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**Pro hac vice* application forthcoming

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GILEAD SCIENCES, INC.,

Plaintiff,

v.

ASPIRO PHARMA LTD., HETERO USA, INC., and HETERO LABS LTD.,

Defendants.

Case No. _____

COMPLAINT

JURY TRIAL DEMANDED

PLAINTIFF GILEAD SCIENCES, INC.'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Gilead Sciences, Inc. ("Gilead") for its Complaint against Defendants Aspiro Pharma Ltd. ("Aspiro"), Hetero USA, Inc. ("Hetero USA"), and Hetero Labs Ltd. ("Hetero Labs") alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the laws of the United States, including 35 U.S.C. §§ 271(a), (b), (c), (e), and (f), arising from Defendants' Abbreviated New Drug Application No. 220566 ("Defendants' ANDA") to the United States Food and Drug Administration, by which Defendants seek approval to market Defendants' ANDA Product, a generic version of Gilead's pharmaceutical product VEKLURY® (remdesivir), prior to the expiration of United States Patent Nos. 10,675,296 (the "'296 Patent"), 11,266,681 (the "'681 Patent"), 11,975,017 (the "'017 Patent"), 11,491,169 (the "'169 Patent"), 11,903,953 (the "'953 Patent"), and 11,975,012 (the "'012 Patent") (collectively the "Asserted Patents"), which cover, *inter alia*, VEKLURY®.

THE PARTIES

2. Plaintiff Gilead is a Delaware corporation with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Gilead researches, develops, and manufactures pharmaceuticals and other medicines to address unmet medical needs and to improve the lives of people around the world who are affected by life-threatening conditions spanning virology, oncology, and inflammation. As is relevant to this lawsuit, Gilead is a leader and pioneer in antiviral development. Gilead developed VEKLURY®, the first and only FDA-approved therapy for treatment of COVID-19 for both hospitalized and nonhospitalized patients.

3. On information and belief, Defendant Aspiro is a corporation organized and existing under the laws of India, having a principal place of business at Plot No. 23, Sy. No. 321, Biotech Park, Phase-III, Karkapatla, Markook Mandal, Siddipet, Telangana 502281, India. On information and belief, Aspiro's U.S. Agent is located at 121 New England Ave., Piscataway, NJ 08854. On information and belief, Aspiro is, by itself and/or through its affiliates and agents, in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic

pharmaceutical products that it distributes in the State of New Jersey and throughout the United States. On information and belief, Aspiro is a wholly owned subsidiary of Hetero Labs, is controlled by Hetero Labs, and is affiliated with Defendant Hetero USA.

4. On information and belief, Defendant Hetero USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. On information and belief, Hetero Labs is, by itself and/or through its affiliates and agents, in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States. On information and belief, Hetero USA is a wholly owned subsidiary of Hetero Labs and is controlled by Hetero Labs.

5. On information and belief, Defendant Hetero Labs is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500018, Telangana, India. On information and belief, Hetero Labs is, by itself and/or through its affiliates and agents, in the business of, *inter alia*, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

6. On information and belief, Aspiro, Hetero USA, and Hetero Labs are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of generic products within the United States. On information and belief, the acts of Aspiro, Hetero USA, and Hetero Labs complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

7. On information and belief, Aspiro, Hetero USA, and Hetero Labs acted in concert to prepare and file Defendants' ANDA and will act in concert to manufacture, import, market, and/or sell the drug that is the subject of Defendants' ANDA, if approved by the FDA.

JURISDICTION

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has subject matter jurisdiction over Gilead's claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. This Court has personal jurisdiction over Aspiro by virtue of, *inter alia*, its having engaged in systematic and continuous contacts with the State of New Jersey, including but not limited to through its United States agent, which is located in Piscataway, NJ, and through its United States affiliate Hetero USA, which has a principal place of business in Piscataway, NJ; having previously admitted, consented to, or declined to contest the jurisdiction of this Court; and/or having availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, Aspiro Pharma Ltd.'s Answer to Complaint at 2–3, *Merck Sharp & Dohme BV v. Aspiro Pharma Ltd.*, Civ. No. 20-3112, Dkt. No. 8 (D.N.J. May 1, 2020).

10. On information and belief, Aspiro is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of New Jersey and throughout the United States.

11. On information and belief, Aspiro regularly and continuously conducts business with the State of New Jersey, either directly or through its affiliates/parents Hetero Labs and Hetero USA, the latter with its principal place of business in Piscataway, NJ, including by selling pharmaceutical products in the State of New Jersey.

12. This Court has personal jurisdiction over Hetero USA by virtue of, *inter alia*, its having a principal place of business in Piscataway, NJ, and its having engaged in systematic and continuous contacts with the State of New Jersey; its having previously admitted, consented to, or declined to contest the jurisdiction of this Court; and/or its having availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero USA, Inc.'s Answer to Complaint at 7–12, *Merck Sharp & Dohme LLC v. Hetero USA, Inc.*, Civ. No. 22-6820, Dkt. No. 11 (D.N.J. Feb. 10, 2023).

13. On information and belief, Hetero USA is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of New Jersey and throughout the United States.

14. This Court has personal jurisdiction over Hetero Labs by virtue of, *inter alia*, its having engaged in systematic and continuous contacts with the State of New Jersey, including but not limited to through its United States subsidiary Hetero USA, which has a principal place of business in Piscataway, NJ; having previously admitted, consented to, or declined to contest the jurisdiction of this Court; and/or having availed itself of this Court's rights, benefits, and privileges by asserting claims and counterclaims in prior District of New Jersey actions. *See, e.g.*, Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero USA, Inc.'s Answer to Complaint at 7–12, *Merck Sharp & Dohme LLC v. Hetero USA, Inc.*, Civ. No. 22-6820, Dkt. No. 11 (D.N.J. Feb. 10, 2023).

15. On information and belief, Hetero Labs is in the business of manufacturing generic pharmaceuticals that it distributes or has distributed in the State of New Jersey and throughout the United States.

16. On information and belief, Hetero Labs regularly and continuously conducts business with the State of New Jersey, either directly or through its subsidiaries Aspiro and Hetero USA, the latter with its principal place of business in Piscataway, NJ, including by selling pharmaceutical products in the State of New Jersey.

17. On information and belief, Defendants collaborate with each other with respect to the manufacture, regulatory approval, market, sale, and/or distribution of generic pharmaceutical products. On information and belief, Aspiro, Hetero USA, and Hetero Labs are agents of one another or operate in concert as integrated parts of the same business group. On information and belief, Defendants collaborate with each other to manufacture and distribute generic pharmaceutical products for sale in the State of New Jersey and throughout the United States.

18. On information and belief, each of Aspiro, Hetero USA, and Hetero Labs has committed, or aided, abetted, contributed to, and/or participated in the commission of acts of patent infringement that will lead to foreseeable harm and injury to Gilead, which sells VEKLURY® for use throughout the United States, including in this judicial District. On information and belief, and as indicated by Defendants' Notice Letter (as further defined herein), Defendants prepared and filed, or aided, abetted, contributed to, and/or participated in the preparation and filing of Defendants' ANDA with the intention of seeking to market Defendants' ANDA Product nationwide, including within this judicial District.

19. On information and belief, Defendants plan to market and sell Defendants' ANDA Product in the State of New Jersey, list Defendants' ANDA Product on the State of New Jersey's prescription drug formulary, and seek Medicaid reimbursement for sales of Defendants' ANDA Product in the State of New Jersey, either directly or through one or more of Defendants' wholly owned subsidiaries, agents, and/or alter egos.

20. On information and belief, Defendants know and intend that Defendants' ANDA Product will be distributed and sold in New Jersey and will thereby displace sales of VEKLURY®, causing injury to Gilead. Defendants intend to take advantage of their established channels of distribution in New Jersey for the sale of Defendants' ANDA Product.

21. This Court also has personal jurisdiction over Aspiro and Hetero Labs under Fed. R. Civ. P. 4(k)(2). On information and belief, Aspiro and Hetero Labs are organized under the laws of India, and to the extent Aspiro and Hetero Labs are not subject to jurisdiction in any State's courts of general jurisdiction, exercising jurisdiction is consistent with the United States Constitution and laws, including because Aspiro and Hetero Labs have sufficient contacts with the United States that relate to the claims in this case. *See* Fed. R. Civ. P. 4(k)(2); *see, e.g.*, *Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co. KG*, 933 F.3d 1302, 1311–12 (Fed. Cir. 2019); *M-I Drilling Fluids UK Ltd. v. Dynamic Air Ltda.*, 890 F.3d 995, 1002 (Fed. Cir. 2018).

VENUE

22. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) with respect to Gilead's claims against Aspiro and Hetero Labs because, *inter alia*, Aspiro and Hetero Labs are foreign corporations that are incorporated in India and may be deemed to reside and be sued in any judicial district in the United States in which Aspiro and Hetero Labs, respectively, is subject to this Court's personal jurisdiction. *See In re HTC Corp.*, 889 F.3d 1349, 1357 (Fed. Cir. 2018).

23. Venue is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b) with respect to Gilead's claims against Hetero USA because, *inter alia*, Hetero USA resides in New Jersey by having its principal place of business in the State of New Jersey and has committed acts of infringement in the State of New Jersey including, *inter alia*, by participating in the submission of Defendants' ANDA in the State of New Jersey.

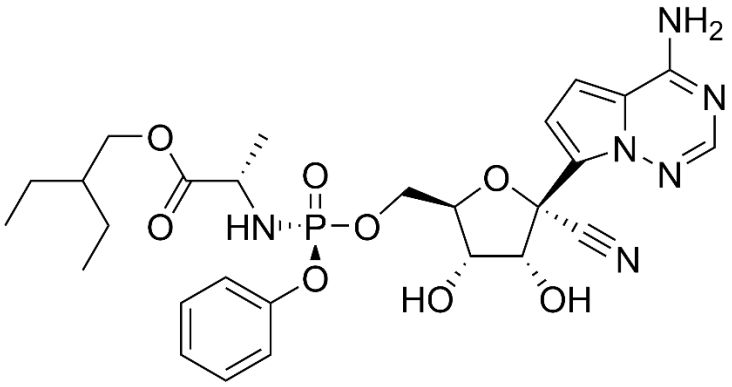
24. Aspiro, Hetero USA, and Hetero Labs have not contested venue in New Jersey in other actions. *See, e.g.*, Aspiro Pharma Ltd.'s Answer to Complaint at 2–3, *Merck Sharp & Dohme BV v. Aspiro Pharma Ltd.*, Civ. No. 20-3112, Dkt. No. 8 (D.N.J. May 1, 2020); Hetero Labs Ltd., Hetero Labs Ltd. Unit-V, Hetero USA, Inc.'s Answer to Complaint at 7–12, *Merck Sharp & Dohme LLC v. Hetero USA, Inc.*, Civ. No. 22-6820, Dkt. No. 11 (D.N.J. February 10, 2023).

VEKLURY®

25. Gilead holds New Drug Application ("NDA") No. 214787 for VEKLURY® (remdesivir) indicated for adults and pediatric patients for the treatment of coronavirus disease 2019 (COVID-19) who are hospitalized or who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression to severe COVID-19.

26. The active ingredient in VEKLURY® is remdesivir, a SARS-CoV-2 nucleotide analog RNA polymerase inhibitor.

27. The chemical name for remdesivir is 2-ethylbutyl N-{(S)-[2-C-(4 aminopyrrolo[2,1-f][1,2,4]triazin-7-yl)-2,5anhydro-d-altrononitril-6-O-yl]phenoxyphosphoryl}-L-alaninate, and it has the following structural formula:



28. The VEKLURY® prescribing information (the "VEKLURY® Label") states VEKLURY® for injection contains 100 mg of remdesivir as a sterile, preservative-free lyophilized powder which requires reconstitution and then further dilution prior to administration by

intravenous infusion. The VEKLURY® Label states the inactive ingredients for VEKLURY® for injection are 3 g betadex sulfobutyl ether sodium and may include hydrochloric acid and/or sodium hydroxide for pH adjustment.

29. The VEKLURY® Label states that the recommended dosage for adults and pediatric patients weighing at least 40 kg is a single loading dose of VEKLURY® 200 mg on Day 1 followed by once-daily maintenance doses of VEKLURY® 100 mg from Day 2, with a 5- to 10-day recommended total treatment duration for hospitalized patients and a 3-day recommended total treatment duration for non-hospitalized patients. The VEKLURY® Label further states that the recommended dosage for pediatric patients less than 28 days old and weighing at least 1.5 kg as well as pediatric patients at least 28 days old and weighing 1.5 kg to less than 3 kg is a single loading dose of VEKLURY® at 2.5 mg/kg on Day 1 followed by once-daily maintenance doses of VEKLURY® at 1.25 mg/kg from Day 2, with a 5- to 10-day recommended total treatment duration for hospitalized patients and a 3-day recommended total treatment duration for non-hospitalized patients. The VEKLURY® Label further states that the recommended dosage for pediatric at least 28 days old and weighing 3 kg to less than 40 kg is a single loading dose of VEKLURY® at 5 mg/kg on Day 1 followed by once-daily maintenance doses of VEKLURY® at 2.5 mg/kg from Day 2, with a 5- to 10-day recommended total treatment duration for hospitalized patients and a 3-day recommended total treatment duration for non-hospitalized patients.

30. The VEKLURY® Label provides detailed instructions for how to reconstitute VEKLURY® for injection and then use the reconstituted product to prepare the diluted drug product for administration.

31. Gilead markets the powder and solution approved under NDA No. 214787 in the United States under the registered trademark VEKLURY®. FDA's *Approved Drug Products with*

Therapeutic Equivalents Evaluations (the "Orange Book") identifies the following patents for VEKLURY®: U.S. Patent Nos. 8,008,264; 8,318,682; 9,724,360; 9,949,994; 10,065,958; 10,675,296; 10,695,361; 11,007,208; 11,266,681; 11,382,926; 11,491,169; 11,492,353; 11,903,953; 11,975,012; 11,975,017; and RE46,762.

32. At least one claim of each of the Asserted Patents (all of which are listed in the Orange Book) covers VEKLURY®, or approved methods of using VEKLURY®.

DEFANDANTS' ANDA

33. On information and belief, Aspiro, Hetero USA, and Hetero Labs acted collaboratively and in concert to file Defendants' ANDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, *i.e.*, 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, sell and/or market a generic version of VEKLURY®, remdesivir powder, intravenous, l00mg/vial ("Defendant's ANDA Product").

34. On information and belief, Aspiro, Hetero USA, and Hetero Labs acted collaboratively and in concert to prepare and submit Defendants' ANDA and continue to act collaboratively and in concert to pursue FDA approval of Defendants' ANDA and to seek to market Defendants' ANDA Product.

35. On information and belief, Aspiro, Hetero USA, and Hetero Labs collaborate with each other to manufacture, market, distribute, offer for sale, and/or sell generic drugs in the U.S. market, including in the State of New Jersey. On information and belief, Aspiro, Hetero USA, and Hetero Labs intend to act collaboratively and in concert to commercially manufacture, market, distribute, import into the United States, offer for sale, and/or sell Defendants' ANDA Product, in the event FDA approves Defendants' ANDA.

36. On information and belief, Defendants' ANDA refers to and relies upon the VEKLURY® NDA and contains data that, according to Defendants, demonstrates the bioequivalence of Defendants' ANDA Product and VEKLURY®.

37. On information and belief, Defendants made and included in their ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III Certification") that Defendants will not seek final approval of Defendants' ANDA prior to the expiration of the following patents: U.S. Patent Nos. 8,008,264; 8,318,682; 9,724,360; 9,949,994; 10,065,958; 10,695,361; 11,007,208; 11,382,926; 11,492,353; and RE46,762.

38. On information and belief, Defendants made and included in their ANDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that, in its opinion and to the best of its knowledge, Defendants' ANDA Product will not infringe any valid and enforceable claims of the Asserted Patents.

39. Gilead received written notice of Defendants' ANDA and Paragraph IV Certification by letter dated June 18, 2025 ("Defendants' Notice Letter"), along with an enclosed statement ("Defendants' Detailed Statement") that purported to provide Defendants' bases for stating that Defendants' ANDA Product will not infringe any valid and enforceable claims of the Asserted Patents.

40. This action is being commenced within 45 days of receipt of Defendants' Notice Letter.

41. Defendants have infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of the filing of Defendants' ANDA with a Paragraph IV Certification and seeking FDA approval of Defendants' ANDA prior to the expiration of the Asserted Patents or any extensions thereof.

42. Defendants have infringed one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A) by virtue of filing Defendants' ANDA seeking FDA approval to commercially manufacture, use, offer for sale, sell, distribute in, or import into the United States a generic version of VEKLURY® prior to the expiration of the Asserted Patents or any extensions thereof. Defendants will infringe one or more claims of the Asserted Patents under 35 U.S.C. §§ 271(a), (b), (c), or (f) should they engage in, induce, or contribute to the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of a generic version of VEKLURY® prior to the expiration of the Asserted Patents or any extensions thereof.

THE ASSERTED PATENTS

'296 Patent

43. Gilead owns by assignment the '296 Patent entitled "Compositions Comprising an RNA Polymerase Inhibitor and Cyclodextrin for Treating Viral Infections." Gilead has all necessary rights in and to the '296 Patent to both assert infringement of and seek relief for infringement of the '296 Patent.

44. The United States Patent and Trademark Office ("USPTO") duly and legally issued the '296 Patent on June 9, 2020. The '296 Patent names Nate Larson and Robert G. Strickley as the inventors of the '296 Patent. The claims of the '296 Patent are valid, enforceable, and not expired.

45. A true and correct copy of the '296 Patent is attached to this Complaint as Exhibit A.

'681 Patent

46. Gilead owns the '681 Patent entitled "Compositions Comprising an RNA Polymerase Inhibitor and Cyclodextrin for Treating Viral Infections." Gilead has all necessary

rights in and to the ’681 Patent to both assert infringement of and seek relief for infringement of the ’681 Patent.

47. The USPTO duly and legally issued the ’681 Patent on March 8, 2022. The ’681 Patent names Nate Larson and Robert G. Strickley as the inventors of the ’681 Patent. The claims of the ’681 Patent are valid, enforceable, and not expired.

48. A true and correct copy of the ’681 Patent is attached to this Complaint as Exhibit B.

’017 Patent

49. Gilead owns the ’017 Patent entitled “Compositions Comprising an RNA Polymerase Inhibitor and Cyclodextrin for Treating Viral Infections.” Gilead has all necessary rights in and to the ’017 Patent to both assert infringement of and seek relief for infringement of the ’017 Patent.

50. The USPTO duly and legally issued the ’017 Patent on May 7, 2024. The ’017 Patent names Nate Larson and Robert G. Strickley as the inventors of the ’017 Patent. The claims of the ’017 Patent are valid, enforceable, and not expired.

51. A true and correct copy of the ’017 Patent is attached to this Complaint as Exhibit C.

’169 Patent

52. Gilead owns the ’169 Patent entitled “Remdesivir Treatment Methods.” Gilead has all necessary rights in and to the ’169 Patent to both assert infringement of and seek relief for infringement of the ’169 Patent.

53. The USPTO duly and legally issued the ’169 Patent on November 8, 2022. The ’169 Patent names Tomas Cihlar as the inventor of the ’169 Patent. The claims of the ’169 Patent are valid, enforceable, and not expired.

54. A true and correct copy of the ’169 Patent is attached to this Complaint as Exhibit D.

'953 Patent

55. Gilead owns the '953 Patent entitled "Remdesivir Treatment Methods." Gilead has all necessary rights in and to the '953 Patent to both assert infringement of and seek relief for infringement of the '953 Patent.

56. The USPTO duly and legally issued the '953 Patent on February 20, 2024. The '953 Patent names Tomas Cihlar as the inventor of the '953 Patent. The claims of the '953 Patent are valid, enforceable, and not expired.

57. A true and correct copy of the '953 Patent is attached to this Complaint as Exhibit E.

'012 Patent

58. Gilead owns the '012 Patent entitled "Remdesivir Treatment Methods." Gilead has all necessary rights in and to the '012 Patent to both assert infringement of and seek relief for infringement of the '012 Patent.

59. The USPTO duly and legally issued the '012 Patent on May 7, 2024. The '012 Patent names Tomas Cihlar as the inventor of the '012 Patent. The claims of the '012 Patent are valid, enforceable, and not expired.

60. A true and correct copy of the '012 Patent is attached to this Complaint as Exhibit F.

COUNT 1
(INFRINGEMENT OF THE '296 PATENT)

61. The above allegations are incorporated herein by reference.

62. On information and belief, Defendants submitted Defendants' ANDA to FDA, and thereby seek FDA approval of Defendants' ANDA Product.

63. On information and belief, for example, Defendants' VEKLURY® ANDA Product contains remdesivir and thus falls within the scope of at least claim 1 of the '296 patent, either literally or under the doctrine of equivalents.

64. Defendants have infringed at least claim 1 of the '296 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United States or importation into the United States of a generic version of VEKLURY® prior to the expiration of the '296 Patent. Defendants' Detailed Statement includes no non-infringement arguments for any claim of the '296 Patent.

65. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product before the expiration of the '296 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '296 Patent, including, but not limited to claim 1, under 35 U.S.C. § 271. Defendants' infringement of at least claim 1 is either literal or under the doctrine of equivalents.

66. Gilead will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '296 Patent and/or if FDA is not enjoined from approving Defendants' ANDA before the '296 Patent expires.

67. Gilead has no adequate remedy at law.

68. Gilead is entitled to an order declaring that Defendants have infringed at least claim 1 of the '296 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

69. Gilead is entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the expiration date of the '296 Patent, including any extensions, adjustments, and exclusivities associated with the '296 Patent.

70. Gilead is entitled to an order requiring that Defendants amend their Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

71. Gilead is entitled to an order declaring that Defendants will infringe at least claim 1 of the '296 Patent by commercially manufacturing, using, offering to sell, sale, or importing Defendants' ANDA Product before the expiration of the '296 Patent under 35 U.S.C. § 271.

72. Defendants were aware of the '296 Patent when they submitted their ANDA. On information and belief, Defendants' statement of the factual and legal basis regarding the invalidity of the '296 Patent is devoid of a good faith basis in either the facts or the law.

COUNT 2
(INFRINGEMENT OF THE '681 PATENT)

73. The above allegations are incorporated herein by reference.

74. On information and belief, Defendants submitted Defendants' ANDA to FDA and thereby seek FDA approval of Defendants' ANDA Product.

75. On information and belief, for example, Defendants' VEKLURY® ANDA Product contains remdesivir and thus falls within the scope of at least claims 1 and 28 of the '681 patent, either literally or under the doctrine of equivalents.

76. Defendants have infringed at least claims 1 and 28 of the '681 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United States or importation into the United States of a generic version of VEKLURY® prior to the expiration of the '681 Patent. Defendants' Detailed Statement includes no non-infringement arguments for claims 1–26 or 28–44 of the '296 Patent

77. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product before the expiration of the '681 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '681 Patent, including, but not limited to claims 1 and 28, under 35 U.S.C. § 271. Defendants' infringement of at least claims 1 and 28 is either literal or under the doctrine of equivalents.

78. Gilead will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '681 Patent and/or if FDA is not enjoined from approving Defendants' ANDA before the '681 Patent expires.

79. Gilead has no adequate remedy at law.

80. Gilead is entitled to an order declaring that Defendants have infringed at least claims 1 and 28 of the '681 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

81. Gilead is entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the expiration date of the '681 Patent, including any extensions, adjustments, and exclusivities associated with the '681 Patent.

82. Gilead is entitled to an order requiring that Defendants amend their Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

83. Gilead is entitled to an order declaring that Defendants will infringe at least claims 1 and 28 of the '681 Patent by commercially manufacturing, using, offering to sell, sale, or importing Defendants' ANDA Product before the expiration of the '681 Patent under 35 U.S.C. § 271.

84. Defendants were aware of the '681 Patent when they submitted their ANDA. On information and belief, Defendants' statement of the factual and legal basis regarding the invalidity of the '681 Patent is devoid of a good faith basis in either the facts or the law.

COUNT 3
(INFRINGEMENT OF THE '017 PATENT)

85. The above allegations are incorporated herein by reference.

86. On information and belief, Defendants submitted Defendants' ANDA to FDA and thereby seek FDA approval of Defendants' ANDA Product.

87. On information and belief, for example, Defendants' VEKLURY® ANDA Product contains remdesivir and thus falls within the scope of at least claims 1, 17, and 33 of the '017 patent, either literally or under the doctrine of equivalents.

88. Defendants have infringed at least claims 1, 17, and 33 of the '017 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United States or importation into the United States of a generic version of VEKLURY® prior to the expiration of the '017 Patent. Defendants' Detailed Statement includes no non-infringement arguments for the '017 Patent.

89. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product before the expiration of the '017 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '017 Patent, including, but not limited to claims 1, 17, and 33, under 35 U.S.C. § 271. Defendants' infringement of at least claims 1, 17, and 33 is either literal or under the doctrine of equivalents.

90. Gilead will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '017 Patent and/or if FDA is not enjoined from approving Defendants' ANDA before the '017 Patent expires.

91. Gilead has no adequate remedy at law.

92. Gilead is entitled to an order declaring that Defendants have infringed at least claims 1, 17, and 33 of the '017 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

93. Gilead is entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the expiration date of the '017 Patent, including any extensions, adjustments, and exclusivities associated with the '017 Patent.

94. Gilead is entitled to an order requiring that Defendants amend their Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

95. Gilead is entitled to an order declaring that Defendants will infringe at least claims 1, 17, and 33 of the '017 Patent by commercially manufacturing, using, offering to sell, sale, or importing Defendants' ANDA Product before the expiration of the '017 Patent under 35 U.S.C. § 271.

96. Defendants were aware of the '017 Patent when they submitted their ANDA. On information and belief, Defendants' statement of the factual and legal basis regarding the invalidity of the '017 Patent is devoid of a good faith basis in either the facts or the law.

COUNT 4
(INFRINGEMENT OF THE '169 PATENT)

97. The above allegations are incorporated herein by reference.

98. On information and belief, Defendants submitted Defendants' ANDA to FDA and thereby seek FDA approval of Defendants' ANDA Product.

99. On information and belief, for example, Defendants' VEKLURY® ANDA Product contains remdesivir and thus falls within the scope of at least claim 1 of the '169 patent, either literally or under the doctrine of equivalents.

100. Defendants have infringed at least claim 1 of the '169 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United States or importation into the United States of a generic version of VEKLURY® prior to the expiration of the '169 Patent. Defendants' Detailed Statement includes no non-infringement arguments for claims 1–17 of the '169 Patent.

101. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product before the expiration of the '169 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '169 Patent, including, but not limited to claim 1, under 35 U.S.C. § 271. Defendants' infringement of at least claim 1 is either literal or under the doctrine of equivalents.

102. Gilead will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '169 Patent and/or if FDA is not enjoined from approving Defendants' ANDA before the '169 Patent expires.

103. Gilead has no adequate remedy at law.

104. Gilead is entitled to an order declaring that Defendants have infringed at least claim 1 of the '169 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

105. Gilead is entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the expiration date of the '169 Patent, including any extensions, adjustments, and exclusivities associated with the '169 Patent.

106. Gilead is entitled to an order requiring that Defendants amend their Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

107. Gilead is entitled to an order declaring that Defendants will infringe at least claim 1 of the '169 Patent by commercially manufacturing, using, offering to sell, sale, or importing Defendants' ANDA Product before the expiration of the '169 Patent under 35 U.S.C. § 271.

108. Defendants were aware of the '169 Patent when they submitted their ANDA. On information and belief, Defendants' statement of the factual and legal basis regarding the invalidity of the '169 Patent is devoid of a good faith basis in either the facts or the law.

COUNT 5
(INFRINGEMENT OF THE '953 PATENT)

109. The above allegations are incorporated herein by reference.

110. On information and belief, Defendants submitted Defendants' ANDA to FDA and thereby seek FDA approval of Defendants' ANDA Product.

111. On information and belief, for example, Defendants' VEKLURY® ANDA Product contains remdesivir and thus falls within the scope of at least claim 1 of the '953 patent, either literally or under the doctrine of equivalents.

112. Defendants have infringed at least claim 1 of the '953 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United

States or importation into the United States of a generic version of VEKLURY® prior to the expiration of the '953 Patent. Defendants' Detailed Statement includes no non-infringement arguments for claims 1, 6–8, or 11–15 of the '953 Patent

113. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product before the expiration of the '953 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '953 Patent, including, but not limited to claim 1, under 35 U.S.C. § 271. Defendants' infringement of at least claim 1 is either literal or under the doctrine of equivalents.

114. Gilead will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '953 Patent and/or if FDA is not enjoined from approving Defendants' ANDA before the '953 Patent expires.

115. Gilead has no adequate remedy at law.

116. Gilead is entitled to an order declaring that Defendants have infringed at least claim 1 of the '953 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

117. Gilead is entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the expiration date of the '953 Patent, including any extensions, adjustments, and exclusivities associated with the '953 Patent.

118. Gilead is entitled to an order requiring that Defendants amend their Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

119. Gilead is entitled to an order declaring that Defendants will infringe at least claim 1 of the '953 Patent by commercially manufacturing, using, offering to sell, sale, or importing Defendants' ANDA Product before the expiration of the '953 Patent under 35 U.S.C. § 271.

120. Defendants were aware of the '953 Patent when they submitted their ANDA. On information and belief, Defendants' statement of the factual and legal basis regarding the invalidity of the '953 Patent is devoid of a good faith basis in either the facts or the law.

COUNT 6
(INFRINGEMENT OF THE '012 PATENT)

121. The above allegations are incorporated herein by reference.

122. On information and belief, Defendants submitted Defendants' ANDA to FDA and thereby seek FDA approval of Defendants' ANDA Product.

123. On information and belief, for example, Defendants' VEKLURY® ANDA Product contains remdesivir and thus falls within the scope of at least claims 1 and 27 of the '012 patent, either literally or under the doctrine of equivalents.

124. Defendants have infringed at least claims 1 and 27 of the '012 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Defendants' ANDA with a Paragraph IV Certification and thereby seeking FDA approval for the commercial manufacture, use, offer to sell, or sale in the United States or importation into the United States of a generic version of VEKLURY® prior to the expiration of the '012 Patent. Defendants' Detailed Statement includes no non-infringement arguments for claims 1, 7–19, 27, or 32–38 of the '012 Patent.

125. Defendants' commercial manufacture, use, offer to sell, sale, or importation of Defendants' ANDA Product before the expiration of the '012 Patent would directly infringe, or contribute to or induce infringement of, one or more claims of the '012 Patent, including, but not

limited to claims 1 and 27, under 35 U.S.C. § 271. Defendants' infringement of at least claims 1 and 27 is either literal or under the doctrine of equivalents.

126. Gilead will be harmed substantially and irreparably if Defendants are not enjoined from infringing the '012 Patent and/or if FDA is not enjoined from approving Defendants' ANDA before the '012 Patent expires.

127. Gilead has no adequate remedy at law.

128. Gilead is entitled to an order declaring that Defendants have infringed at least claims 1 and 27 of the '012 Patent by submitting Defendants' ANDA pursuant to 35 U.S.C. § 271(e)(2)(A).

129. Gilead is entitled to all relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that FDA set the effective date of approval for Defendants' ANDA to be a date which is not any earlier than the expiration date of the '012 Patent, including any extensions, adjustments, and exclusivities associated with the '012 Patent.

130. Gilead is entitled to an order requiring that Defendants amend their Paragraph IV Certification in Defendants' ANDA to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A).

131. Gilead is entitled to an order declaring that Defendants will infringe at least claims 1 and 27 of the '012 Patent by commercially manufacturing, using, offering to sell, sale, or importing Defendants' ANDA Product before the expiration of the '012 Patent under 35 U.S.C. § 271.

132. Defendants were aware of the '012 Patent when they submitted their ANDA. On information and belief, Defendants' statement of the factual and legal basis regarding the invalidity of the '012 Patent is devoid of a good faith basis in either the facts or the law.

PRAYER FOR RELIEF

WHEREFORE, Gilead respectfully requests that this Court enter judgment in its favor and grant the following relief:

A. A judgment that Defendants have infringed directly, contributed to, or induced infringement of one or more claims of the Asserted Patents under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents, by submitting the Defendants' ANDA to FDA to obtain approval for the commercial manufacture, use, offer or sale, sale, distribution in, or importation into the United States of Defendants' ANDA Product before the expiration of the Asserted Patents;

B. A judgment that Defendants will infringe directly, contribute to, or induce the infringement of one more claims of the Asserted Patents under 35 U.S.C. § 271, either literally or under the doctrine of equivalents, if Defendants market, manufacture, use, offer for sale, sell, distribute in, or import into the United States Defendants' ANDA Product before the expiration of the Asserted Patents;

C. A judgment ordering that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), shall not be earlier than the expiration of the Asserted Patents, including any extensions, adjustments, or exclusivities;

D. A judgment ordering that Defendants amend their Paragraph IV Certification to a Paragraph III Certification as provided in 21 C.F.R. § 314.94(a)(12)(viii)(A);

E. Entry of preliminary and permanent injunctions pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 enjoining Defendants, their officers, agents, servants, employees, attorneys, affiliates, divisions, subsidiaries, and those persons in active concert or

participation with any of them from infringing the Asserted Patents, or contributing to or inducing the same, including the manufacture, use, offer to sell, sale, distribution or importation of any current or future versions of Defendants' ANDA Product before the expiration of the Asserted Patents, including any applicable extensions, adjustments, and exclusivities;

F. If Defendants commercially manufacture, use, offer to sell, or sell in the United States or import into the United States Defendants' ANDA Product prior to the expiration of the Asserted Patents, including any extensions, adjustments, or exclusivities, a judgment pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284 awarding Gilead monetary relief, together with interest;

G. An award to Gilead of attorneys' fees in this action as an exceptional case pursuant to 35 U.S.C. § 285; and

H. An award to Gilead of costs and expenses in this action; and

I. Such other and further relief as this Court may deem just and proper.

JURY TRIAL DEMAND

Gilead demands a trial by jury on all issues so triable, pursuant to Fed. R. Civ. P. 38.

s/ *Keith J. Miller*
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**Pro hac vice* application forthcoming

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Dated: July 30, 2025