Kaan Ekiner
COZEN O'CONNOR
1201 N. Market Street
Suite 1001
Wilmington, DE 19801
(302) 295-2046
kekiner@cozen.com

Attorneys for Defendants Aspiro Pharma Ltd., Hetero USA, Inc., and Hetero Labs Ltd.

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

GILEAD SCIENCES, INC., Plaintiff, v. ASPIRO PHARMA LTD., HETERO USA, INC., and HETERO LABS LTD., Defendants.	Civil Action No. 2:25-cv-13936-SRC-SDA

DEFENDANTS ASPIRO PHARMA LTD., HETERO USA, INC., AND HETERO LABS LTD.'S ANSWER AND SEPARATE DEFENSES TO PLAINTIFF'S COMPLAINT

Defendants Aspiro Pharma Ltd. ("Aspiro"), Hetero USA, Inc. ("Hetero USA"), and Hetero Labs Ltd. ("Hetero Labs") (collectively, "Defendants"), by and through their undersigned counsel, file this Answer and Separate Defenses to Plaintiff Gilead Sciences, Inc.'s ("Gilead" or "Plaintiff") Complaint, and state as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations and characterizations in Plaintiff's Complaint except those specifically admitted below. Defendants further deny liability for all allegations of patent liability and that Plaintiff is entitled to the relief requested or any other.

In responding to the Complaint, Defendants use the headings employed by Plaintiff strictly as a convenience to the Court, and does not admit any allegation made in, or inference suggested by, such headings. Defendants answer the numbered paragraphs of Plaintiff's Complaint 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®.

ANSWER: Defendants admit that Plaintiff filed this civil action alleging patent infringement under the patent laws of the United States, Title 35 of the United States Code, of U.S. 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"). Defendants admit that they filed Abbreviated New Drug Application No. 220566 ("Defendants' ANDA") with the U.S. Food and Drug Administration ("FDA") for remdesivir. Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 1.

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.

ANSWER: Paragraph 2 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, on information and belief, Defendants admit that Gilead is a Delaware corporation with a principal place of business at 333 Lakeside Drive, Foster City, California 94404. Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 2, and on that basis deny these allegations.

> 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.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that 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, and that Aspiro's U.S. Agent is located at 121 New England Ave., Piscataway, NJ 08854. Defendants admit that they manufacture high quality generic pharmaceutical products that are ultimately used by consumers in the United States. Defendants admit that Aspiro is a wholly owned subsidiary of Hetero Labs. Except as expressly admitted, Defendants deny the allegations of Paragraph 3.

> 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.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that 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, and that Aspiro's U.S. Agent is located at 121 New England Ave., Piscataway, NJ 08854. Defendants admit that they manufacture high quality generic pharmaceutical products that are ultimately used by consumers in the United States. Defendants admit that Hetero USA is a wholly owned subsidiary of Hetero Labs. Except as expressly admitted, Defendants deny the allegations of Paragraph 4.

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.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that 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. Defendants admit that they manufacture high quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Defendants deny the allegations of Paragraph 5.

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.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 6.

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.

ANSWER: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 7.

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).

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 8.

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).

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this

Court has no bearing on this action. Except as expressly admitted, Defendants deny the allegations of Paragraph 9.

> 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.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they manufacture high quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Defendants deny the allegations of Paragraph 10.

> 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.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 11.

> 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).

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this

Court has no bearing on this action. Except as expressly admitted, Defendants deny the allegations of Paragraph 12.

> 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.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they manufacture high quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Defendants deny the allegations of Paragraph 13.

> 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).

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Prior consent to personal jurisdiction in this Court has no bearing on this action. Except as expressly admitted, Defendants deny the allegations of Paragraph 14.

> 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.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they manufacture high

quality generic pharmaceutical products that are ultimately used by consumers in the United States. Except as expressly admitted, Defendants deny the allegations of Paragraph 15.

> 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.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 16.

> 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.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 17.

> 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.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 18.

> 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.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 19.

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.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 20.

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).

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest personal jurisdiction in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 21.

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).

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 22.

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.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court for the limited purposes of this action only. Except as expressly admitted, Defendants deny the allegations of Paragraph 23.

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).

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court for the limited purposes of this action only. Prior consent to venue in this Court has no bearing on this action. Except as expressly admitted, Defendants deny the allegations of Paragraph 24.

VEKLURY®

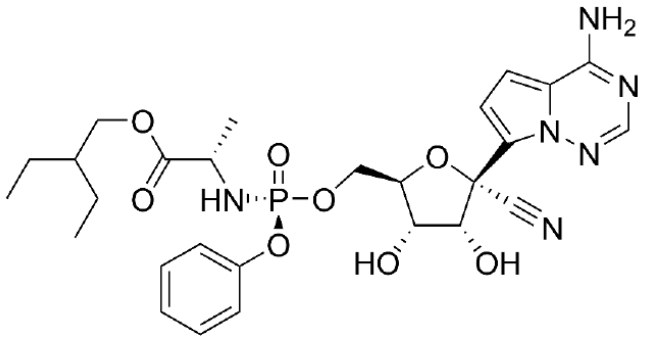
25. Gilead holds New Drug Application ("NDA") No. 214787 for VEKLURY® (remdesivir) indicated for adults and pediatric patients for the treatment of coronavirus disease 2019 (COVID-19) who are hospitalized or who are not hospitalized and have mild-to-moderate COVID-19 and are at high risk for progression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

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the FDA publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") lists Gilead as the holder of New Drug Application ("NDA") No. 214787 for VEKLURY® (remdesivir). Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 25, and on that basis deny these allegations.

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

ANSWER: Admitted.

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:



ANSWER: Admitted.

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.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants lack knowledge or information

sufficient to form a belief about the truth of the allegations of Paragraph 28, and on that basis deny these allegations.

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.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 29, and on that basis deny these allegations.

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.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 30.

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.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the Orange Book lists 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 in connection with VEKLURY®. Except as expressly admitted, Defendants lack knowledge and information sufficient to form a belief about the truth of the allegations of Paragraph 31, and on that basis deny these allegations.

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®.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 32.

DEFENDANTS' 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").

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 33.

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.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer

is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 34.

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.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 35.

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®.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 36.

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.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 37.

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.

ANSWER: Paragraph 38 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, the content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 38.

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.

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that on or about June 18, 2025, Defendants sent a Notice Letter to Gilead. The content of Defendants' Notice Letter speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 39.

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

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 40.

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.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 41.

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.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 42.

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.

ANSWER: Paragraph 43 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '296 Patent is titled "Compositions Comprising an RNA Polymerase Inhibitor and Cyclodextrin for Treating Viral Infections," and that the face of the '296 Patent lists Gilead as the assignee. Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 43, and on that basis deny these allegations.

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.

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '296 Patent was issued by the USPTO on or about June 9, 2020, and that the face of the '296 Patent lists Nate Larson as the inventor. Except as expressly admitted, Defendants deny the allegations of Paragraph 44.

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

ANSWER: Defendants admit that what appears to be an uncertified copy of the '296 Patent was attached to Plaintiff's 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.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '681 Patent is titled "Compositions Comprising an RNA Polymerase Inhibitor and Cyclodextrin for Treating Viral Infections," and that the face of the '681 Patent lists Gilead as the assignee. Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 46, and on that basis deny these allegations.

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.

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '681 Patent was issued by the USPTO on or about March 8, 2022, and that the face of the '681 Patent lists Nate Larson and Robert G. Strickley as inventors. Except as expressly admitted, Defendants deny the allegations of Paragraph 47.

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

ANSWER: Defendants admit that what appears to be an uncertified copy of the '681 Patent was attached to Plaintiff's 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.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '017 Patent is titled "Compositions Comprising an RNA Polymerase Inhibitor and Cyclodextrin for Treating Viral Infections," and that the face of the '017 Patent lists Gilead as the assignee. Except as expressly

admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 49, and on that basis deny these allegations.

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.

ANSWER: Paragraph 50 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '017 Patent was issued by the USPTO on or about May 7, 2024, and that the face of the '017 Patent lists Nate Larson and Robert G. Strickley as inventors. Except as expressly admitted, Defendants deny the allegations of Paragraph 50.

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

ANSWER: Defendants admit that what appears to be an uncertified copy of the '017 Patent was attached to Plaintiff's 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.

ANSWER: Paragraph 52 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '169 Patent is titled "Remdesivir Treatment Methods," and that the face of the '169 Patent lists Gilead as the assignee. Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 52, and on that basis deny these allegations.

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.

ANSWER: Paragraph 53 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '169 Patent was issued by the USPTO on or about November 8, 2022, and that the face of the '169 Patent lists Tomas Cihlar as the inventor. Except as expressly admitted, Defendants deny the allegations of Paragraph 53.

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

ANSWER: Defendants admit that what appears to be an uncertified copy of the '169 Patent was attached to Plaintiff's 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.

ANSWER: Paragraph 55 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '953 Patent is titled "Remdesivir Treatment Methods," and that the face of the '953 Patent lists Gilead as the assignee. Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 55, and on that basis deny these allegations.

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.

ANSWER: Paragraph 56 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the '953 Patent was issued by the USPTO on or about February 20, 2024, and that the face of the '953 Patent lists Tomas Cihlar as the inventor. Except as expressly admitted, Defendants deny the allegations of Paragraph 56.

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

ANSWER: Defendants admit that what appears to be an uncertified copy of the ’953 Patent was attached to Plaintiff’s 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.

ANSWER: Paragraph 58 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the ’012 Patent is titled “Remdesivir Treatment Methods,” and that the face of the ’012 Patent lists Gilead as the assignee. Except as expressly admitted, Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations of Paragraph 58, and on that basis deny these allegations.

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.

ANSWER: Paragraph 59 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that the ’012 Patent was issued by the USPTO on or about May 7, 2024, and that the face of the ’012 Patent lists Tomas Cihlar as the inventor. Except as expressly admitted, Defendants deny the allegations of Paragraph 59.

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

ANSWER: Defendants admit that what appears to be an uncertified copy of the ’012 Patent was attached to Plaintiff’s Complaint as Exhibit F.

COUNT 1
(INFRINGEMENT OF THE ’296 PATENT)

61. The above allegations are incorporated herein by reference.

ANSWER: Defendants' responses to Plaintiff's 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.

ANSWER: Paragraph 62 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 62.

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.

ANSWER: Paragraph 63 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 63.

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.

ANSWER: Paragraph 64 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 64.

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.

ANSWER: Paragraph 65 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 65.

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.

ANSWER: Paragraph 66 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 66.

67. Gilead has no adequate remedy at law.

ANSWER: Paragraph 67 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 67.

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).

ANSWER: Paragraph 68 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 68.

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.

ANSWER: Paragraph 69 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 69.

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).

ANSWER: Paragraph 70 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 70.

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.

ANSWER: Paragraph 71 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 71.

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.

ANSWER: Paragraph 72 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 72.

COUNT 2
(INFRINGEMENT OF THE '681 PATENT)

73. The above allegations are incorporated herein by reference.

ANSWER: Defendants' responses to Plaintiff's 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.

ANSWER: Paragraph 74 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 74.

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.

ANSWER: Paragraph 75 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 75.

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

ANSWER: Paragraph 76 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 76.

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.

ANSWER: Paragraph 77 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 77.

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.

ANSWER: Paragraph 78 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 78.

79. Gilead has no adequate remedy at law.

ANSWER: Paragraph 79 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 79.

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).

ANSWER: Paragraph 80 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 80.

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.

ANSWER: Paragraph 81 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 81.

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).

ANSWER: Paragraph 82 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 82.

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.

ANSWER: Paragraph 83 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 83.

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.

ANSWER: Paragraph 84 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 84.

COUNT 3
(INFRINGEMENT OF THE '017 PATENT)

85. The above allegations are incorporated herein by reference.

ANSWER: Defendants' responses to Plaintiff's 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.

ANSWER: Paragraph 86 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content

of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 86.

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.

ANSWER: Paragraph 87 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 87.

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 the expiration of the '017 Patent. Defendants' Detailed Statement includes no non-infringement arguments for the '017 Patent.

ANSWER: Paragraph 88 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 88.

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.

ANSWER: Paragraph 89 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 89.

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.

ANSWER: Paragraph 90 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 90.

91. Gilead has no adequate remedy at law.

ANSWER: Paragraph 91 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 91.

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).

ANSWER: Paragraph 92 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 92.

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.

ANSWER: Paragraph 93 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 93.

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).

ANSWER: Paragraph 94 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 94.

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.

ANSWER: Paragraph 95 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 95.

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.

ANSWER: Paragraph 96 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 96.

COUNT 4
(INFRINGEMENT OF THE '169 PATENT)

97. The above allegations are incorporated herein by reference.

ANSWER: Defendants' responses to Plaintiff's 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.

ANSWER: Paragraph 98 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 98.

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.

ANSWER: Paragraph 99 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 99.

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.

ANSWER: Paragraph 100 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 100.

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.

ANSWER: Paragraph 101 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 101.

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.

ANSWER: Paragraph 102 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 102.

103. Gilead has no adequate remedy at law.

ANSWER: Paragraph 103 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 103.

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).

ANSWER: Paragraph 104 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 104.

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.

ANSWER: Paragraph 105 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 105.

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).

ANSWER: Paragraph 106 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 106.

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.

ANSWER: Paragraph 107 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 107.

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.

ANSWER: Paragraph 108 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 108.

COUNT 5
(INFRINGEMENT OF THE '953 PATENT)

109. The above allegations are incorporated herein by reference.

ANSWER: Defendants' responses to Plaintiff's 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.

ANSWER: Paragraph 110 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 110.

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.

ANSWER: Paragraph 111 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 111.

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

ANSWER: Paragraph 112 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 112.

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.

ANSWER: Paragraph 113 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 113.

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.

ANSWER: Paragraph 114 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 114.

115. Gilead has no adequate remedy at law.

ANSWER: Paragraph 115 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 115.

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).

ANSWER: Paragraph 116 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 116.

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.

ANSWER: Paragraph 117 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 117.

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).

ANSWER: Paragraph 118 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 118.

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.

ANSWER: Paragraph 119 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 119.

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.

ANSWER: Paragraph 120 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 120.

COUNT 6
(INFRINGEMENT OF THE '012 PATENT)

121. The above allegations are incorporated herein by reference.

ANSWER: Defendants' responses to Plaintiff's 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.

ANSWER: Paragraph 122 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants admit that they filed their

ANDA with the FDA, and that Defendants seek regulatory approval from the FDA for their ANDA. The content of Defendants' ANDA speaks for itself. Except as expressly admitted, Defendants deny the allegations of Paragraph 122.

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.

ANSWER: Paragraph 123 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 123.

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.

ANSWER: Paragraph 124 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 124.

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.

ANSWER: Paragraph 125 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 125.

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.

ANSWER: Paragraph 126 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 126.

127. Gilead has no adequate remedy at law.

ANSWER: Paragraph 127 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 127.

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).

ANSWER: Paragraph 128 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 128.

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.

ANSWER: Paragraph 129 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 129.

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).

ANSWER: Paragraph 130 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 130.

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.

ANSWER: Paragraph 131 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 131.

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.

ANSWER: Paragraph 132 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Defendants deny the allegations of Paragraph 132.

PLAINTIFF'S PRAYER FOR RELIEF

All allegations in Plaintiff's Complaint that are not expressly admitted by Defendants are denied. Defendants deny that Plaintiff is entitled to any of the relief sought in its Prayer for Relief.

DEFENDANTS' SEPARATE DEFENSES

Without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not expressly admitted, Defendants assert the following Separate Defenses to Plaintiff's Complaint without assuming the burden of proof on any defense that would otherwise rest on Plaintiff. Defendants reserve the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

FIRST SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 10,675,296)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Defendants' ANDA No. 220566 has not infringed, do not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '296 patent.

SECOND SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 10,675,296)

The '296 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

THIRD SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,266,681)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Defendants' ANDA No. 220566 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '681 patent.

FOURTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,266,681)

The '681 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

FIFTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,975,017)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Defendants' ANDA No. 220566 has not infringed, do not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '017 patent.

SIXTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,975,017)

The '017 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

SEVENTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,491,169)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Defendants' ANDA No. 220566 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '169 patent.

EIGHTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,491,169)

The '169 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

NINTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,903,953)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Defendants' ANDA No. 220566 has not infringed, do not infringe, and would not, if

marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '953 patent.

TENTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,903,953)

The '953 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

ELEVENTH SEPARATE DEFENSE
(No Infringement of U.S. Patent No. 11,975,012)

The manufacture, use, or sale, offer for sale, or importation of the products that are the subject of Defendants' ANDA No. 220566 has not infringed, do not infringe, and would not, if marketed, manufactured, used, sold, offered for sale, or imported into the United States, infringe any valid or enforceable claim of the '012 patent.

TWELFTH SEPARATE DEFENSE
(Invalidity of U.S. Patent No. 11,975,012)

The '012 patent and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101 *et seq*. including, *inter alia*, §§ 102, 103, and/or 112, or under judicially-created bases for invalidation, including but not limited to, obviousness-type double patenting.

THIRTEENTH SEPARATE DEFENSE
(Failure to State a Claim for Exceptional Case)

Plaintiff's Complaint fails to state a claim for exceptional case under 35 U.S.C. § 285. Defendants' actions in defending this case do not give rise to an exceptional case.

RESERVATION OF DEFENSES

Defendants reserve any and all defenses available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

Dated: September 29, 2025

Respectfully submitted,

s/ Kaan Ekiner

Kaan Ekiner
COZEN O'CONNOR
1201 N. Market Street
Suite 1001
Wilmington, DE 19801
(302) 295-2046
kekiner@cozen.com

Attorneys for Defendants Aspiro Pharma Ltd., Hetero USA, Inc., and Hetero Labs Ltd.

OF COUNSEL:

W. Blake Coblentz
Aaron S. Lukas
COZEN O'CONNOR
2001 M Street, NW, Suite 500
Washington, DC 20036
(202) 912-4800
wcoblentz@cozen.com
alukas@cozen.com

Keri L. Schaubert
COZEN O'CONNOR
3 WTC, 175 Greenwich Street, 55th Floor
New York, NY 10007
(212) 509-9400
kschaubert@cozen.com

CERTIFICATE PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: September 29, 2025

s/ Kaan Ekiner
Kaan Ekiner

CERTIFICATE OF SERVICE

I hereby certify that on September 29, 2025, a true and correct copy of the foregoing **DEFENDANTS ASPIRO PHARMA LTD., HETERO USA, INC., AND HETERO LABS LTD.'S ANSWER AND SEPARATE DEFENSES TO PLAINTIFF'S COMPLAINT** was filed electronically with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all counsel of record.

s/ Kaan Ekiner
Kaan Ekiner