IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GILEAD SCIENCES, INC., GILEAD SCIENCES IRELAND UC, JANSSEN PRODUCTS, L.P., and JANSSEN SCIENCES IRELAND UNLIMITED COMPANY,	)	
Plaintiffs,	)	
v.	)	C. A. No. _____
LUPIN LIMITED, LUPIN PHARMACEUTICALS, INC., MSN LABORATORATORIES PRIVATE LTD., MSN LIFE SCIENCES PRIVATE LTD., and MSN PHARMACEUTICALS INC.,	)	
Defendants.	)	

PLAINTIFFS GILEAD SCIENCES, INC.'S, GILEAD SCIENCES IRELAND UC'S, JANSSEN PRODUCTS, L.P.'S, AND JANSSEN SCIENCES IRELAND UNLIMITED COMPANY'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Gilead Sciences, Inc. and Gilead Sciences Ireland UC (collectively, "Gilead"), and Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company (collectively, "Janssen") (all collectively, "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 U.S., Title 35, United States Code, against Defendants Lupin Limited and Lupin Pharmaceuticals, Inc. (collectively, "Lupin"), and MSN Laboratories Private Ltd., MSN Life Sciences Private Ltd., and MSN Pharmaceuticals Inc. (collectively, "MSN") (all collectively, "Defendants"). This action arises out of Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA").

2. Defendants seek approval to market a generic copy of Janssen's highly successful product, SYMTUZA®, containing a four-drug combination of darunavir, cobicistat, emtricitabine, and tenofovir alafenamide, prior to the expiration of U.S. Patent No. 10,039,718 (the "'718 patent") and U.S. Patent No. 10,786,518 (the "'518 patent") (together, the "Orange Book Patents-In-Suit"), and U.S. Patent No. 8,497,396 (the "'396 patent") and U.S. Patent No. 9,428,473 (the "'473 patent") (together, the "Process Patents-In-Suit") (all patents collectively, the "Patents-In-Suit"). Plaintiffs attach hereto true and accurate copies of each of the Patents-In-Suit as Exhibits A-D.

PARTIES

Plaintiff Gilead

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

4. Plaintiff Gilead Sciences Ireland UC is an Irish company, having its principal place of business at IDA Business & Technology Park, Carrigtohill, County Cork, Ireland.

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

Plaintiff Janssen

6. Plaintiff Janssen Products, L.P., is a partnership organized under the laws of the State of New Jersey, having its headquarters and principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

7. Plaintiff Janssen Sciences Ireland Unlimited Company is an Irish corporation having its principal place of business at Barnahely, Ringaskiddy, County Cork, Ireland.

8. Janssen is an innovator pharmaceutical company that discovers, develops, and brings to market revolutionary pharmaceutical products in areas of unmet medical need, including treatments for mental illness, neurological disorders, fungal infections, HIV/AIDS, and cancer. Janssen markets SYMTUZA in this District and throughout the U.S. Janssen is the co-owner of the '518 patent and holds an exclusive license under the '718 patent for the commercialization of SYMTUZA.

Defendant Lupin

9. On information and belief, Lupin Limited is a foreign corporation organized and existing under the laws of India, having its principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai, 400055, India. On information and belief, Lupin Limited is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market and/or manufacturing active pharmaceutical ingredients ("API") for generic copies of branded pharmaceutical products for the U.S. market.

10. On information and belief, Lupin, along with MSN, prepared and submitted to FDA ANDA No. 216511 (the "SYMTUZA ANDA"), seeking approval to manufacture, import, market, and/or sell a generic copy of Janssen's SYMTUZA product ("Defendants' SYMTUZA ANDA

Product" or "SYMTUZA ANDA Product") in the U.S., including in this District, if FDA approves the SYMTUZA ANDA. On information and belief, Lupin Limited is the holder of the SYMTUZA ANDA.

11. On information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized under the laws of Delaware and its principal place of business is located at 111 S. Calvert Street, Harborplace Tower, 21st Floor, Baltimore, MD 21202. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, among other things, marketing and selling generic copies of branded pharmaceutical products for the U.S. market.

12. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of and is an authorized U.S. agent of Defendant Lupin Limited, including for the SYMTUZA ANDA. On information and belief, Lupin Limited and MSN will manufacture the SYMTUZA ANDA Product for Lupin Pharmaceuticals, Inc., which will market and distribute it. On information and belief, the acts of Lupin Limited and MSN complained of herein were done with the cooperation, participation, and assistance of Lupin Pharmaceuticals, Inc.

13. On information and belief, Lupin and MSN collaborate with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of the SYMTUZA ANDA Product for the U.S. market, including the market in the State of Delaware.

14. On information and belief, Lupin and MSN intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the SYMTUZA ANDA Product, in the event that FDA approves the the SYMTUZA ANDA.

Defendant MSN

15. On information and belief, MSN Laboratories Private Limited ("MSN Labs") is a foreign corperation organized and existing under the laws of the Republic of India, having a place of business at MSN House, Plot No. C-24, Sanathnagar Industrial Estate, Hyderabad, Telangana 500018, India. On information and belief, MSN Labs is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for sale in the U.S. market and/or manufacturing APIs for generic copies of branded pharmaceutical products for sale in the U.S. market through various operating subsidiaries throughout the U.S., including in the State of Delaware.

16. On information and belief, MSN Life Sciences Private Ltd. ("MSN Life") is a foreign corporation organized and existing under the laws of the Republic of India, having a place of business at Sy. No. 455/A, 455/AA, 455/E, and 455/EE, Chandampet (Village), Shankarampet-R (Mandal), Medak District - 502255, Telangana, India. On information and belief, MSN Life is the holder of FDA Drug Master File ("DMF") No. 030650 (the "MSN DMF"), which is referenced by the SYMTUZA ANDA. On information and belief, MSN Life is a wholly owned subsidiary of MSN Labs. On information and belief, MSN Life is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market and/or manufacturing APIs for generic copies of branded pharmaceutical products for the U.S. market, including in the State of Delaware.

17. On information and belief, MSN Pharmaceuticals Inc. ("MSN Pharma") is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at 20 Duke Road, Piscataway, NJ 08854. On information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs and U.S. agent for MSN Life. On information

and belief, MSN Pharma is in the business of, among other things, manufacturing generic copies of branded pharmaceutical products for the U.S. market and/or manufacturing APIs for generic copies of branded pharmaceutical products for the U.S. market, including in the State of Delaware.

18. SYMTUZA includes cobicistat on silicon dioxide ("COBI on SiO_2"). On information and belief, the SYMTUZA ANDA Product will contain COBI on SiO_2. On information and belief, MSN Life manufactures COBI on SiO_2, and MSN Life, MSN Pharma, and MSN Labs act in concert to supply Lupin with COBI on SiO_2 for the SYMTUZA ANDA Product.

19. On information and belief, the acts of Lupin complained of herein were done with the cooperation, participation, and assistance of MSN.

20. On information and belief, Lupin and MSN collaborated to prepare and submit to FDA the SYMTUZA ANDA, seeking approval to manufacture, import, market, and/or sell a generic copy of Janssen's SYMTUZA product in the U.S., including in this District, if FDA approves the SYMTUZA ANDA.

21. On information and belief, Lupin and MSN collaborate with respect to the development, regulatory approval, commercial manufacture, marketing, sale, offer for sale, and/or distribution of the SYMTUZA ANDA Product for the U.S. market, including the market in the State of Delaware.

22. On information and belief, MSN has acted in concert with Lupin and has been actively involved in the submission to FDA of the SYMTUZA ANDA, at least by supplying COBI on SiO_2 to Lupin, authorizing reference to MSN's DMF No. 030650, performing testing and product characterization required for regulatory approval, and providing data regarding COBI on SiO_2 necessary for regulatory approval for inclusion in the SYMTUZA ANDA. On information

and belief, MSN has and will manufacture and supply COBI on SiO_2 to Lupin for use in the SYMTUZA ANDA Product.

23. On information and belief, Lupin and MSN intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell the SYMTUZA ANDA Product, in the event that FDA approves the SYMTUZA ANDA.

24. On information and belief, as the supplier of COBI on SiO_2 for the SYMTUZA ANDA Product, MSN will directly benefit financially if the SYMTUZA ANDA is approved, through sales of the SYMTUZA ANDA Product.

JURISDICTION AND VENUE

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

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

27. On information and belief, this Court has personal jurisdiction over Lupin Pharmaceuticals, Inc., *inter alia*, because Lupin Pharmaceuticals, Inc. is incorporated in Delaware.

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

29. On information and belief, Lupin Pharmaceuticals, Inc., directly and/or through its parent company Lupin Limited, markets, distributes, and sells generic pharmaceutical products throughout the U.S., including in this District.

30. On information and belief, Lupin Pharmaceuticals, Inc. derives substantial revenue from selling generic pharmaceutical products throughout the U.S., including in this District, directly and/or through its parent company Lupin Limited.

31. On information and belief, Lupin Pharmaceuticals, Inc., directly and/or through its parent company Lupin Limited, has an extensive network of physicians, hospitals, long-term care facilities, group purchasing organizations, retailers, wholesalers, and distributors in this District.

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

broad distributorship network within Delaware; and (7) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

33. On information and belief, Lupin Limited has been and is engaging in activities directed toward infringement of the Patents-In-Suit by, among other things, preparing and submitting to FDA the SYMTUZA ANDA, and acting in concert with Lupin Pharmaceuticals, Inc. and MSN in the preparation and submission of the SYMTUZA ANDA seeking FDA approval to market the SYMTUZA ANDA Product throughout the U.S., including in Delaware, before expiration of the Patents-In-Suit.

34. On information and belief, either directly or through its subsidiaries, agents, and/or affiliates, Lupin Limited received more than 75 FDA approvals to market and sell pharmaceutical products throughout the U.S., including in Delaware. On information and belief, Lupin Limited derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

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

36. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. operate and act in concert as an integrated, unitary business. On information and belief, Lupin Limited and Lupin Pharmaceuticals, Inc. work in concert with respect to the manufacturing, marketing,

sale, and distribution of generic pharmaceutical products throughout the U.S., including in Delaware.

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

38. Further, this Court has personal jurisdiction over Lupin Limited because it has previously been sued in this district and has not challenged personal jurisdiction, and Lupin Limited has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district. *See, e.g.*, *Gilead Sciences, Inc. v. Apotex, Inc. et al.*, Civil Action No. 20-189, D.I. 174 (D. Del. Jan. 27, 2021); *Otsuka Pharm. Co., Ltd. v. Lupin Ltd., et al.*, 21-900, D.I. 9 (D. Del. Sep. 7, 2021); *Intercept Pharms., Inc. et al. v. Lupin Ltd., et al.*, 20-1155, D.I. 13 (D. Del. Nov. 30, 2020); *Merck Sharp & Dohme Corp. v. Lupin Ltd., et al.*, 20-776, D.I. 8 (D. Del. June 24, 2020); *Forest Labs, LLC, et al. v. Lupin Ltd., et al.*, Civil Action No. 14-1058, D.I. 15 (D. Del. Sept. 8, 2014); *ViiV Healthcare UK Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No.

14-369, D.I. 10 (D. Del. June 12, 2014); *Teijin Ltd., et al. v. Lupin Ltd., et al.*, Civil Action No. 14-184, D.I. 20 (D. Del. April 1, 2014).

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

40. Venue is proper in this Court for Lupin Pharmaceuticals, Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Lupin Pharmaceuticals, Inc. is incorporated in this District.

41. Venue is proper in this Court for Lupin Limited under 28 U.S.C. § 1391(c)(3) because Lupin Limited is a foreign corporation and may be sued in any judicial district in the U.S. in which it is subject to the court's personal jurisdiction, including in this District.

42. On information and belief, this Court has personal jurisdiction over MSN Pharma, *inter alia*, because MSN Pharma is incorporated in Delaware.

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

44. On information and belief, MSN Pharma, directly and/or through its parent company MSN Labs, markets, distributes, and sells generic pharmaceutical products throughout the U.S., including in this District.

45. On information and belief, MSN Pharma derives substantial revenue from selling generic pharmaceutical products throughout the U.S., including in this District, directly and/or through its parent company MSN Labs.

46. On information and belief, this Court has personal jurisdiction over MSN Labs and MSN Life by virtue of, *inter alia*, their systematic and continuous contacts with this jurisdiction. On information and belief, either directly or through their subsidiaries, agents, and/or affiliates, MSN Labs and MSN Life regularly and continuously transact business within Delaware, including by manufacturing, selling, offering for sale, marketing, distributing, and/or importing generic versions of pharmaceutical products in the U.S., including Delaware. Specifically, on information and belief, this Court has personal jurisdiction over MSN Labs and MSN Life because, *inter alia*, they: (1) intend to manufacture and supply COBI on SiO_2 to market, sell, or distribute the SYMTUZA ANDA Product to residents of Delaware; (2) have continuous and systemic contacts with the State of Delaware and regularly conduct business in the State of Delaware, either directly or through one or more of their affiliates, agents, and/or alter egos; (3) make their generic pharmaceutical products available in Delaware; (4) maintain a broad distributorship network within Delaware; and/or (5) enjoy substantial income from sales of their generic pharmaceutical products in Delaware. Furthermore, MSN Labs exercises control over Defendant MSN Pharma and operates through its wholly-owned subsidiary MSN Pharma, which is incorporated in Delaware.

47. On information and belief, MSN has been and is engaging in activities directed toward infringement of the Patents-In-Suit by, among other things, acting in concert with Lupin in the preparation and submission of the SYMTUZA ANDA seeking FDA approval to market the

SYMTUZA ANDA Product throughout the U.S., including in Delaware, before expiration of the Patents-In-Suit.

48. On information and belief, either directly or through their subsidiaries, agents, and/or affiliates, MSN Labs and MSN Life have submitted 100 ANDAs to FDA for pharmaceutical products and offer over 300 APIs for pharmaceutical products to sell throughout the U.S., including in Delaware. On information and belief, MSN Labs and MSN Life derive substantial revenue from the sale of those products in Delaware and have availed themselves of the privilege of conducting business within Delaware.

49. On information and belief, MSN Labs and MSN Life market and distribute their pharmaceutical products through subsidiaries, agents, and/or affiliates including MSN Pharma, a Delaware corporation that is registered to do business and has appointed an agent to accept service in Delaware.

50. On information and belief, MSN Labs, MSN Pharma, and MSN Life operate and act in concert as an integrated, unitary business. On information and belief, MSN Labs, MSN Pharma, and MSN Life work in concert with respect to the manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the U.S., including in Delaware.

51. Further, this Court has personal jurisdiction over MSN Labs, MSN Pharma, and MSN Life because they have previously been sued in this district and have not challenged personal jurisdiction. *See, e.g.*, *Otsuka Pharmaceutical Co., Ltd. et al. v. MSN Laboratories Private Ltd.*, C.A. No. 20-1428 (D. Del.); *Intercept Pharmaceuticals, Inc. v. MSN Laboratories Private Ltd.*, C.A. No. 20-1214 (D. Del.); *Amgen Inc. v. MSN Laboratories Private Ltd.*, C.A. No. 21-712 (D. Del.).

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

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

54. Venue is proper in this Court for MSN Labs and MSN Life under 28 U.S.C. § 1391(c)(3) because MSN Labs and MSN Life are foreign corporations and may be sued in any judicial district in the U.S. in which they are subject to the court's personal jurisdiction, including in this District.

PATENTS-IN-SUIT

55. On August 7, 2018, the U.S. Patent and Trademark Office duly and legally issued the '718 patent, titled, "Use of Solid Carrier Particles to Improve the Processability of A Pharmaceutical Agent." A true and correct copy of the '718 patent is attached hereto as Exhibit A. The claims of the '718 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '718 patent. Janssen is the exclusive licensee under the '718 patent for the commercialization of SYMTUZA.

56. On September 29, 2020, the U.S. Patent and Trademark Office duly and legally issued the '518 patent, titled, "Compositions and Methods of Treating HIV." A true and correct copy of the '518 patent is attached hereto as Exhibit B. The claims of the '518 patent are valid,

enforceable, and not expired. Janssen Sciences Ireland Unlimited Company and Gilead Sciences, Inc. are the assignees of the '518 patent.

57. On July 30, 2013, the U.S. Patent and Trademark Office duly and legally issued the '396 patent, titled, "Methods and Intermediates for Preparing Pharmaceutical Agents." A true and correct copy of the '396 patent is attached hereto as Exhibit C. The claims of the '396 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '396 patent.

58. On August 30, 2016, the U.S. Patent and Trademark Office duly and legally issued the '473 patent, titled, "Methods and Intermediates for Preparing Pharmaceutical Agents." A true and correct copy of the '473 patent is attached hereto as Exhibit D. The claims of the '473 patent are valid, enforceable, and not expired. Gilead Sciences, Inc. is the assignee of the '473 patent.

ACTS GIVING RISE TO THIS ACTION

SYMTUZA

59. Janssen Products, LP holds approved NDA No. 210455 for tablets containing a four-drug combination of darunavir (DRV), a human immunodeficiency virus (HIV-1) protease inhibitor, cobicistat (COBI), a CYP3A inhibitor, and emtricitabine (FTC) and tenofovir alafenamide (TAF), both HIV-1 nucleoside analog reverse transcriptase inhibitors. The tablets are indicated as a complete regimen for the treatment of HIV-1 infection.

60. Janssen markets the tablets approved under NDA No. 210455 in the U.S. under the registered trademark SYMTUZA. FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") identifies the Orange Book Patents-In-Suit, among other patents, for SYMTUZA.

61. At least one claim of each of the Orange Book Patents-In-Suit covers SYMTUZA, or approved methods of using SYMTUZA. At least one claim of each of the Process Patents-In-Suit covers a method of making COBI or a method of making a component of COBI.

62. Defendants submitted to FDA an ANDA listing SYMTUZA as the reference listed drug ("RLD").

Defendants' Acts Regarding SYMTUZA

63. On information and belief, Defendants submitted to FDA the SYMTUZA ANDA under Section 505(j) of the FDCA, seeking FDA's approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale of the SYMTUZA ANDA Product before the expiration of all four Patents-In-Suit. On information and belief, FDA assigned the ANDA number 216511.

64. On information and belief, Defendants sent a letter dated October 4, 2021 to Janssen and Gilead (the "SYMTUZA Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B). The SYMTUZA Notice Letter states that the SYMTUZA ANDA includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to each of the Orange Book Patents-In-Suit.

65. Janssen and Gilead received the SYMTUZA Notice Letter on or about October 5 and 6, 2021, respectively.

66. The SYMTUZA Notice Letter included an Offer for Confidential Access ("OCA") to the SYMTUZA ANDA on terms and conditions set forth therein. The OCA requested that Gilead accept the terms of the OCA before receiving access to the SYMTUZA ANDA. Gilead agreed to the OCA and requested the SYMTUZA ANDA and the DMF for COBI on SiO_2. Defendants furnished the ANDA. However, Defendants refused to provide the DMF for COBI on

SiO_2. Defendants' failure to provide the DMF impeded Gilead's ability to evaluate infringement of certain Patents-In-Suit.

67. On information and belief, if Defendants had a good faith basis to contest infringement of the Patents-In-Suit, they would have provided their DMF. Defendants did not do so. Under the Hatch-Waxman Act, a patent owner must file an action in federal court within 45 days of receiving a Paragraph IV notice 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, pursuant to 21 U.S.C. § 355(c)(3)(C).

68. Gilead is not aware of any other means of obtaining information regarding the SYMTUZA ANDA Product. 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 their belief, and to present to the Court evidence, that Defendants have and will infringe certain claims of the Patents-In-Suit.

69. The SYMTUZA Notice Letter does not contest infringement of most of the claims of each of the Orange Book Patents-In-Suit.

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

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

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

73. On information and belief, Defendants' proposed label for their SYMTUZA ANDA Product (the "Defendants' Proposed Label") will refer to the product as, *inter alia*, a four-drug combination of darunavir, cobicistat, emtricitabine, and tenofovir alafenamide, indicated as a complete regimen for the treatment of HIV-1 infection.

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

75. On information and belief, the Defendants' Proposed Label will contain data relating to the treatment of patients with HIV-1 infection, obtained from clinical studies involving SYMTUZA.

COUNTS I-VI FOR PATENT INFRINGEMENT

Count I: Infringement of the '718 Patent under 35 U.S.C. § 271(e)(2) by the SYMTUZA ANDA Product

76. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

77. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants have committed an act of infringement of the '718 patent by submitting to FDA the SYMTUZA ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product in the U.S. prior to the expiration of the '718 patent.

78. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product prior to the expiration of the '718 patent, and their inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '718 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

79. The SYMTUZA Notice Letter does not dispute that Defendants infringe claims 1-9, 14-15, and 17-23 of the '718 patent.

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

81. Unless and until Defendants are enjoined from infringing the '718 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count II: Declaratory Judgment of Infringement of the '718 Patent under 35 U.S.C. § 271(a)-(c), (g) by the SYMTUZA ANDA Product

82. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

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

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

85. Defendants have submitted to FDA an ANDA for a generic version of Janssen's SYMTUZA pharmaceutical product. According to the SYMTUZA Notice Letter, Defendants intend to manufacture, use, offer for sale, sell, and/or import the SYMTUZA ANDA Product within the U.S. On information and belief, MSN manufactures and supplies Lupin with COBI on SiO_2 for the SYMTUZA ANDA Product.

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

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

88. On information and belief, upon FDA approval of the SYMTUZA ANDA, Defendants will infringe one or more claims of the '718 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1, 5, and/or 14, by making, using, offering to sell, and/or selling the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product in the U.S., and/or importing said product and/or components of said product into the U.S., and/or by actively inducing and contributing to infringement, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g), unless enjoined by the Court.

89. The SYMTUZA Notice Letter does not dispute that Defendants infringe claims 1-9, 14-15, and 17-23 of the '718 patent.

90. On information and belief, the SYMTUZA ANDA Product will include COBI on SiO_2. Defendants' making, using, offering to sell, and/or selling the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product in the U.S., and/or importing said product and/or components of said product into the U.S., will directly infringe one or more claims of the '718 patent under 35 U.S.C. § 271(a).

91. Defendants have actual knowledge of the '718 patent.

92. On information and belief, Defendants became aware of the '718 patent no later than the filing of their SYMTUZA ANDA.

93. On information and belief, Defendants' efforts to make, use, sell, offer for sell, and/or import the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product have been made and will be made with full knowledge of the '718 patent and without a reasonable basis for believing that they would not be liable for actively inducing and/or

contributing to the infringement of the '718 patent. On information and belief, this knowledge is reflected through, among other things, the SYMTUZA Notice Letter, which does not contest infringement of at least claims 1, 5, and 14 of the '718 patent.

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

95. On information and belief, Defendants will import COBI on SiO_2 into the U.S. to offer for sale, sell, and use in the SYMTUZA ANDA Product, and such importation, offer for sale, sale, and use will constitute direct infringement of at least one claim of the '718 patent.

96. On information and belief, through Defendants' agreement to manufacture and supply COBI on SiO_2 for the SYMTUZA ANDA Product, Defendants will encourage the importation, offer for sale, sale, or use the COBI on SiO_2 composition claimed in the '718 patent within the U.S., and Defendants will know or should know that such conduct will occur.

97. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct with knowledge and specific intent that the conduct infringe the '718 patent.

98. Through at least the foregoing actions, Defendants will actively induce the infringement of at least one claim of the '718 patent under 35 U.S.C. § 271(b).

99. On information and belief, Defendants know or should know that COBI on SiO_2 will be especially made or adapted for use in infringing the '718 patent, such as by incorporating COBI on SiO_2 as a component of the SYMTUZA ANDA Product, a composition claimed in the '718 patent, and that COBI on SiO_2 is not suitable for substantial non-infringing use.

100. The commercial manufacture, use, sale, offer for sale, and/or importation of the SYMTUZA ANDA Product and/or component of the SYMTUZA ANDA Product, such as COBI on SiO_2, will contribute to the actual infringement of the '718 patent.

101. On information and belief, Defendants know or should know that their offer for sale, sale and/or importation of COBI on SiO_2 will contribute to the actual infringement of the '718 patent.

102. Through at least the foregoing actions, Defendants will contribute to the infringement of at least one claim of the '718 patent under 35 U.S.C. § 271(c).

103. On information and belief, if the SYMTUZA ANDA is approved by FDA, Defendants will make the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product, such as COBI on SiO_2, using a process covered by one or more claims of the '718 patent and import that product into the U.S. and/or offer to sell, sell, or use that product in the U.S.

104. On information and belief, the SYMTUZA ANDA Product and/or component of the SYMTUZA ANDA Product, such as COBI on SiO_2, will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

105. Through at least the foregoing actions, Defendants will infringe at least one claim of the '718 patent under 35 U.S.C. § 271(g).

106. Plaintiffs are entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product, such as COBI on SiO_2, by Defendants prior to the expiration of the '718 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '718 patent.

107. The commercial manufacture, importation, use, sale, or offer for sale of the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product, such as COBI on SiO_2, in violation of Plaintiffs' patent rights will cause harm to Plaintiffs' for which damages are inadequate.

108. Unless and until Defendants are enjoined from infringing the '718 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count III: Infringement of the '518 Patent under 35 U.S.C. § 271(e)(2) by the SYMTUZA ANDA Product

109. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

110. Pursuant to 35 U.S.C. § 271(e)(2)(A), Defendants have committed an act of infringement of the '518 patent by submitting to FDA the SYMTUZA ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product in the U.S. prior to the expiration of the '518 patent.

111. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product prior to the expiration of the '518 patent, and their inducement of and/or contribution to such conduct, would constitute infringement of at least one of the claims of the '518 patent either literally or under the doctrine of equivalents, including but not limited to claim 1.

112. The SYMTUZA Notice Letter does not dispute that Defendants infringe claims 1-6 and 8-24 of the '518 patent.

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

114. Unless and until Defendants are enjoined from infringing the '518 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count IV: Declaratory Judgment of Infringement of the '518 Patent under 35 U.S.C. §§ 271(b) and/or (c) by the SYMTUZA ANDA Product

115. Plaintiffs reallege the foregoing paragraphs as if fully set forth herein.

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

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

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

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

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

121. On information and belief, upon FDA approval of the SYMTUZA ANDA, Defendants will infringe one or more claims of the '518 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1-6 and 8-24, by making, using, offering to sell, and/or selling the SYMTUZA ANDA Product in the U.S. and/or importing said product into the U.S. and/or by actively inducing and contributing to infringement of the '518 patent by others, under 35 U.S.C. §§ 271(b) and/or (c) unless enjoined by the Court.

122. The SYMTUZA Notice Letter does not dispute that Defendants infringe claims 1-6 and 8-24 of the '518 patent.

123. Defendants have actual knowledge of the '518 patent.

124. On information and belief, Defendants became aware of the '518 patent no later than the filing of their SYMTUZA ANDA.

125. On information and belief, Defendants' efforts to make, use, sell, offer for sell, and/or import the SYMTUZA ANDA Product have been made and will be made with full knowledge of the '518 patent and without a reasonable basis for believing that they would not be liable for actively inducing or contributing to the infringement of the '518 patent. On information and belief, this knowledge is reflected through, among other things, the SYMTUZA Notice Letter, which does not contest infringement of claims 1-6 and 8-24 of the '518 patent.

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

127. On information and belief, the Defendants' Proposed Label will include directions and instructions that instruct physicians and healthcare providers to administer the SYMTUZA ANDA Product in order to treat HIV-1 in accordance with the methods described and claimed in the '518 patent.

128. On information and belief, physicians and healthcare providers will administer the SYMTUZA ANDA Product in the U.S. according to the directions and instructions in the Defendants' Proposed Label, and such administration will constitute direct infringement of at least one claim of the '518 patent.

129. On information and belief, at least through the Defendants' Proposed Label, Defendants will encourage physicians and healthcare providers to administer the SYMTUZA ANDA Product in order to treat HIV-1 in accordance with the methods described and claimed in the '518 patent, and Defendants will know or should know that such conduct will occur.

130. On information and belief, Defendants will actively induce, encourage, aid, and abet that conduct by physicians and healthcare providers with knowledge and specific intent that the conduct infringes the '518 patent.

131. Through at least the foregoing actions, Defendants will actively induce the infringement of at least one claim of the '518 patent under 35 U.S.C. § 271(b).

132. On information and belief, Defendants know or should know that the SYMTUZA ANDA Product will be especially made or adapted for use in infringing the '518 patent and that the SYMTUZA ANDA Product is not suitable for substantial non-infringing use.

133. The commercial manufacture, use, sale, offer for sale, and/or importation of the SYMTUZA ANDA Product will contribute to the actual infringement of the '518 patent.

134. On information and belief, Defendants know or should know that their offer for sale, sale and/or importation of the SYMTUZA ANDA Product will contribute to the actual infringement of the '518 patent.

135. Through at least the foregoing actions, Defendants will contribute to the infringement of at least one claim of the '518 patent under 35 U.S.C. § 271(c).

136. Plaintiffs are entitled to a declaratory judgment that the manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product by the Defendants prior to the expiration of the '518 patent will constitute direct infringement and/or will induce and/or contribute to the actual and direct infringement of the '518 patent.

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

138. Unless and until Defendants are enjoined from infringing the '518 patent, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

Count V: Declaratory Judgment of Infringement of the '396 Patent under 35 U.S.C. § 271(g) by the SYMTUZA ANDA Product

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

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

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

142. Defendants have submitted to FDA an ANDA for a generic copy of Janssen's SYMTUZA pharmaceutical product. According to the SYMTUZA Notice Letter, Defendants intend to manufacture, use, offer for sale, sell, and/or import the SYMTUZA ANDA Product within the U.S. On information and belief, MSN manufactures and holds the DMF for the COBI on SiO_2 in the SYMTUZA ANDA Product.

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

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

145. On information and belief, including due to Defendants' failure to provide their DMF for COBI on SiO_2, if the SYMTUZA ANDA is approved by FDA, Defendants will infringe

one or more claims of the '396 patent, either literally or under the doctrine of equivalents, including but not limited to claim 2 of the '396 patent, by importing, offering to sell, selling, and/or using a product made by a process claimed in the '396 patent, under 35 U.S.C. § 271(g), and will continue to do so unless enjoined by the Court.

146. On information and belief, if the SYMTUZA ANDA is approved by FDA, Defendants will import COBI made by a process claimed in the '396 patent, into the U.S. and/or offer to sell, sell, or use that product in the U.S.

147. On information and belief, the COBI made by the claimed process will not be materially changed by a subsequent process nor will it become a trivial and nonessential component of another product.

148. Through at least the foregoing actions, Defendants will infringe at least one claim of the '396 patent under 35 U.S.C. § 271(g).

149. Gilead is entitled to a declaratory judgment that the use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product and/or COBI made by a process claimed in the '396 patent by Defendants prior to the expiration of the '396 patent will constitute direct infringement of the '396 patent.

150. The importation, use, sale, or offer for sale of the SYMTUZA ANDA Product and/or COBI made by a process claimed in the '396 patent in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

151. Unless and until Defendants are enjoined from infringing the '396 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

Count VI: Declaratory Judgment of Infringement of the '473 Patent under 35 U.S.C. § 271(g) by the SYMTUZA ANDA Product

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

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

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

155. Defendants have submitted to FDA an ANDA for a generic copy of Janssen's SYMTUZA pharmaceutical product. According to the SYMTUZA Notice Letter, Defendants intend to manufacture, use, offer for sale, sell, and/or import the SYMTUZA ANDA Product within the U.S. On information and belief, MSN manufactures and holds the DMF for the COBI on SiO_2 in the SYMTUZA ANDA Product.

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

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

158. On information and belief, including due to Defendants' failure to provide their DMF for COBI on SiO_2, if the SYMTUZA ANDA is approved by FDA, Defendants will infringe one or more claims of the '473 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1 of the '473 patent, by importing, offering to sell, selling, and/or using a product made by a process claimed in the '473 patent, under 35 U.S.C. § 271(g), and will continue to do so unless enjoined by the Court.

159. On information and belief, if the SYMTUZA ANDA is approved by FDA, Defendants will import a product made by a process claimed in the '473 patent, into the U.S. and/or offer to sell, sell, or use that product in the U.S.

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

161. Through at least the foregoing actions, Defendants will infringe at least one claim of the '473 patent under 35 U.S.C. § 271(g).

162. Gilead is entitled to a declaratory judgment that the use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product and/or COBI made by a process claimed in the '473 patent by Defendants prior to the expiration of the '473 patent will constitute direct infringement of the '473 patent.

163. The importation, use, sale, or offer for sale of the SYMTUZA ANDA Product and/or COBI made by a process claimed in the '473 patent in violation of Gilead's patent rights will cause harm to Gilead for which damages are inadequate.

164. Unless and until Defendants are enjoined from infringing the '473 patent, Gilead will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

A) A judgment that Defendants have infringed the '718 patent and the '518 patent under 35 U.S.C. § 271(e)(2)(A);

B) A judgment and order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the SYMTUZA ANDA shall be a date which is not earlier

than the day after the latest expiration date of the '718 patent and the '518 patent as extended by any applicable periods of exclusivity to which Plaintiffs are or will be entitled;

C) A judgment declaring that Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the SYMTUZA ANDA Product and/or components of the SYMTUZA ANDA Product in or into the U.S. prior to the expiration of the '718 patent, '518 patent, '396 patent and '473 patent (including such actions by its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with Defendants or acting on Defendants' behalf) will constitute infringement of the '718 patent, '518 patent, '396 patent and '473 patent under 35 U.S.C. §§ 271 (a), (b), (c), and/or (g) and providing any further necessary or proper relief based on the Court's declaratory judgment or decree;

D) An order under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Defendants, their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, and/or selling in the U.S., and/or importing into the U.S. the SYMTUZA ANDA Product until the day after the latest expiration date of the '718 patent, '518 patent, '396 patent and '473 patent , including any extensions and/or additional periods of exclusivity to which Plaintiffs are or will be entitled, and from otherwise infringing one or more claims of the '718 patent, '518 patent, '396 patent and '473 patent;

E) A declaration that this case is exceptional;

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

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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

Attorneys for Plaintiffs

OF COUNSEL:

Irena Royzman
Jonathan Pepin
KRAMER LEVIN NAFTALIS & FRANKEL LLP
1177 Avenue of the Americas
New York, NY 10036
(212) 715-9100

Hannah Lee
KRAMER LEVIN NAFTALIS & FRANKEL LLP
990 March Road
Menlo Park, CA 94025
(650) 752-1700

Attorneys for Plaintiffs Janssen Products, L.P. and Janssen Sciences Ireland Unlimited Company

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

Kelley Chandler
ROPES & GRAY LLP
2099 Pennsylvania Avenue, N.W.
Washington, DC 20006-6807
(212) 508-4600

Attorneys for Plaintiff Gilead Sciences, Inc. and Gilead Sciences Ireland UC

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