apotex will encourage physicians and healthcare providers to administer the GENVOYA ANDA Product in order to treat HIV-1 infection in accordance with the methods described and claimed in the ’065 patent, and Apotex will know that such conduct will occur.

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

63. On information and belief, Apotex will actively induce, encourage, aid and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the ’065 patent.

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

64. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '065 patent under 35 U.S.C. § 271(b).

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

65. On information and belief, Apotex knows that the GENVOYA ANDA Product will be especially made or adapted for use in infringing the '065 patent and that the GENVOYA ANDA Product is not suitable for substantial non-infringing use.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

66. On information and belief, if the GENVOYA ANDA is approved by the FDA, the commercial manufacture, use, offer to sell, and/or sale of the GENVOYA ANDA Product in the United States, and/or the importation of said product into the United States will infringe the '065 patent.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

67. On information and belief, if the GENVOYA ANDA is approved by the FDA, Apotex's offer to sell and/or sale of the GENVOYA ANDA Product in the United States, and/or the importation of said product into the United States will contribute to the actual infringement of the '065 patent.

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

68. On information and belief, Apotex knows that its offer to sell and/or sale of the GENVOYA ANDA Product in the United States, and/or the importation of said product into the United States will contribute to the actual infringement of the '065 patent.

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

69. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '065 patent under 35 U.S.C. § 271(c).

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

70. On information and belief, if the GENVOYA ANDA is approved by FDA, Apotex will import a product made by a process claimed in the '065 patent into the United States and/or offer to sell, sell, or use that product in the United States.

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

71. On information and belief, the product made by a process claimed in the '065 patent will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

72. Through at least the foregoing actions, Apotex will infringe at least one claim of the '065 patent under 35 U.S.C. § 271(g).

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

73. Gilead is entitled to a declaratory judgment that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product in or into the United States, and/or Apotex's inducement and contribution to the same, prior to the expiration of the '065 patent will constitute infringement of the '065 patent.

ANSWER: Paragraph 73 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

74. The commercial manufacture, importation, use, sale, or offer for sale of the GENVOYA ANDA Product in or into the United States in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

75. Unless and until Apotex is enjoined from infringing the '065 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

Count III: Infringement of the '769 Patent Under 35 U.S.C. § 271(e)(2) by the GENVOYA ANDA Product

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

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 75 as if fully set forth herein.

77. Pursuant to 35 U.S.C. § 271(e)(2)(A), Apotex has committed an act of infringement of the '769 patent by submitting to FDA the GENVOYA ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product in or into the United States prior to the expiration of the '769 patent.

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

78. Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product prior to the expiration of the '769 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '769 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

79. On information and belief, for example, the GENVOYA ANDA Product contains tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that the Apotex ANDA Product contains tenofovir alafenamide hemifumarate. Apotex's ANDA speaks for itself. Apotex denies any and all remaining allegations contained in this Paragraph.

80. On information and belief, Apotex also seeks approval to market the GENVOYA ANDA Product for a use claimed in at least claim 10 of the '769 patent.

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

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

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

82. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

Count IV: Declaratory Judgment of Infringement of the '769 Patent Under 35 U.S.C. §§ 271(a)-(c) and/or (g) by the GENVOYA ANDA Product

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

ANSWER: Apotex incorporates its responses to Paragraphs 1 to 82 as if fully set forth herein.

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

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

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

ANSWER: Paragraph 85 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

86. Apotex has submitted to FDA an ANDA for a generic version of Gilead's GENVOYA® product. According to Apotex's GENVOYA Notice Letter, Apotex intends to commercially manufacture, use, offer for sale, sell, and/or import the GENVOYA ANDA Product in or into the United States.

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex's ANDA and notice letter speak for themselves. Apotex denies any and all remaining allegations contained in this Paragraph.

87. Although FDA has not approved the GENVOYA ANDA, Apotex has made, and will continue to make, substantial preparation in the United States to commercially manufacture, use, sell, offer to sell, and/or import the GENVOYA ANDA Product.

ANSWER: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

88. Apotex's actions indicate that it does not intend to change its course of conduct.

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

89. On information and belief, upon FDA approval of the GENVOYA ANDA, Apotex will infringe one or more claims of the '769 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, by making, using, offering to sell, and/or selling the GENVOYA ANDA Product in the United States, and/or importing said product into the United States, and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

ANSWER: Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

90. On information and belief, for example, the GENVOYA ANDA Product contains tenofovir alafenamide hemifumarate, wherein the composition comprises less than about 5% by

weight of tenofovir alafenamide monofumarate, and thus falls within the scope of at least claim 1 of the '769 patent, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 90 contains legal conclusions and allegations to which no answer is required. . To the extent an answer may be required, Apotex admits that the Apotex ANDA Product contains tenofovir alafenamide hemifumarate. Apotex's ANDA speaks for itself. Apotex denies any and all remaining allegations contained in this Paragraph.

91. On information and belief, if the GENVOYA ANDA is approved by FDA, Apotex will commercially manufacture, use, offer to sell, and/or sell the GENVOYA ANDA Product in the United States, and/or import said product into the United States.

ANSWER: Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

92. Through at least the foregoing actions, Apotex will directly infringe one or more claims of the '769 patent under 35 U.S.C. § 271(a).

ANSWER: Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

93. On information and belief, Apotex has actual knowledge of the '769 patent.

ANSWER: Paragraph 93 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits it had knowledge of the '769 patent when it submitted ANDA No. 218575 to the FDA. Apotex denies any and all remaining allegations contained in this Paragraph.

94. On information and belief, Apotex became aware of the '769 patent no later than the filing of its GENVOYA ANDA.

ANSWER: Paragraph 94 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits it had knowledge of the '769 patent when it submitted ANDA No. 218575 to the FDA. Apotex denies any and all remaining allegations contained in this Paragraph.

95. On information and belief, if the GENVOYA ANDA is approved by FDA, the commercial manufacture, use, offer to sell, and/or sale of the GENVOYA ANDA Product in the United States, and/or importation of said product into the United States will directly infringe one or more claims of the '769 patent.

ANSWER: Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

96. On information and belief, if the GENVOYA ANDA is approved by the FDA, Apotex will actively induce, encourage, aid and abet the commercial manufacture, use, offer for sale, and/or sale of the GENVOYA ANDA Product in the United States, and/or importation of said product into the United States, with knowledge and specific intent that the conduct infringes the '769 patent.

ANSWER: Paragraph 96 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex admits that it filed ANDA No. 218575 seeking approval to engage in the commercial manufacture, use or sale of the Apotex ANDA Product prior to the expiration of the Patents-in-Suit. Apotex denies any and all remaining allegations contained in this Paragraph.

97. On information and belief, the Proposed Label will include directions and instructions that instruct physicians and healthcare providers to administer the GENVOYA ANDA Product in order to treat HIV-1infection in accordance with the methods described and claimed in the '769 patent.

ANSWER: Paragraph 97 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

98. On information and belief, at least through the Proposed Label Apotex will encourage physicians and healthcare providers to administer the GENVOYA ANDA Product in order to treat HIV-1 infection in accordance with the methods described and claimed in the '769 patent, and Apotex will know that such conduct will occur.

ANSWER: Paragraph 98 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

99. On information and belief, Apotex will actively induce, encourage, aid and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the '769 patent.

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

100. Through at least the foregoing actions, Apotex will actively induce the infringement of at least one claim of the '769 patent under 35 U.S.C. § 271(b).

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

101. On information and belief, Apotex knows that the GENVOYA ANDA Product will be especially made or adapted for use in infringing the '769 patent, and that the GENVOYA ANDA Product is not suitable for substantial non-infringing use.

ANSWER: Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

102. On information and belief, if the GENVOYA ANDA is approved by the FDA, the commercial manufacture, use, offer to sell, and/or sale of the GENVOYA ANDA Product in the United States, and/or the importation of said product into the United States will infringe the '769 patent.

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

103. On information and belief, if the GENVOYA ANDA is approved by the FDA, Apotex's offer to sell and/or sale of the GENVOYA ANDA Product in the United States, and/or the importation of said product into the United States will contribute to the actual infringement of the '769 patent.

ANSWER: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

104. On information and belief, Apotex knows that its offer to sell and/or sale of the GENVOYA ANDA Product in the United States, and/or the importation of said product into the United States will contribute to the actual infringement of the '769 patent.

ANSWER: Paragraph 104 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

105. Through at least the foregoing actions, Apotex will contribute to the infringement of at least one claim of the '769 patent under 35 U.S.C. § 271(c).

ANSWER: Paragraph 105 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

106. On information and belief, if the GENVOYA ANDA is approved by FDA, Apotex will import a product made by a process claimed in the '769 patent into the United States and/or offer to sell, sell, or use that product in the United States.

ANSWER: Paragraph 106 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

107. On information and belief, the product made by a process claimed in the '769 patent will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

ANSWER: Paragraph 107 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

108. Through at least the foregoing actions, Apotex will infringe at least one claim of the '769 patent under 35 U.S.C. § 271(g).

ANSWER: Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

109. Gilead is entitled to a declaratory judgment that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product in or into the United States, and/or Apotex's inducement and contribution to the same, prior to the expiration of the '769 patent will constitute infringement of the '769 patent.

ANSWER: Paragraph 109 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

110. The commercial manufacture, importation, use, sale, or offer for sale of the GENVOYA ANDA Product in or into the United States in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

ANSWER: Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

111. Unless and until Apotex is enjoined from infringing the '769 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Apotex denies the allegations of this Paragraph.

PRAYER FOR RELIEF

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

(A) A judgment that Apotex has infringed the '065 patent and the '769 patent under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the GENVOYA ANDA shall be a date which is not earlier than the day after the latest expiration date of the '065 patent and the '769 patent, as extended by any applicable periods of exclusivity to which Gilead is or will be entitled;

(C) A judgment declaring that Apotex's commercial manufacture, use, offer for sale, sale, and/or importation of the GENVOYA ANDA Product in or into the United States prior to the expiration of the '065 patent and the '769 patent (including such actions by its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Apotex or acting on Apotex's behalf) will constitute infringement of the '065 patent and the '769 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

(D) An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Apotex, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the United States, and/or importing into the United States, the GENVOYA ANDA Product until the day after the latest expiration date of the '065 patent and the '769 patent, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled, and from otherwise infringing one or more claims of the '065 patent and the '769 patent;

(E) A declaration that this case is exceptional;

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

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

ANSWER: Apotex denies all allegations not expressly admitted herein. Apotex further denies that Plaintiff is entitled to any of the relief requested in paragraphs (A) through (G), and

requests that Plaintiff's Complaint be dismissed with prejudice and that Apotex be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

AFFIRMATIVE AND OTHER DEFENSES

Apotex asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST AFFIRMATIVE DEFENSE
(INVALIDITY)

The claims of the '065 patent are invalid under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 102, 103 and 112.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY)

The claims of the '769 patent are invalid under 35 U.S.C. §§ 101, *et seq*. including, *inter alia*, §§ 103 and 112.

THIRD AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product specified in ANDA No. 218575 does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '065 patent.

FOURTH AFFIRMATIVE DEFENSE
(NO DIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product specified in ANDA No. 218575 does not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '769 patent.

FIFTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product specified in ANDA No. 218575 does not and will not induce the infringement of, and has not contributed to and does not and will not contribute to the infringement of, any valid and enforceable claim of the '065 patent.

SIXTH AFFIRMATIVE DEFENSE
(NO INDIRECT INFRINGEMENT)

The manufacture, use, offer for sale, sale, or importation of Apotex's ANDA Product specified in ANDA No. 218575 does not and will not induce the infringement of, and has not contributed to and does not and will not contribute to the infringement of, any valid and enforceable claim of the '769 patent.

SEVENTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

EIGHTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM FOR EXCEPTIONAL CASE)

Plaintiff fails to state a proper claim for an exceptional case.

NINTH ADDITIONAL DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

RESERVATION OF ADDITIONAL DEFENSES

Apotex reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Apotex Inc. and Apotex Corp., (collectively, "Apotex" or "Defendants/Counterclaim-Plaintiffs"), by way of its attorneys, hereby states for its Counterclaims against Gilead Sciences, Inc. ("Gilead" or "Plaintiff/Counterclaim-Defendant"), the following, without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiff/Counterclaim-Defendant:

Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Affirmative Defenses to the Complaint.

THE PARTIES

1. Apotex repeats and incorporates by reference each of the foregoing paragraphs of Apotex's Answer and Separate Defenses to the Complaint.

2. Apotex Inc. is a corporation organized and existing under the laws of Canada, with a place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

3. Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston Florida, 33326.

4. Upon information and belief, Plaintiff/Counterclaim-Defendant Gilead is a corporation organized and existing under the laws of the state of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, California 94404.

JURISDICTION

5. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Defendants/Counterclaim-Plaintiffs and Plaintiff/Counterclaim-Defendant, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

8. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiff/Counterclaim-Defendant does business in this jurisdiction.

9. Venue is proper in this judicial district under 28 U.S. C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

10. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent No. 8,754,065 ("the '065 patent ") and U.S. Patent No. 9,296,769 ("the '769 patent") (together "the Patents-in-Suit"). Upon information and belief, true and correct copies of the Patents-in-Suit were attached to the Complaint as Exhibits A and B.

11. On or about June 17, 2014, the U.S. Patent & Trademark Office ("USPTO") issued the '065 patent.

12. On or about March 29, 2016, the USPTO issued the '769 patent.

13. Upon information and belief, Plaintiff/Counterclaim-Defendant Gilead is the assignee of the '065 patent.

14. Upon information and belief, Plaintiff/Counterclaim-Defendant Gilead is the assignee of the '769 patent.

15. Plaintiff/Counterclaim-Defendant Gilead purports to be the holder of New Drug Application ("NDA") No. 207561 for cobicistat, elvitegravir, emtricitabine, and tenofovir alafenamide oral tablets (150 mg, 150 mg, 200 mg, EQ 10 mg base). Gilead sells its combination drug oral tablets in the United States under the trademark GENVOYA®.

16. Plaintiff/Counterclaim-Defendant purports and claims to have the rights to enforce the Patents-in-Suit, and have listed the Patents-in-Suit in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with GENVOYA®.

17. Apotex has filed Abbreviated New Drug Application ("ANDA") No. 218575 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Apotex's proposed cobicistat, elvitegravir, emtricitabine, and tenofovir alafenamide product described therein ("the Apotex ANDA Product"), identifying NDA No. 207561 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3 ("the Apotex Genvoya ANDA").

18. The Apotex ANDA seeks FDA approval to market the Apotex ANDA Product described within ANDA No. 218575 before the expiration of the Patents-in-Suit listed in the

Orange Book, and the Apotex Genvoya ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the Patents-in-Suit.

19. Plaintiff/Counterclaim-Defendant sued Apotex in this District for alleged infringement of the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Invalidity of the '065 Patent)

20. Apotex realleges and incorporates by reference the allegations of paragraphs 1-19 as though fully set forth herein.

21. There is an actual, substantial, and continuing case or controversy between Defendants/Counterclaim-Plaintiffs and Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '065 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '065 patent.

22. The claims of the '065 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

23. The claims of the '065 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, as set forth in Apotex's Notice Letter, mailed to Plaintiff/Counterclaim-Defendant on June 1, 2023 in connection with Apotex's Genvoya ANDA, because each and every element of each and every claim of the '065 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '065 patent, including, but not limited to, those references and/or products disclosed in Apotex's Notice, namely:

1) Vasireddy, U. *et al.*, U.S. Patent Publication No. 2009/0286981, "Process for the Preparation of Tenofovir," published November 19, 2009;
2) Yadav, A.V. *et al.*, "Co-Crystals: A Novel Approach to Modify Physicochemical Properties of Active Pharmaceutical Ingredients," 71(4) Ind. J. Pharm Sci. 359, 359–60 (2009);
3) Dova, E. *et al.*, U.S. Patent Publication No. 2009/0176983, "Tenofovir Disoproxil Hemi-Fumaric Acid Co-Crystal," published July 9, 2009;
4) Lee *et al.*, "Characterization and Anisotropic Lattice Expansion/Contraction of Polymorphs of Tenofovir Disoproxil Fumarate," 10 Crys. Growth & Des. 2314–22 (2010);
5) Dova, E. *et al.*, PCT Publication No. WO2008143500, "Tenofovir Disoproxil Hemi-Fumaric Acid Co-Crystal," published November 27, 2008;
6) Becker, M. *et al.*, U.S. Patent No. 7,390,791, "Prodrugs of Phosphonate Nucleotide Analogues," issued June 24, 2008;
7) Cihlar, Thomas, "Amidate Prodrugs of Nucleoside Phosphonates: from Design to *in vivo* Proof of Concept," 10 Collection Symposium Series 45, 46 (2008);
8) EMEA *Scientific Discussion* for the Approval of Viread 17/43 (2005).

24. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '065 patent, and would have had a reasonable expectation of success in doing so.

25. There is no objective evidence of non-obviousness of the claims of the '065 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '065 patent.

26. Apotex is entitled to a judicial declaration that the claims of the '065 patent are invalid.

27. Apotex reserves the right to provide additional bases for invalidity of each claim of the '065 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT II

(Declaratory Judgment of Noninfringement of the '065 Patent)

28. Apotex realleges and incorporates by reference the allegations of paragraphs 1-28 as though fully set forth herein.

29. There is an actual, substantial, and continuing case or controversy between Defendants/Counterclaim-Plaintiffs and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '065 patent.

30. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in the Apotex Genvoya ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '065 patent, either literally or under the doctrine of equivalents.

31. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in Apotex's Genvoya ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '065 patent, either literally or under the doctrine of equivalents.

COUNT III

(Declaratory Judgment of Invalidity of the '769 Patent)

32. Apotex realleges and incorporates by reference the allegations of paragraphs 1-31 as though fully set forth herein.

33. There is an actual, substantial, and continuing case or controversy between Defendants/Counterclaim-Plaintiffs and the Plaintiff/Counterclaim-Defendant regarding *inter*

alia, the invalidity of the '769 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '769 patent.

34. The claims of the '769 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially created bases for invalidation.

35. The claims of the '769 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, as set forth in Apotex's Notice Letter mailed to Plaintiff/Counterclaim-Defendant on June 1, 2023 in connection with Apotex's Genvoya ANDA, because each and every element of each and every claim of the '769 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '769 patent, including, but not limited to, those references and/or products disclosed in Apotex's Notice, namely:

1) Vasireddy, U. *et al.*, U.S. Patent Publication No. 2009/0286981, "Process for the Preparation of Tenofovir," published November 19, 2009;
2) Yadav, A.V. *et al.*, "Co-Crystals: A Novel Approach to Modify Physicochemical Properties of Active Pharmaceutical Ingredients," 71(4) Ind. J. Pharm Sci. 359, 359–60 (2009);
3) Dova, E. *et al.*, U.S. Patent Publication No. 2009/0176983, "Tenofovir Disoproxil Hemi-Fumaric Acid Co-Crystal," published July 9, 2009;
4) Lee *et al.*, "Characterization and Anisotropic Lattice Expansion/Contraction of Polymorphs of Tenofovir Disoproxil Fumarate," 10 Crys. Growth & Des. 2314–22 (2010);
5) Dova, E. *et al.*, PCT Publication No. WO2008143500, "Tenofovir Disoproxil Hemi-Fumaric Acid Co-Crystal," published November 27, 2008;
6) Becker, M. *et al.*, U.S. Patent No. 7,390,791, "Prodrugs of Phosphonate Nucleotide Analogues," issued June 24, 2008;
7) Cihlar, Thomas, "Amidate Prodrugs of Nucleoside Phosphonates: from Design to *in vivo* Proof of Concept," 10 Collection Symposium Series 45, 46 (2008);

8) EMEA *Scientific Discussion* for the Approval of Viread 17/43 (2005).

36. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '769 patent, and would have had a reasonable expectation of success in doing so.

37. There is no objective evidence of non-obviousness of the claims of the '769 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '769 patent.

38. Apotex is entitled to a judicial declaration that the claims of the '769 patent are invalid.

39. Apotex reserves the right to provide additional bases for invalidity of each claim of the '769 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT IV

(Declaratory Judgment of Noninfringement of the '769 Patent)

40. Apotex realleges and incorporates by reference the allegations of paragraphs 1-39 as though fully set forth herein.

41. There is an actual, substantial, and continuing case or controversy between Defendants/Counterclaim-Plaintiffs and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '769 patent.

42. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in the Apotex Genvoya ANDA has not infringed, does not

infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’769 patent, either literally or under the doctrine of equivalents.

43. Apotex is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Apotex ANDA Product described in the Apotex Genvoya ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the ’769 patent, either literally or under the doctrine of equivalents.

REQUEST FOR RELIEF

WHEREFORE, Apotex respectfully requests that the Court enter judgment in its favor and against Plaintiff/Counterclaim Defendant Gilead Sciences, Inc. as follows:

(A) Dismissing Plaintiff/Counterclaim Defendant’s Complaint, and each and every claim by Plaintiff/Counterclaim Defendant against Defendants/Counterclaim-Plaintiffs for relief contained therein, with prejudice;

(B) Declaring that Defendants/Counterclaim-Plaintiffs do not infringe any valid claim of the ’065 patent and ’769 patent, and that the claims of the ’065 patent and ’769 patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, *et seq.* including, *inter alia*, §§ 102, 103, and 112;

(C) Declaring that the products which are the subject of Apotex’s ANDA No. 218575 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 ’065 patent and ’769 patent under 35 U.S.C. § 271;

(D) Declaring this case exceptional and awarding Defendants/Counterclaim-Plaintiffs reasonable attorneys' fees and costs under 35 U.S.C. § 285;

(E) Awarding Defendants/Counterclaim-Plaintiffs its costs and expenses; and

(F) Awarding Defendants/Counterclaim-Plaintiffs such other and further relief as the Court deems just and proper.

Dated: December 4, 2023

/s/ Cortlan S. Hitch
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