Keith J. Miller, Esq.
ROBINSON MILLER LLC
One Newark Center
Newark, NJ 07102
973-690-5400
kmiller@rwmlegal.com

Attorney for Gilead Sciences, Inc. and Gilead Pharmasset LLC

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC. and GILEAD PHARMASSET LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendant(s).	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC (collectively, "Gilead" or "Plaintiffs"), by their undersigned attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA") and Defendant Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively, "Teva" or "Defendants"). This action arises out of the filing by Teva of Abbreviated New Drug

Application ("ANDA") No. 211353 with the United States Food and Drug Administration ("FDA").

2. In ANDA No. 211353, Teva seeks approval to market a generic version of Gilead's groundbreaking Sovaldi® product (the "Teva ANDA Product"), prior to the expiration of U.S. Patent Nos. 7,964,580 (the "'580 patent"); 8,334,270 (the "'270 patent"); 8,580,765 (the "'765 patent"); 9,085,573 (the "'573 patent"); 7,429,572 (the "'572 patent"); 8,415,322 (the "'322 patent"); 8,633,309 (the "'309 patent"); 9,284,342 (the "'342 patent"); 8,618,076 (the "'076 patent"); 9,549,941 (the "'941 patent"); 8,889,159 (the "'159 patent"); 8,629,263 (the "'263 patent"); 8,735,569 (the "'569 patent"); 9,637,512 (the "'512 patent"); 8,642,756 (the "'756 patent"); 9,206,217 (the "'217 patent"); and 9,340,568 (the "'568 patent") (collectively, the "patents-in-suit").

PARTIES

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

4. Plaintiff Gilead Pharmasset LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 303-A College Road, East Princeton, New Jersey 08540.

5. Gilead Sciences, Inc. is a research-based pharmaceutical company that discovers, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for hepatitis C virus ("HCV"), hepatitis B virus ("HBV"), human immunodeficiency virus ("HIV"), liver diseases, serious cardiovascular and respiratory diseases, and cancer. Gilead's portfolio of products includes treatments for chronic HCV infection using

the drug sofosbuvir. Gilead sells sofosbuvir under the trade name Sovaldi® in this District and throughout the United States.

6. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. On information and belief, Defendant Teva Industries is a foreign limited liability company organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

8. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Industries and is controlled and/or dominated by Teva Industries.

9. On information and belief, Defendants, themselves and through their subsidiaries, affiliates, and agents, manufacture, distribute, and/or import generic pharmaceutical products for sale and use throughout the United States, including in this District.

10. On information and belief, Defendants are agents of each other and/or work in concert with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products, including the Teva ANDA Product, throughout the United States, including in this District.

11. On information and belief, Defendants prepared and filed ANDA No. 211353 and will be involved in the manufacture, importation, marketing and sale of the Teva ANDA Product in the United States, including in this District, if ANDA No. 211353 is approved.

JURISDICTION AND VENUE

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

13. On information and belief, Teva USA, in concert with Teva Industries, develops, formulates, manufactures, imports, offers for sale, sells, commercializes, markets, and/or distributes generic pharmaceutical products in or into the United States, including in or into the State of New Jersey.

14. On information and belief, Teva USA, acting in concert with Teva Industries, prepared and filed ANDA No. 211353, seeking approval from FDA to sell the Teva ANDA Product throughout the United States, including within the State of New Jersey.

15. By submitting ANDA No. 211353 to FDA, Teva USA, acting in concert with Teva Industries, has made clear that it intends to use its distribution channels to market the Teva ANDA Product in the State of New Jersey. If ANDA No. 211353 is approved, the Teva ANDA Product would, among other things, be marketed and distributed in the State of New Jersey, and/or prescribed by physicians practicing and dispensed by pharmacies located within the State of New Jersey, all of which would have a substantial effect on the State of New Jersey.

16. On information and belief, Teva Industries, acting in concert with Teva USA, participated in the preparation and/or filing of ANDA No. 211353, seeking approval from FDA to sell the Teva ANDA Product throughout the United States, including within the State of New Jersey.

17. Teva USA and Teva Industries therefore committed an act of infringement in the State of New Jersey, by participating in the preparation, filing, and submission of ANDA No. 211353 pursuant to § 505(j) of the Federal Food Drug and Cosmetic Act to FDA, accompanied by a Paragraph IV certification.

18. This Court has personal jurisdiction over Teva USA because, on information and belief, Teva USA regularly and continuously transacts business in this District, including by selling

and distributing pharmaceutical products in the State of New Jersey, either on its own or through its subsidiaries, affiliates, and/or agents.

19. This Court also has personal jurisdiction over Teva USA because it is registered to do business in the State of New Jersey and has also designated Corporate Creations Network Inc. as its agent for service of process in the State of New Jersey. Corporate Creations Network Inc. is located at 811 Church Road #105, Cherry Hill, New Jersey 08002.

20. On information and belief, Teva USA has at all relevant times purposefully directed activities at residents in the State of New Jersey, including but not limited to, its business of preparing generic pharmaceutical products that it distributes in the State of New Jersey, and Teva USA plans to continue such activities.

21. On information and belief, Teva USA avails itself of the benefits and protections of the laws of the State of New Jersey. For example, Teva USA is registered with the New Jersey Department of Health as a drug manufacturer and wholesaler under Registration Nos. 5000583 and 5003436, respectively.

22. On or about February 15, 2018, Gilead received a letter, dated February 13, 2018, from Teva USA (the "Notice Letter"). The Notice Letter states that Teva USA had submitted, and FDA had received, an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). On information and belief, Teva USA prepared the Notice Letter in the State of New Jersey and sent the Notice Letter from its New jersey place of business located at 200 Elmora Avenue, Elizabeth, New Jersey 07202. Teva USA further included an Offer of Confidential Access ("OCA") in the Notice letter. In the OCA, Teva indicated that Gilead could request access to Teva's ANDA by returning an executed copy of the OCA to Teva's New Jersey facility at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

23. Teva USA has previously been sued in this District and has not challenged personal jurisdiction or venue. *See* Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Ltd., and Actavis LLC's Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement, *Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 3:17-cv-11510 (D.N.J. Jan. 16, 2018), ECF No. 11; Answer and Affirmative Defenses of Defendant Teva Pharmaceuticals USA, Inc. with Counterclaims, *Mitsubishi Tanabe Pharma Corp. et al. v. MSN Lab. Private Ltd., et al.*, No. 3:17-cv-05302 (D.N.J. Jan. 11, 2018), ECF No. 61.

24. This Court has personal jurisdiction over Teva Industries pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Gilead's claims arise under federal law; (b) Teva Industries is a foreign company not subject to personal jurisdiction in the courts of any state; and (c) Teva Industries 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 Teva Industries satisfies due process.

25. Teva Industries has previously been sued in this District and has not challenged personal jurisdiction or venue. *See* Defendants Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Ltd., and Actavis LLC's Answer, Affirmative Defenses, and Counterclaims to Plaintiffs' Complaint for Patent Infringement, *Boehringer Ingelheim Pharmaceuticals, Inc. et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 3:17-cv-11510 (D.N.J. Jan. 16, 2018), ECF No. 11.

26. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400(b) because Teva USA committed an act of infringement in the District and has a regular and established place of

business in this District. Teva submitted its ANDA No. 211353 pursuant to 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act, and, upon receiving approval of its ANDA, will manufacture, sell, offer to sell, and/or import the Teva ANDA Product in the United States, including in this District. On information and belief, Teva USA also prepared its ANDA and Notice Letter in the State of New Jersey. Teva USA has thus committed an act of infringement in this District. On information and belief, Teva USA also has regular and established places of business in this District located at 8 Gloria Lane, Fairfield, New Jersey 07004 and 200 Elmora Avenue, Elizabeth, New Jersey 07202.

27. Venue is proper in this Court under 28 U.S.C. §§ 1391(c)(3) and 1400(b) because Teva Industries 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.

PATENTS-IN-SUIT

28. On June 21, 2011, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,964,580 (the "'580 patent"), titled "Nucleoside Phosphoramidate Prodrugs." A true and correct copy of the '580 patent is attached hereto as Exhibit A. The claims of the '580 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '580 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

29. On December 18, 2012, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,334,270 (the "'270 patent"), titled "Nucleoside Phosphoramidate Prodrugs." A true and correct copy of the '270 patent is attached hereto as Exhibit B. The claims of the '270 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '270 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

30. On November 12, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,580,765 (the "'765 patent"), titled "Nucleoside Phosphoramidate

Prodrugs." A true and correct copy of the '765 patent is attached hereto as Exhibit C. The claims of the '765 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '765 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

31. On July 21, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,085,573 (the "'573 patent"), titled "Nucleoside Phosphoramidate Prodrugs." A true and correct copy of the '573 patent is attached hereto as Exhibit D. The claims of the '573 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '573 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

32. On September 30, 2008, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 7,429,572 (the "'572 patent"), titled "Modified Fluorinated Nucleoside Analogues." A true and correct copy of the '572 patent is attached hereto as Exhibit E. The claims of the '572 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '572 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

33. On April 9, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,415,322 (the "'322 patent"), titled "Modified Fluorinated Nucleoside Analogues." A true and correct copy of the '322 patent is attached hereto as Exhibit F. The claims of the '322 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '322 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

34. On January 21, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,633,309 (the "'309 patent"), titled "Nucleoside Phosphoramidates." A true and correct copy of the '309 patent is attached hereto as Exhibit G. The claims of the '309 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '309 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

35. On March 15, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,284,342 (the "'342 patent"), titled "Nucleoside Phosphoramidates." A true and correct copy of the '342 patent is attached hereto as Exhibit H. The claims of the '342 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '342 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

36. On December 31, 2013, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,618,076 (the "'076 patent"), titled "Nucleoside Phosphoramidates." A true and correct copy of the '076 patent is attached hereto as Exhibit I. The claims of the '076 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '076 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

37. On January 24, 2017, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,549,941 (the "'941 patent"), titled "Compositions and Methods for Treating Hepatitis C Virus." A true and correct copy of the '941 patent is attached hereto as Exhibit J. The claims of the '941 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '941 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

38. On November 18, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,889,159 (the "'159 patent"), titled "Compositions and Methods for Treating Hepatitis C Virus." A true and correct copy of the '159 patent is attached hereto as Exhibit K. The claims of the '159 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '159 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

39. On January 14, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,629,263 (the "'263 patent"), titled "Nucleoside Phosphoramidates." A true and

correct copy of the ’263 patent is attached hereto as Exhibit L. The claims of the ’263 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the ’263 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

40. On May 27, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,735,569 (the “’569 patent”), titled “Nucleoside Phosphoramidates.” A true and correct copy of the ’569 patent is attached hereto as Exhibit M. The claims of the ’569 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the ’569 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

41. On May 2, 2017, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,637,512 (the “’512 patent”), titled “Nucleoside Phosphoramidates.” A true and correct copy of the ’512 patent is attached hereto as Exhibit N. The claims of the ’512 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the ’512 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

42. On February 4, 2014, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 8,642,756 (the “’756 patent”), titled “Nucleoside Phosphoramidates.” A true and correct copy of the ’756 patent is attached hereto as Exhibit O. The claims of the ’756 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the ’756 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

43. On December 8, 2015, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,206,217 (the “’217 patent”), titled “Nucleoside Phosphoramidates.” A true and correct copy of the ’217 patent is attached hereto as Exhibit P. The claims of the ’217 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the ’217 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

44. On May 17, 2016, the U.S. Patent and Trademark Office duly and legally issued U.S. Patent No. 9,340,568 (the "'568 patent"), titled "Solid Forms of an Antiviral Compound." A true and correct copy of the '568 patent is attached hereto as Exhibit Q. The claims of the '568 patent are valid, enforceable, and not expired. Gilead Pharmasset LLC is the assignee of the '568 patent, and Gilead Sciences, Inc. is the exclusive licensee thereof.

ACTS GIVING RISE TO THIS ACTION

45. Gilead Sciences, Inc. holds New Drug Application ("NDA") No. 204671 for 400 mg sofosbuvir tablets for the treatment of adult patients with genotype 1, 2, 3 or 4 chronic hepatitis C virus infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen, and for the treatment of pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic hepatitis C virus infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

46. The 400 mg sofosbuvir tablets approved under the NDA are marketed in the United States under the trade name Sovaldi®. FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the following patents as covering Sovaldi®: U.S. Patent Nos. 7,964,580; 8,334,270; 8,580,765; 9,085,573; 8,633,309; 9,284,342; 8,618,076; 9,549,941; and 8,889,159.

47. As described above, on or about February 15, 2018, Gilead received the Notice Letter, stating that Teva had submitted, and FDA had received, ANDA No. 211353.

48. The Notice Letter further states that Teva has submitted ANDA No. 211353 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the Teva ANDA Product before the expiration of U.S. Patent Nos. 7,964,580; 8,334,270; 8,580,765; 9,085,573; 8,633,309; 9,284,342; 8,618,076; 9,549,941; and 8,889,159.

49. In the Notice Letter, Teva states that its ANDA includes certifications pursuant to 21 U.S.C. § 355(j)(2)(A) with respect to the '580, '270, '765, '573, '309, '342, '076, '941, and '159 patents. The Notice Letter further alleges that these patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, importation, offer for sale, and sale of the Teva ANDA Product in the United States. In the Notice Letter, Teva states that the Teva ANDA Product does not infringe claims 4-9 and 19 of the '270 patent or any of the claims of the '342, '076, '159 and '941 patents. The Notice Letter also states that claims 1-3, 10-18, and 20-25 of the '270 patent and all claims of the '580, '765, '573 and '309 patents are invalid. Teva does not contest infringement of claims 1-3, 10-18, and 20-25 of the '270 patent or any of the claims of the '580, '765, '573, and '309 patents, except on the basis that those claims are allegedly invalid, and Teva does not contest validity of any claims of the '076, '342, '159, and '941 patents.

50. By filing ANDA No. 211353, Teva has necessarily represented to FDA that the Teva ANDA Product has the same active ingredient as Sovaldi®, has the same dosage form and strength as Sovaldi®, and is bioequivalent to Sovaldi®.

51. On information and belief, Teva is seeking approval to market the Teva ANDA Product for the same approved indication as Sovaldi®.

52. Teva provided its OCA to ANDA No. 211353 under 21 U.S.C. § 355(j)(5)(C)(i)(III) and on the terms and conditions set forth in the Notice Letter. Teva requested that Gilead accept the OCA before receiving access to Teva's ANDA. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information." The OCA contained unreasonable restrictions, above and beyond those

that would apply under a protective order, on who could view the ANDA. For example, the OCA limited access to outside counsel from one law firm and did not permit Gilead to share the ANDA with in-house counsel, in-house scientists, or independent experts. The OCA further unreasonably limited the fields of practice and other activities of outside counsel and any other person who accepted access to the ANDA. The OCA also did not provide access to the full ANDA filed with FDA but instead only offered unidentified portions of the ANDA selected by Teva. The OCA further did not provide access to Teva's Drug Master File or correspondence with FDA post-dating the filing of the ANDA.

53. After receiving the Notice Letter, Gilead and Teva negotiated in good faith, but were unable to reach a mutually-acceptable agreement under which Teva would provide its ANDA to Gilead. Teva's final proposal still did not permit Gilead to share the ANDA with in-house counsel or in-house scientists, and only contemplated access for independent experts approved by Teva. Teva's proposal also continued to unreasonably limit the fields of practice and other activities of any person, including outside counsel, who accepts access to the ANDA. As a result, Gilead has been unable to access Teva's ANDA.

54. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter in order to receive certain benefits under the Act, including a stay of approval of the generic drug for up to 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

55. Gilead is not aware of any other means of obtaining information regarding the Teva ANDA Product within the 45-day statutory period. In the absence of such information, Gilead resorts to the judicial process and the aid of discovery to obtain under appropriate judicial

safeguards such information as is required to confirm its belief and to present to the Court evidence that Teva infringes certain claims of the patents-in-suit.

56. This action is being commenced before the expiration of 45 days from the date Gilead received the Notice Letter, which triggers a stay of FDA approval of Teva's ANDA No. 211353, pursuant to 21 U.S.C. § 355(J)(5)(B)(iii).

COUNT I

(INFRINGEMENT OF THE '580 PATENT UNDER 35 U.S.C. § 271(e)(2))

57. Gilead realleges paragraphs 1-56 as if fully set forth herein.

58. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '580 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '580 patent.

59. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '580 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '580 patent, including but not limited to claim 8.[1]

60. On information and belief, for example, the Teva ANDA Product contains sofosbuvir, which can be represented by the nomenclature (S)-isopropyl 2-(((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl)amino)propanoate, and thus falls within the scope of at least claim 8 of the '580 patent.

[1] Gilead will identify all asserted claims of the '580 patent in accordance with this Court's Local Rules and/or scheduling order.

61. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '580 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '580 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

62. Gilead realleges paragraphs 1-61 as if fully set forth herein.

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

64. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

65. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

66. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import the Teva ANDA Product.

67. Teva's recent actions indicate that it does not intend to change its course of conduct.

68. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '580 patent, either literally or under the doctrine of equivalents, including but not limited to claim 8,[2] by making, using, offering to sell, and/or selling the Teva ANDA Product in the United States and/or importing said product into the United States

[2] Gilead will identify all asserted claims of the '580 patent in accordance with this Court's Local Rules and/or scheduling order.

and/or by actively inducing and contributing to infringement of the ’580 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

69. For example, on information and belief, the Teva ANDA Product contains sofosbuvir, which can be represented by the nomenclature (S)-isopropyl 2-(((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl)amino)propanoate, and thus falls within the scope of at least claim 8 of the ’580 patent.

70. Teva has actual knowledge of the ’580 patent.

71. On information and belief, Teva became aware of the ’580 patent no later than the date on which that patent was listed in the Orange Book.

72. On information and belief, Teva has acted with full knowledge of the ’580 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’580 patent. Further, on information and belief, Teva knows or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the ’580 patent. On information and belief, this knowledge is reflected through, among other things, Teva’s Notice Letter, which does not contest infringement of any claims of the ’580 patent, except on the basis that those claims are allegedly invalid.

73. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the

claims of the ’580 patent, either literally or under the doctrine of equivalents, including but not limited to claim 8, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva’s specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead’s rights under the ’580 patent.

74. On information and belief, Teva’s commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the ’580 patent, either literally or under the doctrine of equivalents, including but not limited to claim 8, under 35 U.S.C. § 271(b).

75. On information and belief, Teva’s commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the ’580 patent, either literally or under the doctrine of equivalents, including but not limited to claim 8, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the ’580 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

76. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the ’580 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’580 patent.

77. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '580 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III

(INFRINGEMENT OF THE '270 PATENT UNDER 35 U.S.C. § 271(e)(2))

78. Gilead realleges paragraphs 1-77 as if fully set forth herein.

79. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '270 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '270 patent.

80. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to expiration of the '270 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '270 patent, including but not limited to claim 1.[3]

81. On information and belief, for example, the Teva ANDA Product contains sofosbuvir, which can be represented by the nomenclature (S)-isopropyl 2-(((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl)amino)propanoate, and thus falls within the scope of at least claim 1 the '270 patent.

82. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '270 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

[3] Gilead will identify all asserted claims of the '270 patent in accordance with this Court's Local Rules and/or scheduling order.

COUNT IV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '270 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

83. Gilead realleges paragraphs 1-82 as if fully set forth herein.

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

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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

86. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

87. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

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

89. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '270 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[4] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '270 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

[4] Gilead will identify all asserted claims of the '270 patent in accordance with this Court's Local Rules and/or scheduling order.

90. On information and belief, for example, the Teva ANDA Product contains sofosbuvir, which can be represented by the nomenclature (S)-isopropyl 2-(((S)-(((2R,3R,4R,5R)-5-(2,4-dioxo-3,4-dihydropyrimidin-1(2H)-yl)-4-fluoro-3-hydroxy-4-methyltetrahydrofuran-2-yl)methoxy)(phenoxy)phosphoryl)amino)propanoate, and thus falls within the scope of at least claim 1 of the '270 patent.

91. Teva has actual knowledge of the '270 patent.

92. On information and belief, Teva became aware of the '270 patent no later than the date on which that patent was listed in the Orange Book.

93. On information and belief, Teva has acted with full knowledge of the '270 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '270 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the '270 patent. On information and belief, this knowledge is reflected through, among other things, Teva's Notice Letter, which does not contest infringement of any claims of the '270 patent, and specifically contests infringement of claims 1-3, 10-18, and 20-25 of the '270 patent only on the basis that those claims are allegedly invalid.

94. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered or sale, and/or sold by Teva in the United States, by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '270 patent, either literally or under the doctrine of equivalents, including but not

limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '270 patent.

95. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '270 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

96. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the'270 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '270 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

97. Gilead is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '270 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '270 patent.

98. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '270 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT V

(INFRINGEMENT OF THE '765 PATENT UNDER 35 U.S.C. § 271(e)(2))

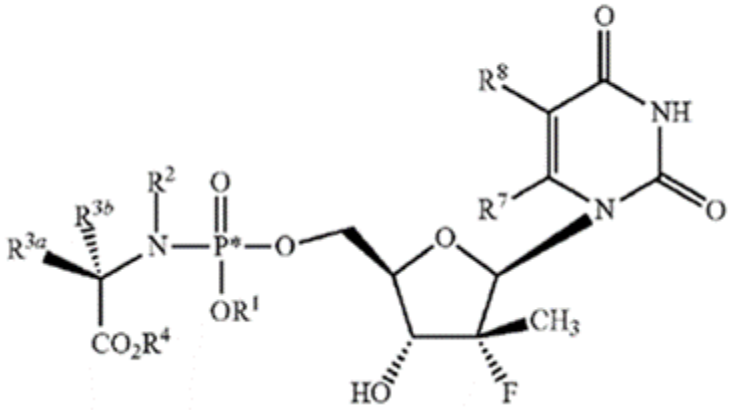
99. Gilead realleges paragraphs 1-98 as if fully set forth herein.

100. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '765 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product in the United States, prior to the expiration of the '765 patent.

101. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to expiration of the '765 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '765 patent, including but not limited to claim 1.[5]

102. On information and belief, for example, the Teva ANDA Product contains sofosbuvir, which is a compound that can be represented by the following formula:

[5] Gilead will identify all asserted claims of the '765 patent in accordance with this Court's Local Rules and/or scheduling order.



wherein P* is a chiral phosphorous atom, R^1 is unsubstituted phenyl, R^2 is hydrogen, R^{3a} is H and R^{3b} is CH_3, R^4 is ^{i}Pr, and R^7 and R^8 are H, and thus falls within the scope of at least claim 1 of the '765 patent.[6]

103. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '765 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '765 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

104. Gilead realleges paragraphs 1-103 as if fully set forth herein.

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

106. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

[6] Claim 1 of the '765 patent was corrected by Certificate of Correction dated December 23, 2014.

107. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

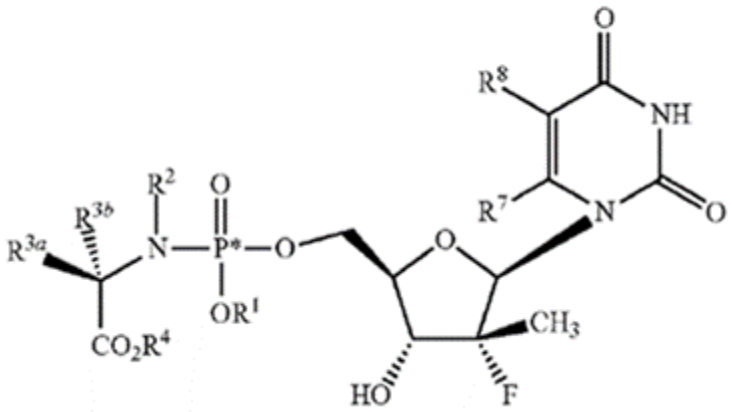
108. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

109. Teva's recent actions indicate that it does not intend to change the course of its conduct.

110. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '765 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[7] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '765 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

111. For example, on information and belief, the Teva ANDA Product contains sofosbuvir, which is a compound that can be represented by the following formula:

[7] Gilead will identify all asserted claims of the '765 patent in accordance with this Court's Local Rules and/or scheduling order.



wherein P* is a chiral phosphorous atom, R^1 is unsubstituted phenyl, R^2 is hydrogen, R^{3a} is H and R^{3b} is CH_3, R^4 is ^{i}Pr, and R^7 and R^8 are H, and thus falls within the scope of at least claim 1 of the '765 patent.[8]

112. Teva has actual knowledge of the '765 patent.

113. On information and belief, Teva became aware of the '765 patent no later than the date on which that patent was listed in the Orange Book.

114. On information and belief, Teva has acted with full knowledge of the '765 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '765 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the '765 patent. On information and belief, this knowledge is reflected through, among other things, Teva's Notice Letter, which does not contest infringement of any claims of the '765 patent, except on the basis that those claims are allegedly invalid.

115. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United

[8] Claim 1 of the '765 patent was corrected by Certificate of Correction dated December 23, 2014.

States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '765 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '765 patent.

116. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '765 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

117. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '765 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '765 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

118. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '765 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '765 patent.

119. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '765 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VII

(INFRINGEMENT OF THE '573 PATENT UNDER 35 U.S.C. § 271(e)(2))

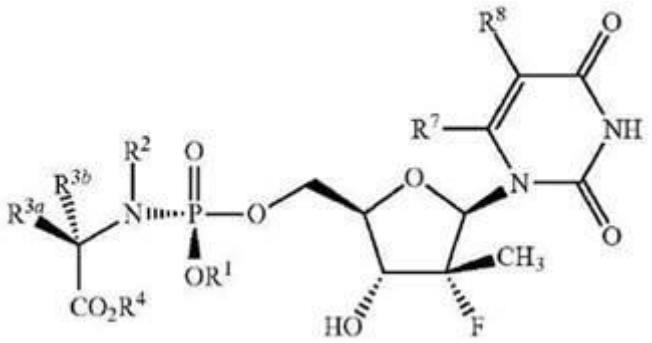
120. Gilead realleges paragraphs 1-119 as if fully set forth herein.

121. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '573 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '573 patent.

122. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '573 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '573 patent, including but not limited to claim 1.[9]

123. On information and belief, for example, the Teva ANDA Product contains sofosbuvir, a compound that can be represented by the following formula:

[9] Gilead will identify all asserted claims of the '573 patent in accordance with this Court's Local Rules and/or scheduling order.



wherein R^1 is unsubstituted phenyl, R^2 is hydrogen, R^{3a} is H and R^{3b} is CH_3, R^4 is i-propyl, and R^7 and R^8 are H, and thus falls within the scope of at least claim 1 of the '573 patent.

124. If Teva's manufacture and sale of the Teva ANDA Product prior to expiration of the '573 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT VIII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '573 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

125. Gilead realleges paragraphs 1-124 as if fully set forth herein.

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

127. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

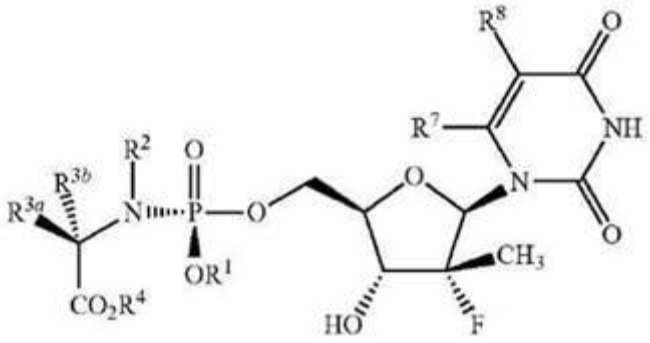
128. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

129. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

130. Teva's recent actions indicate that it does not intend to change its course of conduct.

131. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '573 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[10] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States and/or by actively inducing and contributing to infringement of the '573 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

132. For example, on information and belief, the Teva ANDA Product contains sofosbuvir, a compound that can be represented by the following formula:



wherein R^1 is unsubstituted phenyl, R^2 is hydrogen, R^{3a} is H and R^{3b} is CH_3, R^4 is i-propyl, and R^7 and R^8 are H, and thus falls within the scope of at least claim 1 of the '573 patent.

133. Teva has actual knowledge of the '573 patent.

[10] Gilead will identify all asserted claims of the '573 patent in accordance with this Court's Local Rules and/or scheduling order.

134. On information and belief, Teva became aware of the '573 patent no later than the date on which that patent was listed in the Orange Book.

135. On information and belief, Teva has acted with full knowledge of the '573 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '573 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the '573 patent. On information and belief, this knowledge is reflected through, among other things, Teva's Notice Letter, which does not contest infringement of any claims of the '573 patent, except on the basis that those claims are allegedly invalid.

136. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '573 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '573 patent.

137. On information and belief, Teva's commercial manufacture, use, importation, offer to sell, and/or sale of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '573 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

138. On information and belief, Teva's commercial manufacture, use, importation, offer to sell, and/or sale of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '573 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '573 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

139. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '573 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '573 patent.

140. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '573 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT IX

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '572 PATENT)

141. Gilead realleges paragraphs 1-140 as if fully set forth herein.

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

143. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

144. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

145. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

146. Teva's recent actions indicate that it does not intend to change its course of conduct.

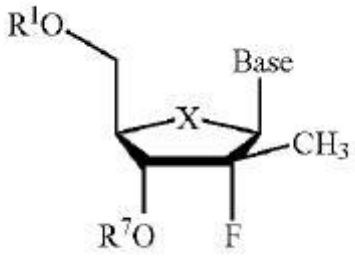
147. Teva became aware of the '572 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '572 patent and will have knowledge of the '572 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

148. The claims of the '572 patent relate to, *inter alia*, certain metabolites of sofosbuvir and certain intermediates that can be used in making sofosbuvir.

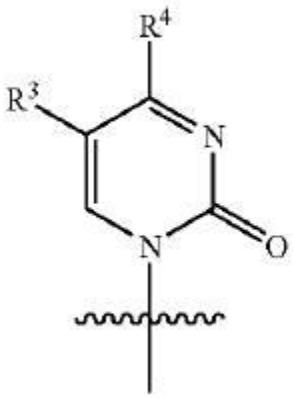
149. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '572 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce

infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '572 patent, under 35 U.S.C. §§ 271(a), (b) and/or (c), including but not limited to claim 1.[11]

150. For example, on information and belief, the Teva ANDA Product contains, and/or will metabolize into, and/or will be manufactured using a (2'R)-2'-deoxy-2'-fluoro-2'-C-methyl nucleoside (β-D or β-L) or its pharmaceutically acceptable salt of the structure:



wherein Base is a pyrimidine base represented by the following formula:



wherein X is O, R^1 is H, a monophosphate, a diphosphate, or a triphosphate, R^7 is H; R^3 is H, and R^4 is OH, and thus falls within the scope of at least claim 1 of the '572 patent.

151. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in

[11] Gilead will identify all asserted claims of the '572 patent in accordance with this Court's Local Rules and/or scheduling order.

the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '572 patent.

152. On information and belief, Teva's commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

153. On information and belief, Teva's commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '572 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '572 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

154. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the

'572 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '572 patent.

155. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '572 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT X

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '322 PATENT)

156. Gilead realleges paragraphs 1-156 as if fully set forth herein.

157. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

158. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

159. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

160. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

161. Teva's recent actions indicate that it does not intend to change its course of conduct.

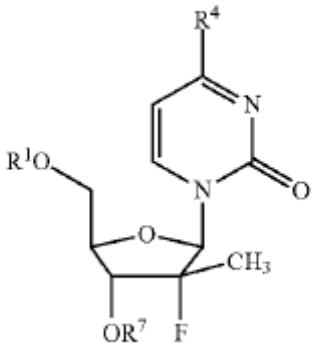
162. Teva became aware of the '322 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '322 patent and will have knowledge of the

'322 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

163. The claims of the '322 patent relate to methods of inhibiting proliferation of hepatitis C virus or the treatment of a hepatitis C virus infection with metabolites of sofosbuvir.

164. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '322 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '322 patent, under 35 U.S.C. §§ 271(a), (b) and/or (c), including but not limited to claim 9.[12]

165. On information and belief, for example, the use of the Teva ANDA Product, in accordance with its label, will inhibit the proliferation of hepatitis C virus in a human subject infected with the virus by a method comprising providing to the subject an antivirally effective amount of a compound of the following structure, which is formed during the metabolism of the Teva ANDA Product:



[12] Gilead will identify all asserted claims of the '322 patent in accordance with this Court's Local Rules and/or scheduling order.

or its pharmaceutically acceptable salt wherein R^1 is triphosphate; R^7 is H; and R^4 is OH, and thus falls within the scope of at least claim 9 of the '322 patent.

166. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '322 patent, either literally or under the doctrine of equivalents, including but not limited to claim 9, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '322 patent.

167. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '322 patent, either literally or under the doctrine of equivalents, including but not limited to claim 9, under 35 U.S.C. § 271(b).

168. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '322 patent, either literally or under the doctrine of equivalents, including but not limited to claim 9, under 35 U.S.C. § 271(c).

On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '322 patent, and the Teva ANDA Product is not suitable for substantial non-infringing use.

169. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '322 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '322 patent.

170. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '322 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XI

(INFRINGEMENT OF THE '309 PATENT UNDER 35 U.S.C. § 271(e)(2))

171. Gilead realleges paragraphs 1-171 as if fully set forth herein.

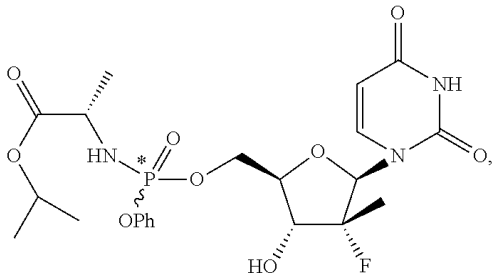
172. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '309 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '309 patent.

173. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '309 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '309 patent, including but not limited to claim 1.[13]

[13] Gilead will identify all asserted claims of the '309 patent in accordance with this Court's Local Rules and/or scheduling order.

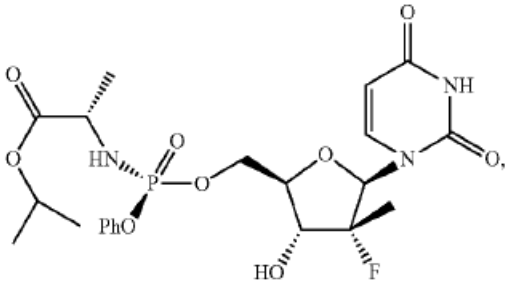
174. On information and belief, for example, the Teva ANDA Product contains a compound represented by the following formula (4):

(4)



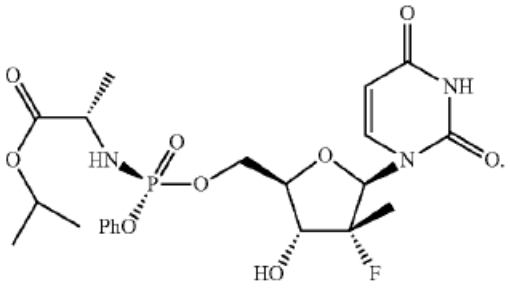
wherein P* represents a chiral phosphorous atom and wherein the compound is at least 97% of the S_p stereoisomer represented by the formula (S_p-4):

(S_P-4)



and not more than 3% of the R_p stereoisomer represented by the formula (R_p-4):

(R_P-4)



, and thus falls within the scope of at least claim 1 of the ’309 patent.

175. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '309 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '309 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

176. Gilead realleges paragraphs 1-176 as if fully set forth herein.

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

178. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

179. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

180. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

181. Teva's recent actions indicate that it does not intend to change its course of conduct.

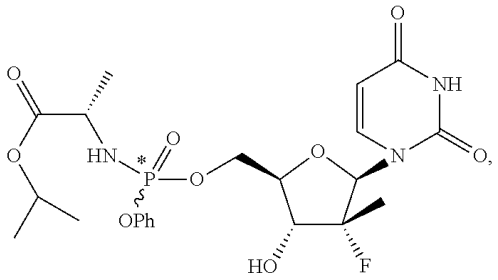
182. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '309 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[14] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States,

[14] Gilead will identify all asserted claims of the '309 patent in accordance with this Court's Local Rules and/or scheduling order.

and/or by actively inducing and contributing to infringement of the '309 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

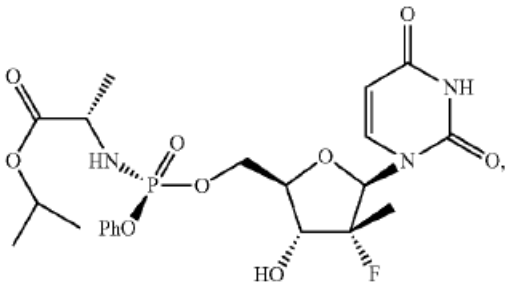
183. For example, on information and belief, the Teva ANDA Product contains a compound represented by the following formula:

(4)



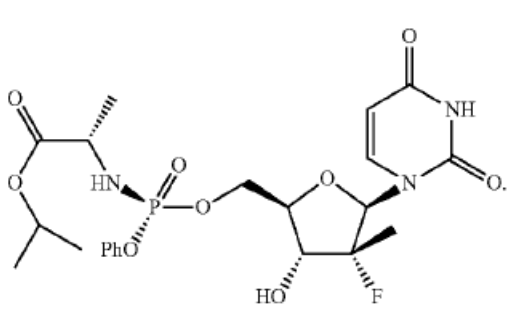
wherein P* represents a chiral phosphorous atom and wherein the compound is at least 97% of the S_p stereoisomer represented by the formula (S_p-4):

(S_P-4)



and not more than 3% of the R_p stereoisomer represented by the formula (R_p-4):

(R_P-4)



, and thus falls within the scope of at least claim 1 of the '309 patent.

184. Teva has actual knowledge of the ’309 patent.

185. On information and belief, Teva became aware of the ’309 patent no later than the date on which that patent was listed in the Orange Book.

186. On information and belief, Teva has acted with full knowledge of the ’309 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’309 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the ’309 patent. On information and belief, this knowledge is reflected through, among other things, Teva’s Notice Letter, which does not contest infringement of any claims of the ’309 patent, except on the basis that those claims are allegedly invalid.

187. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the ’309 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva’s specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead’s rights under the ’309 patent.

188. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '309 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

189. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '309 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '309 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

190. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '309 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '309 patent.

191. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '309 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIII

(INFRINGEMENT OF THE '342 PATENT UNDER 35 U.S.C. § 271(e)(2))

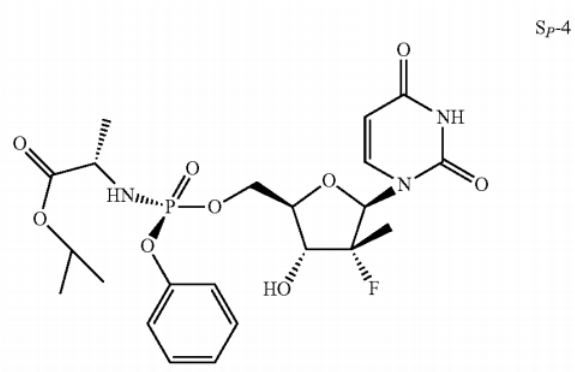
192. Gilead realleges paragraphs 1-192 as if fully set forth herein.

193. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '342 patent by submitting ANDA No. 211353 to obtain approval to engage in

the commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '342 patent.

194. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '342 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '342 patent, including but not limited to claim 1.[15]

195. For example, on information and belief, the Teva ANDA Product contains a compound represented by the following formula (S_p-4):



having XRPD 2θ-reflections (°) at about: 6.1 and 12.7, and thus falls within the scope of at least claim 1 of the '342 patent.

196. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '342 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '342 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

197. Gilead realleges paragraphs 1-197 as if fully set forth herein.

[15] Gilead will identify all asserted claims of the '342 patent in accordance with this Court's Local Rules and/or scheduling order.

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

199. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

200. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

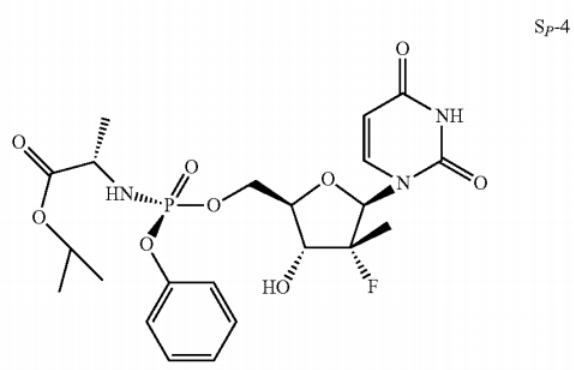
201. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

202. Teva's recent actions indicate that it does not intend to change its course of conduct.

203. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[16] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '342 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

204. For example, on information and belief, the Teva ANDA Product contains a compound represented by the following formula (S_p-4):

[16] Gilead will identify all asserted claims of the '342 patent in accordance with this Court's Local Rules and/or scheduling order.



having XRPD 2θ-reflections (°) at about: 6.1 and 12.7, and thus falls within the scope of at least claim 1 of the ’342 patent.

205. Teva has actual knowledge of the ’342 patent.

206. On information and belief, Teva became aware of the ’342 patent no later than the date on which that patent was listed in the Orange Book.

207. On information and belief, Teva has acted with full knowledge of the ’342 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’342 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the ’342 patent.

208. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the ’342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva’s specific intent and encouragement, and will be

conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '342 patent.

209. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

210. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '342 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '342 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

211. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '342 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '342 patent.

212. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '342 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XV

(INFRINGEMENT OF THE '076 PATENT UNDER 35 U.S.C. § 271(e)(2))

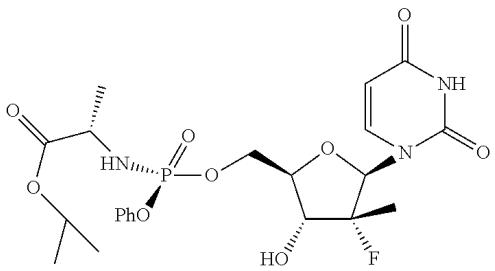
213. Gilead realleges paragraphs 1-213 as if fully set forth herein.

214. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '076 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '076 patent.

215. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '076 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '076 patent, including but not limited to claim 1.[17]

216. For example, on information and belief, the Teva ANDA Product contains a compound represented by the following formula (S_p-4):

(S_p-4)



having XRPD 2θ-reflections (°) at about: 6.1, 8.2, 10.4, 12.7, 17.2, 17.7, 18.0, 18.8, 19.4, 19.8, 20.1, 20.8, 21.8, and 23.3, and thus falls within the scope of at least claim 1 of the '076 patent.

217. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '076 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

[17] Gilead will identify all asserted claims of the '076 patent in accordance with this Court's Local Rules and/or scheduling order.

COUNT XVI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '076 PATENT UNDER 35 U.S.C. §§ 271(a)-(c), (g))

218. Gilead realleges paragraphs 1-218 as if fully set forth herein.

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

220. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

221. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

222. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

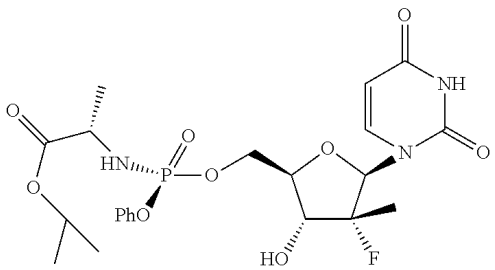
223. Teva's recent actions indicate that it does not intend to change its course of conduct.

224. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[18] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '076 patent by others, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

[18] Gilead will identify all asserted claims of the '076 patent in accordance with this Court's Local Rules and/or scheduling order.

225. For example, on information and belief, the Teva ANDA Product contains a compound represented by the following formula (S_p-4):

(S_p-4)



having XRPD 2θ-reflections (°) at about: 6.1, 8.2, 10.4, 12.7, 17.2, 17.7, 18.0, 18.8, 19.4, 19.8, 20.1, 20.8, 21.8, and 23.3, and thus falls within the scope of at least claim 1 of the '076 patent.

226. Teva has actual knowledge of the '076 patent.

227. On information and belief, Teva became aware of the '076 patent no later than the date on which that patent was listed in the Orange Book.

228. On information and belief, Teva has acted with full knowledge of the '076 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '076 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the '076 patent.

229. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the

Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '076 patent.

230. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

231. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '076 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '076 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

232. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '076 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '076 patent.

233. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '076 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVII

(INFRINGEMENT OF THE '941 PATENT UNDER 35 U.S.C. § 271(e)(2))

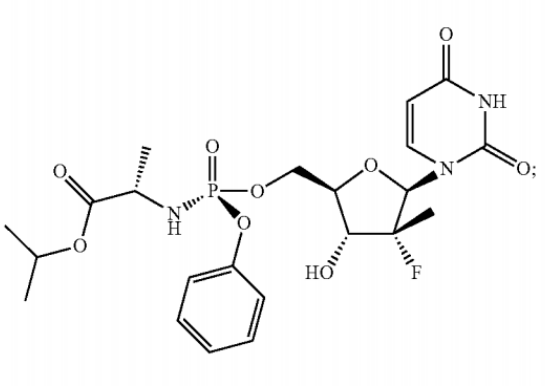
234. Gilead realleges paragraphs 1-234 as if fully set forth herein.

235. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '941 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '941 patent.

236. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '941 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '941 patent, including but not limited to claim 1.[19]

237. For example, upon information and belief, the Teva ANDA Product is a composition comprising about 25% to about 35% w/w of a crystalline compound having the structure:

[19] Gilead will identify all asserted claims of the '941 patent in accordance with this Court's Local Rules and/or scheduling order.



, and about 55% w/w to about 65% w/w of a diluent consisting of mannitol and microcrystalline cellulose, wherein the crystalline compound has XRPD 2θ-reflections)(°) at about: 6.1 and 12.7, and will be administered in combination with a daily dose of about 800 mg to about 1200 mg ribavirin to treat a human infected with hepatitis C virus, and thus falls within the scope of at least claim 1 of the ’941 patent.

238. If Teva’s marketing and sale of the Teva ANDA Product prior to expiration of the ’941 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XVIII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE ’941 PATENT UNDER 35 U.S.C. §§ 271(a)-(c))

239. Gilead realleges paragraphs 1-239 as if fully set forth herein.

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

241. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

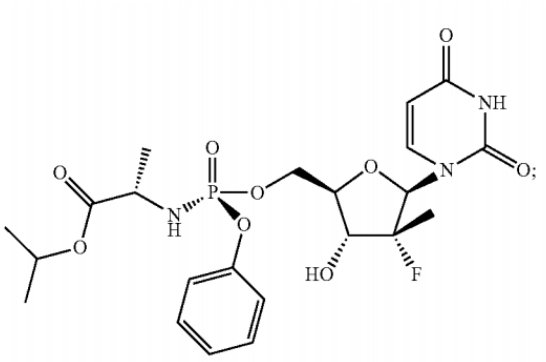
242. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

243. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

244. Teva's recent actions indicate that it does not intend to change its course of conduct.

245. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '941 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1,[20] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '941 patent by others, under 35 U.S.C. §§ 271(a), (b) and/or (c), unless enjoined by the Court.

246. On information and belief, for example, the Teva ANDA Product is a composition comprising about 25% to about 35% w/w of a crystalline compound having the structure:



[20] Gilead will identify all asserted claims of the '941 patent in accordance with this Court's Local Rules and/or scheduling order.

, and about 55% w/w to about 65% w/w of a diluent consisting of mannitol and microcrystalline cellulose, wherein the crystalline compound has XRPD 2θ-reflections)(°) at about: 6.1 and 12.7, and will be administered in combination with a daily dose of about 800 mg to about 1200 mg ribavirin to treat a human infected with hepatitis C virus, and thus falls within the scope of at least claim 1 of the '941 patent.

247. Teva has actual knowledge of the '941 patent.

248. On information and belief, Teva became aware of the '941 patent no later than the date on which that patent was listed in the Orange Book.

249. On information and belief, Teva has acted with full knowledge of the '941 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '941 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the '941 patent.

250. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '941 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with

knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '941 patent.

251. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '941 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

252. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '941 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the '941 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

253. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '941 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '941 patent.

254. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '941 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XIX

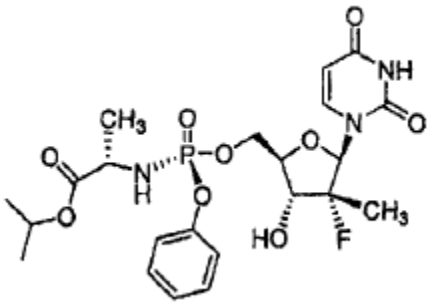
(INFRINGEMENT OF THE '159 PATENT UNDER 35 U.S.C. § 271(e)(2))

255. Gilead realleges paragraphs 1-255 as if fully set forth herein.

256. Pursuant to 35 U.S.C. § 271(e)(2)(A), Teva has committed an act of infringement with respect to the '159 patent by submitting ANDA No. 211353 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product in the United States prior to the expiration of the '159 patent.

257. Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product prior to the expiration of the '159 patent, and its inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '159 patent, including but not limited to claims 1 and 16.[21]

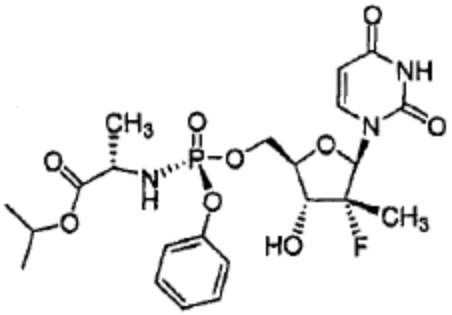
258. For example, on information and belief, the Teva ANDA Product is a pharmaceutical composition comprising about 25% to about 35% w/w of a crystalline compound having the structure:



and at least one pharmaceutically acceptable excipient, wherein the crystalline compound has XRPD 2θ-reflections (°) at about 6.1 and 12.7, and thus falls within the scope of at least claim 1 of the '159 patent.[22]

259. Similarly, on information and belief, the Teva ANDA Product is a unit dosage form comprising about 400 mg of a crystalline compound having the structure:

[21] Gilead will identify all asserted claims of the '159 patent in accordance with this Court's Local Rules and/or scheduling order.
[22] Claim 1 of the '159 patent was corrected by Certificate of Correction dated April 14, 2015.



and at least one pharmaceutically acceptable excipient, wherein the crystalline compound has XRPD 2θ-reflections (°) at about 6.1 and 12.7, and thus falls within the scope of at least claim 16 of the '159 patent.[23]

260. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '159 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XX

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '159 PATENT UNDER 35 U.S.C. §§ 271(a)-(c), (g))

261. Gilead realleges paragraphs 1-261 as if fully set forth herein.

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

263. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

264. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

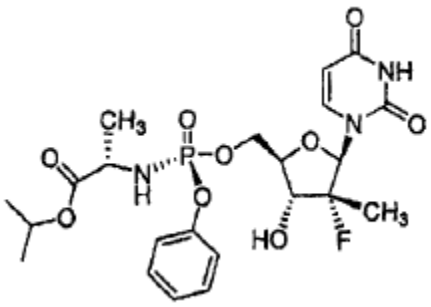
[23] Claim 16 of the '159 patent was corrected by Certificate of Correction dated April 14, 2015.

265. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

266. Teva's recent actions indicate that it does not intend to change its course of conduct.

267. On information and belief, upon FDA approval of Teva's ANDA No. 211353, Teva will infringe one or more claims of the '159 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 16,[24] by making, using, offering to sell, and selling the Teva ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '159 patent by others, under 35 U.S.C. § 271(a), (b),(c), and/or (g), unless enjoined by the Court.

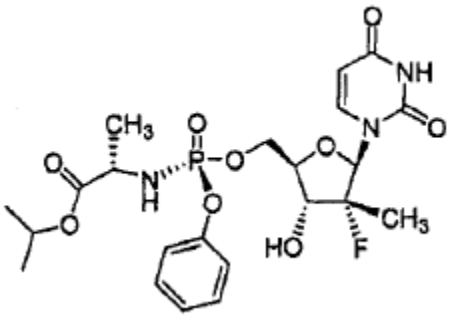
268. For example, on information and belief, the Teva ANDA Product is a pharmaceutical composition comprising about 25% to about 35% w/w of a crystalline compound having the structure:



and at least one pharmaceutically acceptable excipient, wherein the crystalline compound has XRPD 2θ-reflections (°) at about 6.1 and 12.7, and thus falls within the scope of at least claim 1 of the '159 patent.

[24] Gilead will identify all asserted claims of the '159 patent in accordance with this Court's Local Rules and/or scheduling order.

269. Similarly, on information and belief, the Teva ANDA Product is a unit dosage form comprising about 400 mg of a crystalline compound having the structure:



and at least one pharmaceutically acceptable excipient, wherein the crystalline compound has XRPD 2θ-reflections (°) at about 6.1 and 12.7, and thus falls within the scope of at least claim 16 of the ’159 patent.

270. Teva has actual knowledge of the ’159 patent.

271. On information and belief, Teva became aware of the ’159 patent no later than the date on which that patent was listed in the Orange Book.

272. On information and belief, Teva has acted with full knowledge of the ’159 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’159 patent. Further, on information and belief, Teva knows, or is willfully blind to the fact that, the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product will constitute infringement of the ’159 patent.

273. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the

claims of the ’159 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 16, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva’s specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead’s rights under the ’159 patent.

274. On information and belief, Teva’s commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the ’159 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 16, under 35 U.S.C. § 271(b).

275. On information and belief, Teva’s commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the ’159 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 16, under 35 U.S.C. § 271(c). On information and belief, Teva knows or should know that the Teva ANDA Product will be especially made or adapted for use in infringing the ’159 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

276. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the ’159 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the ’159 patent.

277. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '159 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '263 PATENT)

278. Gilead realleges paragraphs 1-278 as if fully set forth herein.

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

280. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

281. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

282. While ANDA No. 211353 has not been approved by the FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

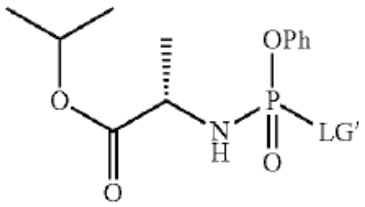
283. Teva's recent actions indicate that it does not intend to change its course of conduct.

284. Teva became aware of the '263 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '263 patent and will have knowledge of the '263 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

285. The claims of the '263 patent relate to certain phosphoramidate intermediates that are used in making sofosbuvir.

286. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva, prior to the expiration of the '263 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '263 patent, under 35 U.S.C. §§ 271(a), (b), and/or (c), including but not limited to claims 1 and 11.[25]

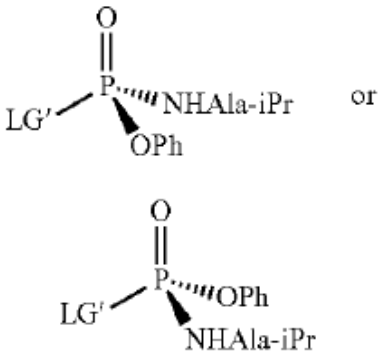
287. For example, on information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a compound represented by the structure:



wherein LG' is tosylate, camphorsulfonate, an aryloxide, or an aryloxide substituted with at least one electron withdrawing group, and thus falls within the scope of at least claim 1 of the '263 patent.

288. Similarly, on information and belief, in the commercial manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a compound represented by the structure:

[25] Gilead will identify all asserted claims of the '263 patent in accordance with this Court's Local Rules and/or scheduling order.



wherein LG' is a leaving group, and thus falls within the scope of at least claim 11 of the '263 patent.

289. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '263 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 11, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '263 patent.

290. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '263 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 11, under 35 U.S.C. § 271(b).

291. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '263 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 11, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '263 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

292. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA product by Teva prior to the expiration of the '263 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '263 patent.

293. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '263 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '569 PATENT)

294. Gilead realleges paragraphs 1-294 as if fully set forth herein.

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

296. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

297. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

298. While ANDA No. 211353 has not been approved by the FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

299. Teva's recent actions indicate that it does not intend to change its course of conduct.

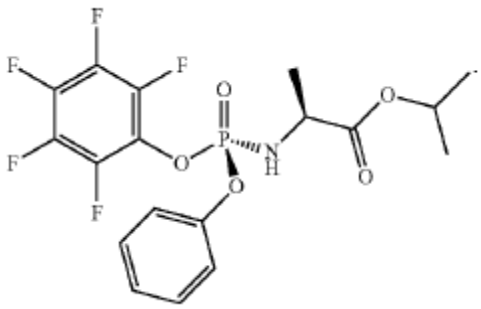
300. Teva became aware of the '569 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '569 patent and will have knowledge of the '569 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

301. The claims of the '569 patent relate to certain phosphoramidate intermediates that are used in making sofosbuvir.

302. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '569 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '569 patent, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), including but not limited to claim 1.[26]

[26] Gilead will identify all asserted claims of the '569 patent in accordance with this Court's Local Rules and/or scheduling order.

303. For example, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a compound represented by the following structure:



and thus falls within the scope of at least claim 1 of the '569 patent.

304. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '569 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '569 patent.

305. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA,

would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '569 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

306. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '569 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '569 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

307. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '569 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '569 patent.

308. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '569 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXIII

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '512 PATENT)

309. Gilead realleges paragraphs 1-309 as if fully set forth herein.

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

311. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

312. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

313. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

314. Teva's recent actions indicate that it does not intend to change its course of conduct.

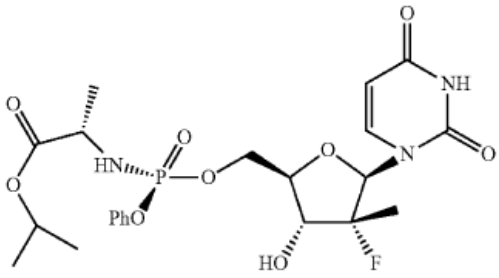
315. Teva became aware of the '512 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '512 patent and will have knowledge of the '512 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

316. The claims of the '512 patent relate to a process for making sofosbuvir.

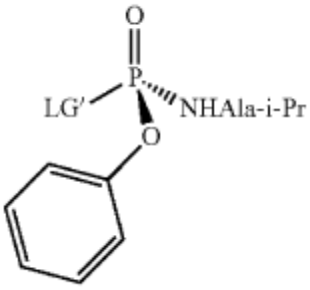
317. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '512 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '512 patent, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), including but not limited to claim 1.[27]

318. For example, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will use a diastereoselective process for preparing (S_p-4):

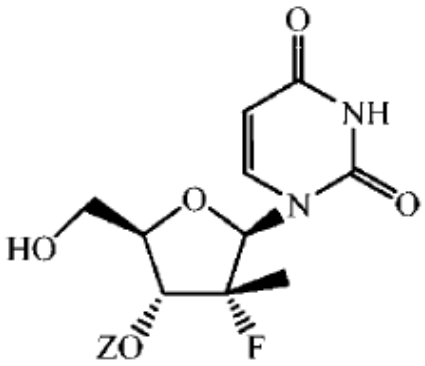
[27] Gilead will identify all asserted claims of the '512 patent in accordance with this Court's Local Rules and/or scheduling order.



comprising reacting compound C:



wherein LG' is p-nitrophenoxide, 2,4-dinitrophenoxide or pentafluorophenoxide with a basic reagent and compound 3:



wherein Z is hydrogen, to obtain S_p-4; or reacting compound C with a basic reagent and compound 3, wherein Z is a protecting group, and deprotecting to obtain S_p-4, and thus falls within the scope of at least claim 1 of the '512 patent.[28]

319. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '512 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '512 patent.

[28] Claim 1 of the '512 patent was corrected by Certificate of Correction dated February 20, 2018.

320. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '512 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(b).

321. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '512 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '512 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

322. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '512 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '512 patent.

323. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '512 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXIV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '756 PATENT)

324. Gilead realleges paragraphs 1-324 as if fully set forth herein.

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

326. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

327. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

328. While ANDA No. 211353 has not been approved by FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

329. Teva's recent actions indicate that it does not intend to change its course of conduct.

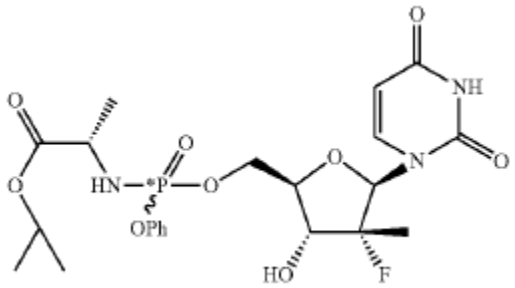
330. Teva became aware of the '756 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '756 patent and will have knowledge of the '756 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

331. The claims of the '756 patent relate to a process for making sofosbuvir.

332. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '756 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of the '756 patent, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), including but not limited to claims 1 and 13.[29]

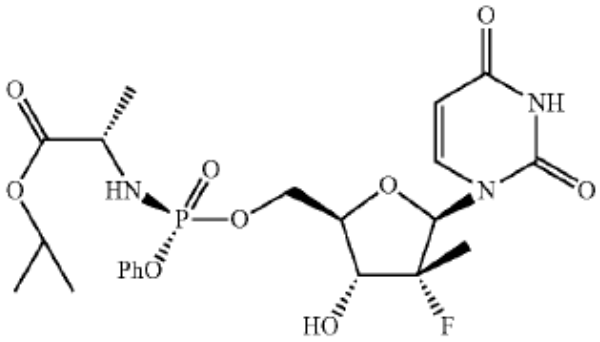
[29] Gilead will identify all asserted claims of the '756 patent in accordance with this Court's Local Rules and/or scheduling order.

333. For example, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will use process for preparing a compound represented by formula (4), or a phosphorous-based diastereomer thereof:



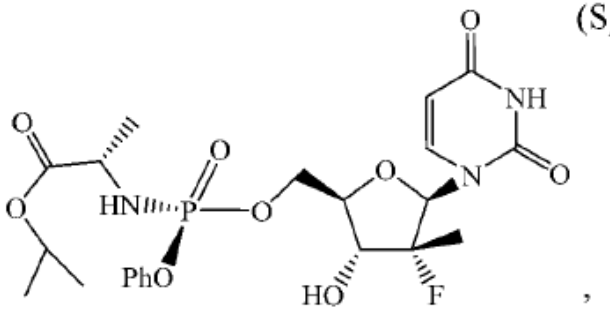
wherein *P represents a chiral phosphorus atom, and wherein said phosphorous-based diastereomer is represented by formula (R_p-4) or (S_p-4):

(R_P-4)



or

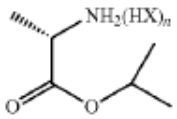
(S_P-4)



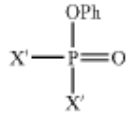
,

which comprises reacting a mixture comprising an isopropyl-alanate (A), a di-X'-phenylphosphate (B), 2'-deoxy-2'-fluoro-2'-C-methyluridine (3), and a base to obtain a first mixture comprising (4), or the phosphorous-based diastereomer thereof:

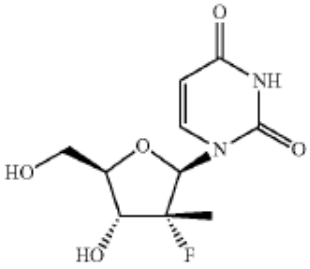
(A)



(B)



(3)

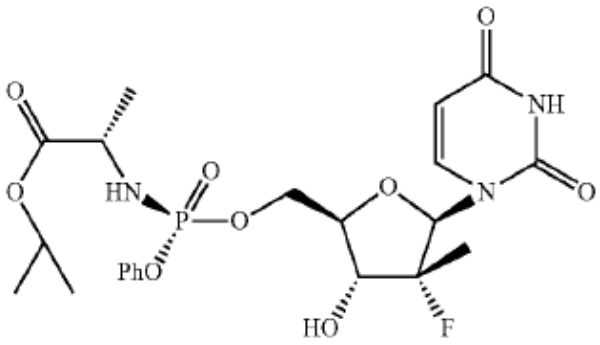


wherein X is a conjugate base of an acid, n is 0 or 1, and X' is a halogen; reacting the first mixture with a protecting compound to obtain a second mixture comprising protected (4), or the phosphorous-based diastereomer thereof; and optionally subjecting the second mixture to crystallization, chromatography, or extraction in order to obtain (4), or the phosphorous-based diastereomer thereof, and thus falls within the scope of at least claim 1 of the '756 patent.[30]

334. Similarly, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will use a process for preparing a crystalline compound (R_p-4) or (S_p-4):

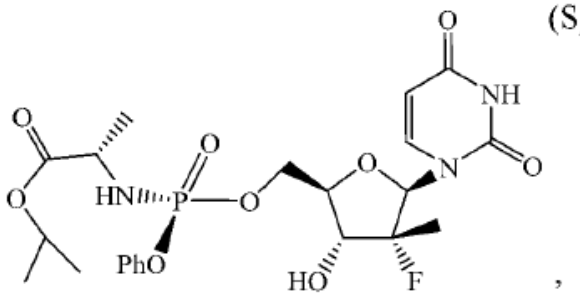
[30] Claim 1 of the '756 patent was corrected by Certificate of Correction dated February 13, 2018.

(R_P-4)



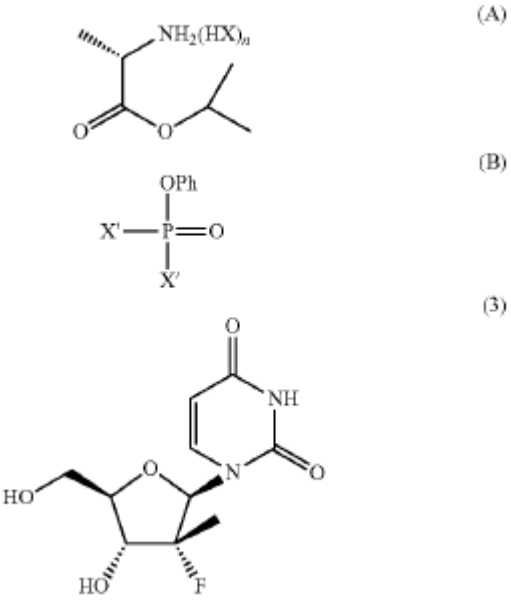
or

(S_P-4)



,

which comprises reacting a mixture comprising an isopropyl-alanate (A), a di-X'-phenylphosphate (B), 2'-deoxy-2'-fluoro-2'-C-methyluridine (3), and a base to obtain a first mixture comprising (R_p-4) or (S_p-4)



wherein X is a conjugate base for an acid, n is 0 or 1, and X' is a halogen; reacting the first mixture with a protecting compound to obtain a second mixture; and optionally subjecting the second mixture to crystallization, chromatography, or extraction in order to obtain a third mixture, and thus falls within the scope of at least claim 13 of the '756 patent.[31]

335. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '756 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 13, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be

[31] Claim 13 of the '756 patent was corrected by Certificate of Correction dated February 13, 2018.

conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '756 patent.

336. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '756 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 13, under 35 U.S.C. § 271(b).

337. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '756 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 13, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '756 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

338. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '756 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '756 patent.

339. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '756 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXV

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '217 PATENT)

340. Gilead realleges paragraphs 1-339 as if fully set forth herein.

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

342. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

343. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Teva Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

344. While ANDA No. 211353 has not been approved by the FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA product.

345. Teva's recent actions indicate that it does not intend to change its course of conduct.

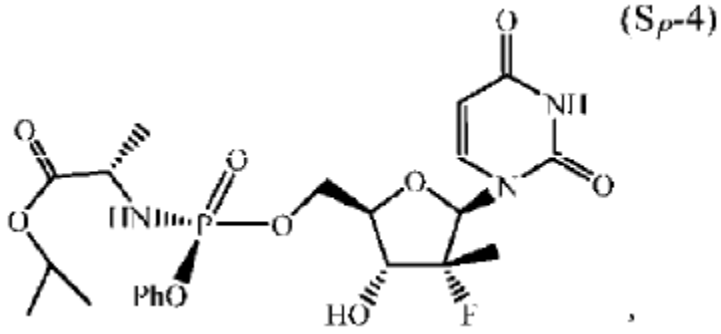
346. Teva became aware of the '217 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '217 patent and will have knowledge of the '217 patent when they manufacture, use, offer for sale, sell and/or import the Teva ANDA Product within the United States.

347. The claims of the '217 patent relate to crystalline forms of sofosbuvir.

348. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '217 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of

the ’217 patent, under 35 U.S.C. §§ 271(a), (b) and/or (c), including but not limited to claims 1 and 2.[32]

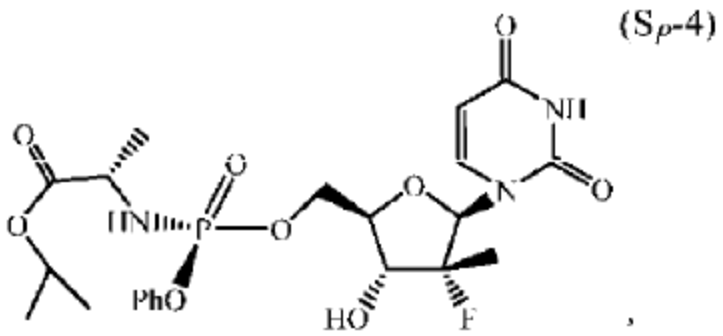
349. For example, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a compound represented by the formula (S_p-4)



wherein the compound is monoclinic crystalline having unit cell parameters a~12.88 Å, b~6.17 Å, c~17.73 Å and β~92.05°; a~20.09 Å, b~6.10 Å, c~23.01 Å and β~112.29°; a~12.83 Å, b~6.15 Å, c~17.63 Å and β~91.75°; or a~12.93 Å, b~6.18 Å, c~18.01 Å and β~96.40°, and thus falls within the scope of at least claim 1 of the ’217 patent.[33]

350. Similarly, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a compound represented by the formula (S_p-4)

[32] Gilead will identify all asserted claims of the ’217 patent in accordance with this Court’s Local Rules and/or scheduling order.
[33] Claim 1 of the ’217 patent was corrected by Certificate of Correction dated February 27, 2018.



wherein the compound is monoclinic crystalline having XRPD 2θ-reflections (°) at about 5.2, 7.5, 9.6, 16.7, 18.3, and 22.2; 5.0, 7.3, 9.4, and 18.1; 4.9, 6.9, 9.8, 19.8, 20.6, 24.7, and 26.1; 6.9, 9.8, 19.7, 20.6, and 24.6; 5.0, 6.8, 19.9, 20.6, 20.9, and 24.9; or 5.2, 6.6, 7.1, 15.7, 19.1, and 25.0, and thus falls within the scope of at least claim 2 of the '217 patent.[34]

351. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '217 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 2, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '217 patent.

[34] Claim 2 of the '217 patent was corrected by Certificate of Correction dated February 27, 2018.

352. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '217 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 2, under 35 U.S.C. § 271(b).

353. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '217 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1 and 2, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '217 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

354. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '217 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '217 patent.

355. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '217 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT XXVI

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '568 PATENT)

356. Gilead realleges paragraphs 1-355 as if fully set forth herein.

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

358. 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 United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

359. Teva has submitted an ANDA for a generic version of sofosbuvir. According to the Notice Letter, Teva intends to manufacture, use, offer for sale, sell, and/or import the Teva ANDA Product within the United States.

360. While ANDA No. 211353 has not been approved by the FDA, Teva has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell and/or import the Teva ANDA Product.

361. Teva's recent actions indicate that it does not intend to change its course of conduct.

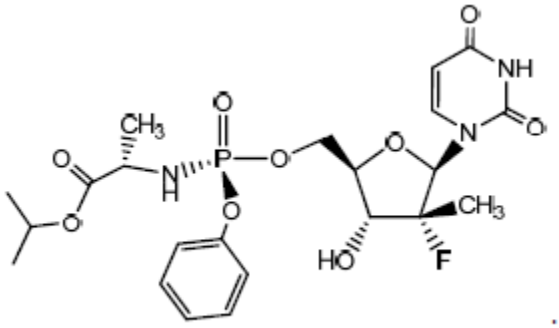
362. Teva became aware of the '568 patent no later than the date of filing of this Complaint. As a result, Teva has knowledge of the '568 patent and will have knowledge of the '568 patent when it manufactures, uses, offers for sale, sells and/or imports the Teva ANDA Product within the United States.

363. The claims of the '568 patent relate to crystalline forms of sofosbuvir.

364. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '568 patent will directly and/or indirectly infringe, contribute to the infringement of and/or induce infringement of, either literally or under the doctrine of equivalents, at least one of the claims of

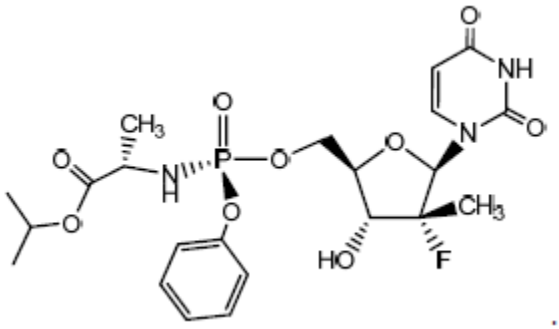
the ’568 patent, under 35 U.S.C. §§ 271(a), (b) and/or (c), including but not limited to claims 1, 3, 5 and 7.[35]

365. For example, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a crystalline compound I



characterized by an XRPD spectrum comprising peaks at 12.6 and 13.5 °2θ±0.2° 2θ, and thus falls within the scope of at least claim 1 of the ’568 patent.[36]

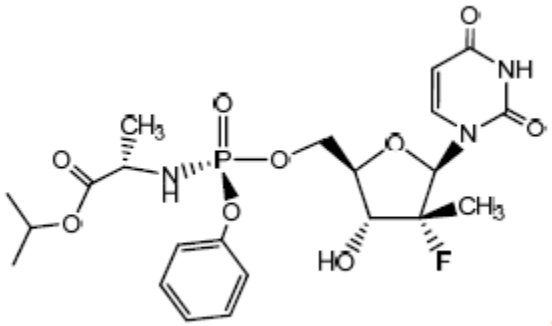
366. Similarly, on information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will manufacture a crystalline compound I



[35] Gilead will identify all asserted claims of the ’568 patent in accordance with this Court’s Local Rules and/or scheduling order.
[36] Claim 1 of the ’568 patent was corrected by Certificate of Correction dated October 31, 2017.

characterized by a ^{13}C SSNMR spectrum comprising peaks at 18.6, 164.5, and 171.8 ppm±0.2 ppm, and thus falls within the scope of at least claim 3 of the '568 patent.[37]

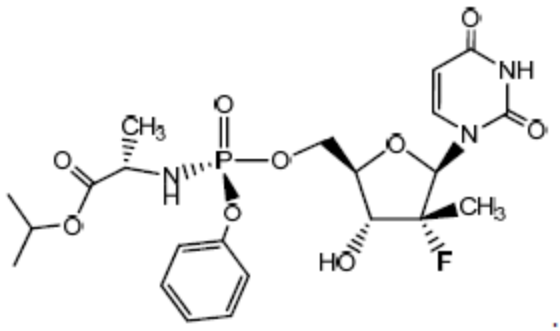
367. On information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will also manufacture a crystalline compound I



characterized by an XRPD spectrum comprising peaks at 8.6, 9.2 and 17.1 °2θ±0.2° 2θ, and thus falls within the scope of at least claim 5 of the '568 patent.[38]

368. On information and belief, in the commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, Teva will also manufacture a crystalline compound I

[37] Claim 3 of the '568 patent was corrected by Certificate of Correction dated October 31, 2017.
[38] Claim 5 of the '568 patent was corrected by Certificate of Correction dated October 31, 2017.



characterized by a ^{13}C SSNMR spectrum comprising peaks at 23.5, 70.1, and 152.4 ppm±0.2 ppm, and thus falls within the scope of at least claim 7 of the '568 patent.[39]

369. On information and belief, the Teva ANDA Product, if approved by FDA, will be commercially manufactured, used, imported, offered for sale, and/or sold by Teva in the United States by it or on its behalf, and will be administered by patients and/or medical practitioners in the United States according to the directions and instructions in the proposed package insert, which will constitute direct infringement by patients and/or medical practitioners of at least one of the claims of the '568 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 3, 5, and 7, under 35 U.S.C. § 271(a). On information and belief, the administration of the Teva ANDA Product will occur with Teva's specific intent and encouragement, and will be conduct that Teva knows or should know will occur. On information and belief, Teva will actively induce, encourage, aid, and abet that conduct by patients and/or medical practitioners, with knowledge and specific intent that the conduct will be in contravention of Gilead's rights under the '568 patent.

370. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA,

[39] Claim 7 of the '568 patent was corrected by Certificate of Correction dated October 31, 2017.

would actively, intentionally, and knowingly induce infringement of at least one of the claims of the '568 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 3, 5, and 7, under 35 U.S.C. § 271(b).

371. On information and belief, Teva's commercial manufacture, use, offer for sale, sale, and/or importation of the Teva ANDA Product, once ANDA No. 211353 is approved by FDA, would contribute to infringement of at least one of the claims of the '568 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 3, 5, and 7, under 35 U.S.C. § 271(c). On information and belief, Teva knows that the Teva ANDA Product is especially made or adapted for use in infringing the '568 patent, and that the Teva ANDA Product is not suitable for substantial non-infringing use.

372. Gilead is entitled to a declaratory judgment that future manufacture, use, offer for sale, sale and/or importation of the Teva ANDA Product by Teva prior to the expiration of the '568 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '568 patent.

373. If Teva's marketing and sale of the Teva ANDA Product prior to expiration of the '568 patent and all other relevant exclusivities are not enjoined, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

EXCEPTIONAL CASE

374. Teva was aware of at least the '580, '270, '765, '573, '309, '342, '076, '941, and '159 patents prior to filing of an ANDA for a generic version of Gilead's Sovaldi® and sending the Notice Letter to Gilead.

375. The actions of Defendants render this an exceptional case under 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Gilead hereby demands a trial by jury of all issues that are or may become so triable.

PRAYER FOR RELIEF

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

a. A judgment that Teva has infringed the claims of U.S. Patent Nos. 7,964,580; 8,334,270; 8,580,765; 9,085,573; 8,633,309; 9,284,342; 8,618,076; 9,549,941; and 8,889,159 by submitting ANDA No. 211353, and that Teva's making, using, offering to sell, or selling in the United States, or importing into the United States the Teva ANDA Product will infringe the claims of the '580, '270, '765, '573, '309, '342, '076, '941, and '159 patents, either literally or under the doctrine of equivalents.

b. An order pursuant to 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271 declaring that Teva's manufacture, use, offer to sell, sale, and/or importation of the Teva ANDA Product in or into the United States prior to the expiration of U.S. Patent Nos. 7,964,580; 8,334,270; 8,580,765; 9,085,573; 8,633,309; 9,284,342; 8,618,076; 9,549,941; 8,889,159; 7,429,572; 8,415,322; 8,629,263; 8,735,569; 8,642,756; 9,637,512; 9,206,217; and 9,340,568 will infringe and/or actively induce or contribute to the infringement of one or more claims of the '580, '270, '765, '573, '309, '342, '076, '941, '159, '572, '322, '263, '569, '756, '512, '217, and '568 patents, and providing any further necessary or proper relief based on the Court's declaratory judgment or decree.

c. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 211353 shall be a date which is not earlier than the latest expiration date of the '580, '270, '765, '573, '309, '342, '076, '941, and '159 patents, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled.

d. An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Teva, 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 Teva ANDA Product until after the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled.

e. Damages or other monetary relief under 35 U.S.C. §§ 271(a), (b), (c) and (e)(4)(c), and/or 35 U.S.C. § 284, including costs, fees, pre- and post-judgment interest, to Gilead if Teva engages in commercial manufacture, use, offers to sell, sale, and/or importation in or into the United States of the Teva ANDA Product prior to the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Gilead is or will be entitled.

f. An order that this case is exceptional under 35 U.S.C. § 285, and that Gilead be awarded reasonable attorneys' fees and costs; and

g. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: March 26, 2018

ROBINSON MILLER LLC

BY: *Keith J. Miller*
Keith J. Miller, Esq.
One Newark Center, 19th Floor
Newark, NJ 07102
(973) 690-5400
kmiller@rwmlegal.com

OF COUNSEL:

Gregory Booker
Robert M. Oakes
222 Delaware Avenue, 17th Floor
P.O. Box 1114
Wilmington, DE 19899-1114
Phone: 302-652-5070 / Fax: 302-652-0607

Juanita R. Brooks (brooks@fr.com)
Jonathan E. Singer (singer@fr.com)
W. Chad Shear (shear@fr.com)

OF COUNSEL:

David B. Bassett
WILMER CUTLER PICKERING HALE & DORR LLP
7 World Trade Center
250 Greenwich Street
New York, New York 10007
(212) 230-8800
David.Bassett@wilmerhale.com

Vinita Ferrera
Emily Whelan
Shirley X. Li Cantin
WILMER CUTLER PICKERING HALE & DORR LLP
60 State Street
Boston, MA 02109
(617) 526-6000
Vinita.Ferrera@wilmerhale.com
Emily.Whelan@wilmerhale.com
Shirley.Cantin@wilmerhale.com

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC

Geoffrey D. Biegler (biegler@fr.com)
FISH & RICHARDSON P.C.
12390 El Camino Real
San Diego, CA 92130
Phone: 858-678-5070 / Fax: 858-678-5099

John M. Farrell (farrell@f.com
FISH & RICHARDSON P.C.
500 Arguello Street, Suite 500
Redwood City, CA 94063
Phone: 650-839-5070 / Fax: 650-839-0607

Attorneys for Plaintiffs Gilead Sciences, Inc. and Gilead Pharmasset LLC

LOCAL CIVIL RULE 11.2 CERTIFICATION

Plaintiffs, by their undersigned counsel, hereby certify that the same product and patents at issue in this action are the subject of the following action currently pending in this District, captioned *Gilead Sciences, Inc., et al. v. Natco Pharma Limited, et al.*, Docket No. 3:18-cv-3592.

Dated: March 26, 2018

Respectfully submitted,

s/Keith J. Miller
Keith J. Miller (kmiller@rwmlegal.com)

ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2760 (Facsimile)