Rebekah R. Conroy
Surinder K. Aggarwal
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: (973) 400-181
rconroy@stoneconroy.com
saggawaral@stoneconroy.com

OF COUNSEL:
Neal Seth *(pro hac vice)*
Wesley E. Weeks *(pro hac vice)*
WILEY REIN LLP
2050 M Street NW
Washington, DC 20036
Tel: (202) 719-7000
nseth@wiley.law
wweeks@wiley.law

Attorneys for Defendants Hetero Labs Limited Unit V and Hetero USA, Inc.

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

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, and SLOAN-KETTERING INSTITUTE FOR CANCER RESEARCH, Plaintiffs, v. HETERO LABS LIMITED UNIT V, and HETERO USA, INC., Defendants.	Honorable Stanley R. Chesler Civil Action No. 2:22-cv-03212(SRC)(LDW) **(Filed Electronically)**

DEFENDANTS HETRO LABS LIMITED UNIT V AND HETERO USA, INC.'S ANSWER TO FIRST AMENDED COMPALINT, DEFENSES AND COUNTERCLAIMS

Defendants Hetero Labs Limited Unit V and Hetero USA, Inc. (collectively, "Hetero"), by their undersigned attorney, for their Answer to the Complaint for Patent Infringement filed by Plaintiffs Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), The Regents of the University of California ("Regents"), and Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") (collectively, "Plaintiffs"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Hetero denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 8,445,507 ("the 507 Patent"), 9,481,663 ("the 663 Patent"), 9,884,054 ("the 054 Patent"), RE49,353 ("the RE353 Patent"), 10,702,508 ("the 508 Patent"), and 10,849,888 ("the 888 Patent") (collectively, the "Patents-In-Suit").

ANSWER: Paragraph 1 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiffs' Complaint purports to assert an action for alleged infringement of United States Patent Nos. 8,445,507 ("the '507 Patent"), 9,481,663 ("the '663 Patent"), 9,884,054 ("the '054 Patent"), RE49,353 ("the RE353 Patent"), 10,702,508 ("the '508 Patent"), and 10,849,888 ("the '888 Patent"). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

2. This action relates to the submission of Abbreviated New Drug Application No. 217185 ("the ANDA") by Defendants to the United States Food and Drug Administration ("FDA")

seeking approval to market a proposed generic version of Erleada® ("Proposed ANDA Product") prior to the expiration of the Patents-In-Suit.

ANSWER: Paragraph 2 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiffs' Complaint purports to assert an action for patent infringement based on Hetero's filing of Abbreviated New Drug Application ("ANDA") No. 217185 seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market generic versions of Erleada® prior to the expiration of United States Patent Nos. 8,445,507 ("the '507 Patent"), 9,481,663 ("the '663 Patent"), 9,884,054 ("the '054 Patent"), RE49,353 ("the RE353 Patent"), 10,702,508 ("the '508 Patent"), and 10,849,888 ("the '888 Patent"). Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 2 of the Complaint and therefore denies them.

THE PARTIES

3. Aragon is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 10990 Wilshire Boulevard, Suite 440, Los Angeles, California 90024.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 3 of the Complaint and, therefore, denies all allegations.

4. JBI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 4 of the Complaint and, therefore, denies all allegations.

5. Regents is a California non-profit constitutional corporation and the governing body of an educational institution, having its principal place of business at 1111 Franklin Street, Oakland, California 94607.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 5 of the Complaint and, therefore, denies all allegations.

6. Sloan-Kettering is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 1275 York Avenue, New York, New York 10065.

ANSWER: Hetero is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 6 of the Complaint and, therefore, denies all allegations.

7. On information and belief, Hetero Labs is a corporation organized under the laws of India, having its principal place of business at Sy. No.: 439, 440, 441 & 458, TSIIC Formulation SEZ, Jadcherla Mandal, Polepally Village, Mahabubnagar, Telangana, India 509301.

ANSWER: Hetero admits that Hetero Labs Limited 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. Hetero denies any remaining allegations contained in Paragraph 7 of the Complaint.

8. On information and belief, Hetero USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

ANSWER: Admitted.

JURISDICTION AND VENUE

9. This is an action for patent infringement arising under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including § 271(e)(2), and also including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02 for patent infringement arising under 35 U.S.C. § 100 *et seq.*, including § 271(a)-(c).

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that this Court has subject matter jurisdiction over Plaintiffs' claims for infringement under only 35 U.S.C. § 271(e)(2)(A). Hetero denies that this Court has subject matter jurisdiction over any claims for infringement asserted by Plaintiffs under any other provision. Hetero denies any remaining allegations contained in Paragraph 9 of the Complaint.

10. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest that the Court has subject matter jurisdiction over this action. Hetero denies all remaining allegations of Paragraph 10.

11. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 11.

12. Defendants do not contest, for purposes of this action, the propriety of venue and jurisdiction in this judicial district. *See* ECF No. 21 (¶ 12).

ANSWER: Solely for purposes of this action, Hetero does not contest the propriety of venue and jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 12.

13. On information and belief, Defendants cooperate, collaborate, or act in concert for the purposes of manufacturing, selling, marketing, distributing, and importing generic drug products in New Jersey and throughout the United States.

ANSWER: Denied.

14. On information and belief, Hetero Labs has substantial, continuous, and systematic contacts with New Jersey.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 14.

15. On information and belief, Hetero Labs develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale 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 may be required, solely for purposes of this action, Hetero does

not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 15.

16. On information and belief, Hetero Labs, alone or together with Hetero USA, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in New Jersey.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 16.

17. On information and belief, Hetero Labs consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-20-cv-14389, *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-15449, *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-05797, *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-17463, *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-14111.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 17.

18. This Court has personal jurisdiction over Hetero Labs by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume

of prescription drugs in New Jersey; and (4) its conduct by and through, and in concert with, Hetero USA.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 18.

19. This Court has personal jurisdiction over Hetero Labs because, *inter alia*, this action arises from actions of Hetero Labs directed toward New Jersey. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Proposed ANDA Product prior to the expiration of the Patents-In-Suit. If FDA approval is obtained, the Proposed ANDA Product would be sold in New Jersey, causing injury to Plaintiffs in New Jersey.

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 19.

20. Exercising personal jurisdiction over Hetero Labs in this district would not be unreasonable given Hetero Labs' contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 20.

21. In the alternative, this Court has personal jurisdiction over Hetero Labs because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met: (a) Plaintiffs' claims arise under federal law; (b) Hetero Labs is a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Hetero Labs has sufficient contacts with the United States as a whole, including, but not limited to, filing Abbreviated New Drug Applications with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Hetero Labs satisfies due process, and is consistent with the United States Constitution and Laws.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 21.

22. Venue is proper under 28 U.S.C. § 1391(c)(3) because Hetero Labs is a foreign corporation.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 22.

23. On information and belief, Hetero USA has substantial, continuous, and systematic contacts with New Jersey.

ANSWER: Paragraph 23 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does

not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 23.

24. On information and belief, Hetero USA develops, manufactures, markets, and distributes pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

ANSWER: Paragraph 24 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 24.

25. On information and belief, Hetero USA has substantial, continuous, and systematic contacts with New Jersey, including that it is registered to do business in New Jersey (Entity Id. No. 0400362826) and is registered as a drug wholesaler in New Jersey (Registration No. 5004050).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 25.

26. On information and belief, Hetero USA has a regular and established business at 1035 Centennial Avenue, Piscataway, New Jersey 08854 and has registered this address with the New Jersey Department of Health.

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 26.

27. On information and belief, Hetero USA, alone or together with Hetero Labs, has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led or will lead to foreseeable harm and injury to Plaintiffs throughout the United States, including in New Jersey.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 27.

28. On information and belief, Hetero USA consented to jurisdiction, did not contest jurisdiction, or asserted counterclaims in New Jersey in one or more prior litigations, for example: *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-20-cv-14389; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-15449; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-19-cv-05797; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-17463; *Celgene Corp. v. Hetero Labs Ltd.*, No. 2-18-cv-14111.

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 28.

29. This Court has personal jurisdiction over Hetero USA by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; and (4) its conduct by and through, and in concert with, Hetero Labs.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 29.

30. This Court has personal jurisdiction over Hetero USA because, *inter alia*, this action arises from actions of Hetero USA directed toward New Jersey. For example, Defendants submitted the ANDA seeking approval to commercially manufacture, use, sell, offer for sale, or import the Proposed ANDA Product prior to the expiration of the Patents-In-Suit. If FDA approval is obtained, the Proposed ANDA Product would be sold in New Jersey, causing injury to Plaintiffs in New Jersey.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 30.

31. Exercising personal jurisdiction over Hetero USA in this district would not be unreasonable given Hetero USA's contacts in this district and the interest in this district of resolving disputes related to products to be sold herein.

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 31.

32. On information and belief, Hetero USA has committed an act of infringement in this judicial district by submitting the ANDA with the FDA on or about February 14, 2022.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 32.

33. On information and belief, Defendants are cooperating, collaborating, or acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, or selling with respect to the Proposed ANDA Product.

ANSWER: Paragraph 33 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 33.

34. On information and belief, Hetero USA has committed acts or caused acts to be committed in preparation for and submission of the ANDA in this judicial district.

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 34.

35. On information and belief, Hetero USA will directly benefit if the ANDA is approved by participating in the distribution, offer for sale, or sale of the Proposed ANDA Product.

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest personal jurisdiction in this District. Hetero denies all remaining allegations of Paragraph 35.

36. Venue is proper under 28 U.S.C. § 1400(b) because Hetero USA has committed an act of infringement and has a regular and established place of business in this judicial district.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, solely for purposes of this action, Hetero does not contest the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 36.

ERLEADA®

37. JBI holds approved New Drug Application No. 210951 for apalutamide, which is prescribed and sold as Erleada®.

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies New Drug Application ("NDA") No. 210951 in connection with Erleada® and further identifies JBI as the holder of NDA No. 210951. All remaining allegations are denied.

38. On information and belief, Defendants know that JBI holds approved New Drug Application No. 210951.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies New Drug Application ("NDA") No. 210951 in connection with Erleada® and further identifies JBI as the holder of NDA No. 210951. All remaining allegations are denied.

39. Erleada® is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Erleada® is supplied as tablets for oral administration containing the active pharmaceutical ingredient apalutamide.

ANSWER: Hetero admits that the prescribing information for Erleada® speaks for itself. All remaining allegations are denied.

40. The International Union of Pure and Applied Chemistry (IUPAC) name for apalutamide is 4-[7-(6-Cyano-5-trifluoromethylpyridin-3-yl)-8-oxo-6-thioxo-5,7-diazaspiro[3.4]oct-5-yl]-2-fluoro-N-methylbenzamide.

ANSWER: Hetero admits that the prescribing information for Erleada® speaks for itself. All remaining allegations are denied.

THE PATENTS-IN-SUIT

41. On May 21, 2013, the 507 Patent, titled "Androgen Receptor Modulator for the Treatment of Prostate Cancer and Androgen Receptor-Associated Diseases" was duly and legally issued to Regents as assignee. A copy of the 507 Patent is attached as Exhibit A.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '507 patent is attached to the Complaint as Exhibit A; that the '507 patent is entitled "Androgen Receptor Modulator for the Treatment of Prostate Cancer and Androgen Receptor-Associated Diseases"; that the issue date identified on the cover of the '507 patent is May 21, 2013; and that Regents is identified as the assignee of the '507 patent. Hetero denies that the '507 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 41 of the Complaint.

42. On November 1, 2016, the 663 Patent, titled "Crystalline Forms of an Androgen Receptor Modulator" was duly and legally issued to Aragon and Sloan-Kettering as assignees. A copy of the 663 Patent is attached as Exhibit B.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '663 patent is attached to the Complaint as Exhibit B; that the '663 patent is entitled "Crystalline Forms of an Androgen Receptor Modulator"; that the issue date identified on the cover of the '663 patent is November 1, 2016; and that Aragon and Sloan-Kettering is identified as the assignee of the '663 patent. Hetero denies that the '663 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 42 of the Complaint.

43. On February 6, 2018, the 054 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 054 Patent is attached as Exhibit C.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '054 patent is attached to the Complaint as Exhibit C; that the '054 patent is entitled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer"; that the issue date identified on the cover of the '054 patent is February 6, 2018; and that Aragon is identified as the assignee of the '054 patent. Hetero denies that the '054 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 43 of the Complaint.

44. On January 3, 2023, the RE353 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as

assignee. The RE353 Patent is a reissue of U.S. Patent No. 10,052,314 ("the 314 Patent"), previously asserted in this case. A copy of the RE353 Patent is attached as Exhibit D.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the RE353 patent is attached to the Complaint as Exhibit D; that the RE353 patent is entitled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer"; that the issue date identified on the cover of the RE353 patent is January 3, 2023; that Aragon is identified as the assignee of the RE353 patent; and that the RE355 patent is a reissue of the '314 patent previously asserted in this case. Hetero denies that the RE353 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 44 of the Complaint.

45. On July 7, 2020, the 508 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 508 Patent is attached as Exhibit E.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '508 patent is attached to the Complaint as Exhibit E; that the '508 patent is entitled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer"; that the issue date identified on the cover of the '508 patent is July 7, 2020; and that Aragon is identified as the assignee of the '508 patent. Hetero denies that the '508 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 45 of the Complaint.

46. On December 1, 2020, the 888 Patent, titled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 888 Patent is attached as Exhibit F.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that what purports to be a copy of the '888 patent is attached to the Complaint as Exhibit F; that the '888 patent is entitled "Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer"; that the issue date identified on the cover of the '888 patent is December 1, 2020; and that Aragon is identified as the assignee of the '888 patent. Hetero denies that the '888 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 46 of the Complaint.

47. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-In-Suit are listed in the FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also known as the "Orange Book") as covering Erleada®.

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the Patents-In-Suit in connection with New Drug Application ("NDA") No. 210951 for Erleada®. All remaining allegations are denied.

48. On information and belief, Defendants know that the Patents-In-Suit are listed in the Orange Book as covering Erleada®.

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the Patents-In-Suit in connection with New Drug Application ("NDA") No. 210951 for Erleada®. All remaining allegations are denied.

DEFENDANTS' NOTICE LETTERS AND THE ANDA

49. By letter dated April 18, 2022, addressed to JBI, Sloan-Kettering, Aragon and Regents ("2022 Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217185 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The 2022 Notice Letter stated that the ANDA seeks the FDA approval necessary to engage in activities that constitute or require the commercial manufacture, use, sale, offer for sale in, or importation into the United States, of the Proposed ANDA Product, described in the 2022 Notice Letter as "Apalutamide Tablets; Oral 60 mg" prior to the expiration of the 507 Patent, the 663 Patent, the 054 Patent, the 314 Patent, the 508 Patent, and the 888 Patent.

ANSWER: Hetero admits to sending a Notice Letter dated April 18, 2022, to Plaintiffs, informing Plaintiffs that Hetero is seeking approval to engage in the commercial manufacture, use, and sale of the product described in its ANDA as soon as legally permissible, prior to the expiration of the Patents-in-Suit. All other allegations of Paragraph 49 are denied.

50. The 2022 Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

51. The ANDA includes a Paragraph IV Certification that the claims of the 507 Patent, the 663 Patent, the 054 Patent, the 314 Patent, the 508 Patent, and the 888 Patent are invalid, unenforceable, or not infringed.

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

52. The 2022 Notice Letter stated that the Proposed ANDA Product will not literally infringe the claims of the 663 Patent because the Proposed ANDA Product "is not the claimed polymorphic form."

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

53. The 2022 Notice Letter stated that the Proposed ANDA Product will not infringe the claims of the 663 Patent under the doctrine of equivalents because the Proposed ANDA Product "is not the claimed polymorphic form."

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

54. The 2022 Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA. The parties agreed on revised terms for the OCA. On May 6, 2022, Defendants produced documents that Defendants purported to be the ANDA.

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

55. On information and belief, the Proposed ANDA Product contains some amount of crystalline Form B of apalutamide.

ANSWER: Denied.

56. On information and belief, the drug substance in and used for the Proposed ANDA Product contains some amount of crystalline Form B of apalutamide.

ANSWER: Denied.

57. Plaintiffs commenced this action within 45 days of the date of receipt of the 2022 Notice Letter.

ANSWER: Admitted.

58. Defendants filed an Answer, along with Affirmative Defenses, on August 5, 2022.

ANSWER: Admitted.

59. On January 3, 2023, the RE353 Patent issued as a reissue of the 314 Patent. Accordingly, Plaintiffs submitted Form 3542 identifying the RE353 Patent for listing in the Orange Book.

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that the RE353 Patent issued on January 3, 2023 as a reissue of the 314 patent. Hetero admits that electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the RE353 Patent in connection with New Drug Application ("NDA") No. 210951 for Erleada®. All remaining allegations are denied.

60. On January 27, 2023, Plaintiffs notified Defendants of the RE353 Patent.

ANSWER: Admitted.

61. By letter dated September 11, 2023, addressed to JBI, Sloan-Kettering, Aragon, and Regents ("2023 Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 217185 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The 2023 Notice Letter stated that the ANDA seeks the FDA approval necessary to engage in activities that constitute or require the commercial manufacture, use, sale, offer for sale in, or importation into the United States, of the Proposed ANDA Product, described in the 2023 Notice Letter as "Apalutamide Tablets; Oral 60 mg" prior to the expiration of the RE353 Patent.

ANSWER: Hetero admits to sending a Notice Letter dated September 11, 2023, to Plaintiffs, informing Plaintiffs that Hetero is seeking approval to engage in the commercial

manufacture, use, and sale of the product described in its ANDA as soon as legally permissible, prior to the expiration of the RE353 patent. All other allegations of Paragraph 61 are denied.

62. The 2023 Notice Letter stated that Defendants had received a Paragraph IV acknowledgement letter from the FDA.

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

63. The ANDA includes a Paragraph IV Certification that the claims of the RE353 Patent are invalid, unenforceable, and/or will not be infringed.

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

64. The 2023 Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA.

ANSWER: Hetero admits that its Notice Letter speaks for itself. All remaining allegations are denied.

65. On information and belief, Defendants have actual knowledge of each of the Patents-In-Suit, at least as shown by the discussion of the Orange Book listing for Erleada® in the 2022 Notice Letter and 2023 Notice Letter.

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

66. On information and belief, Defendants seek to obtain FDA approval to manufacture, use, import, offer to sell, and sell its Proposed ANDA Product in the United States before the expiration of the Patents-In-Suit.

ANSWER: Admitted.

67. Plaintiffs are timely amending the pleadings to include allegations of infringement of the RE353 Patent.

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero admits that Plaintiffs are amending the pleadings to include allegations of infringement of the RE535 Patent. All remaining allegations are denied.

COUNT I – CLAIM FOR INFRINGEMENT OF THE 507 PATENT

68. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to Paragraphs 1-67, as if fully set forth herein.

69. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

ANSWER: Admitted.

70. On information and belief, because the Proposed ANDA Product contains apalutamide, the Proposed ANDA Product and the use of the Proposed ANDA Product infringe at least claims 1, 2, 3, 11, 19, and 22 of the 507 Patent.

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

71. On information and belief, the Proposed ANDA Product infringes at least claims 1 and 22 of the 507 Patent because it contains the compound apalutamide.

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

72. On information and belief, the Proposed ANDA Product infringes at least claims 2 and 11 of the 507 Patent because it is a pharmaceutical composition comprising a therapeutically effective amount of the compound apalutamide and a pharmaceutically acceptable carrier, diluent, or adjuvant.

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

73. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 3 and 19 of the 507 Patent because physicians and/or patients will practice a method for treating a hyperproliferative disorder, specifically prostate cancer, said method comprising administering, causing to be administered, or directing the administration of the compound apalutamide to a subject, specifically a patient, in need of such treatment, thereby treating the prostate cancer.

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 73.

74. On information and belief, Defendants will induce infringement of at least claims 3 and 19 of the 507 Patent by actively inducing the use of the Proposed ANDA Product to practice a method for treating a hyperproliferative disorder, specifically prostate cancer, said method comprising administering, causing to be administered, or directing the administration of the compound apalutamide to a subject, specifically a patient, in need of such treatment, thereby treating the prostate cancer.

ANSWER: Paragraph 74 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 74.

75. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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

76. The 2022 Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 507 Patent. The 2022 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 507 Patent.

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

77. On information and belief, Defendants have actual knowledge of the 507 Patent, at least as shown by the 2022 Notice Letter.

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

78. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, by submitting

or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 507 Patent.

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

79. On information and belief, the Proposed ANDA Product and its use, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, under at least one of 35 U.S.C. § 271(a), (b), or (c).

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

80. On information and belief, the manufacture, use, import, offer to sell, or sale of the Proposed ANDA Product will directly infringe the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

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

81. On information and belief, physicians and/or patients will directly infringe the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, by the use of the Proposed ANDA Product upon approval.

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

82. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients,

in a manner that infringes the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22, for the pecuniary benefit of Defendants.

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

83. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22. On information and belief, Defendants will actively induce the infringement of the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

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

84. On information and belief, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22. On information and belief, Defendants will thus contribute to the infringement of the claims of the 507 Patent, including at least claims 1, 2, 3, 11, 19, and 22.

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

85. On information and belief, the actions described in this Complaint relating to the ANDA and the 507 Patent were done by and for the benefit of Defendants.

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 85.

86. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 86.

COUNT II – CLAIM FOR INFRINGEMENT OF THE 663 PATENT

87. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to Paragraphs 1-86, as if fully set forth herein.

88. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 663 Patent, including at least claims 1, 13, and 17.

ANSWER: Admitted.

89. On information and belief, because the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product contain some amount of crystalline Form B of apalutamide, the Proposed ANDA Product and the drug substance infringe at least claims 1, 13, and 17 of the 663 Patent.

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

90. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe at least claim 1 of the 663 Patent because they contain crystalline Form B of apalutamide that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

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

91. On information and belief, the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product infringe at least claim 13 of the 663 Patent because they are a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta.

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

92. On information and belief, the use of the Proposed ANDA Product and the drug substance in and used for the Proposed ANDA Product will infringe at least claim 17 of the 663 Patent because physicians and/or patients will practice a method of treating prostate cancer in a mammal, specifically a patient, said method comprising administering, causing to be administered, or directing the administration of a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta to the patient in need of such treatment.

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

93. On information and belief, Defendants will induce infringement of at least claim 17 of the 663 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating prostate cancer in a mammal, specifically a patient, said method comprising administering, causing to be administered, or directing the administration of a pharmaceutical composition comprising apalutamide and at least one additional ingredient selected from pharmaceutically acceptable carriers, diluents and excipients, in which the apalutamide in the composition comprises the crystalline Form B that is characterized as having at least one of an X-Ray powder diffraction (XRPD) pattern substantially the same as shown in FIG. 2 of the 663 Patent or an X-ray powder diffraction (XRPD) pattern with characteristic peaks at 12.1±0.1° 2-Theta, 16.0±0.1° 2-Theta, 16.7±0.1° 2-Theta, 20.1±0.1° 2-Theta, 20.3±0.1° 2-Theta to the patient in need of such treatment.

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

94. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 663 Patent, including at least claims 1, 13, and 17, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 663 Patent, including at least claims 1, 13, and 17, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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

95. The 2022 Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 663 Patent. The 2022 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 663 Patent.

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

96. On information and belief, Defendants have actual knowledge of the 663 Patent, at least as shown by the 2022 Notice Letter.

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

97. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 663 Patent, including at least claims 1, 13, and 17, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 663 Patent.

ANSWER: Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 97.

98. On information and belief, the Proposed ANDA Product and its use, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 663 Patent, including at least claims 1, 13, and 17, under at least one of 35 U.S.C. § 271(a), (b), or (c).

ANSWER: Paragraph 98 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 98.

99. On information and belief, the manufacture, use, import, offer to sell, or sale of the Proposed ANDA Product will directly infringe the claims of the 663 Patent, including at least claims 1, 13, and 17.

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

100. On information and belief, physicians and/or patients will directly infringe the claims of the 663 Patent, including at least claims 1, 13, and 17, by the use of the Proposed ANDA Product upon approval.

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

101. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17, for the pecuniary benefit of Defendants.

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

102. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17. On information and belief, Defendants will actively induce the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

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

103. On information and belief, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 663 Patent, including at least claims 1, 13, and 17. On information and belief, Defendants will thus contribute to the infringement of the claims of the 663 Patent, including at least claims 1, 13, and 17.

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

104. On information and belief, the actions described in this Complaint relating to the ANDA and the 663 Patent were done by and for the benefit of Defendants.

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

105. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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

COUNT III – CLAIM FOR INFRINGEMENT OF THE 054 PATENT

106. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to Paragraphs 1-105, as if fully set forth herein.

107. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 054 Patent, including at least claims 6 and 15.

ANSWER: Admitted.

108. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 6 and 15 of the 054 Patent because physicians and/or patients will practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of a therapeutically effective amount of an anti-androgen to a male human in need of such treatment, wherein the anti-androgen is apalutamide that is administered orally to the male human at a dose of about 240 mg per day.

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

109. On information and belief, Defendants will induce infringement of at least claims 6 and 15 of the 054 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of a therapeutically effective amount of an anti-androgen to a male human in need of such treatment, wherein the anti-androgen is apalutamide that is administered orally to the male human at a dose of about 240 mg per day.

ANSWER: Paragraph 109 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 109.

110. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 054 Patent, including at least claims 6 and 15, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label

provided by Defendants in practicing the claims of the 054 Patent, including at least claims 6 and 15, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Paragraph 110 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 110.

111. The 2022 Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 054 Patent. The 2022 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 054 Patent.

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

112. On information and belief, Defendants have actual knowledge of the 054 Patent, at least as shown by the 2022 Notice Letter.

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

113. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 054 Patent, including at least claims 6 and 15, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 054 Patent.

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

114. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of

the 054 Patent, including at least claims 6 and 15, under at least one of 35 U.S.C. § 271(a), (b), or (c).

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

115. On information and belief, physicians and/or patients will directly infringe the claims of the 054 Patent, including at least claims 6 and 15, by the use of the Proposed ANDA Product upon approval.

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

116. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 054 Patent, including at least claims 6 and 15, for the pecuniary benefit of Defendants.

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

117. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 054 Patent, including at least claims 6 and 15. On information and belief, Defendants will actively induce the infringement of the claims of the 054 Patent, including at least claims 6 and 15.

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

118. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 054 Patent, including at least claims 6 and 15. On information and belief, Defendants will thus contribute to the infringement of the claims of the 054 Patent, including at least claims 6 and 15.

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

119. On information and belief, the actions described in this Complaint relating to the ANDA and the 054 Patent were done by and for the benefit of Defendants.

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

120. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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

COUNT IV – CLAIM FOR INFRINGEMENT OF THE RE353 PATENT

121. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to Paragraphs 1-120, as if fully set forth herein.

122. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the RE353 Patent, including at least claims 1 and 19.

ANSWER: Admitted.

123. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 1 and 19 of the RE353 Patent because physicians and/or patients will practice a method

of treating a male human with non-metastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of an anti-androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide, wherein said method further comprises administering a gonadotropin releasing hormone (GnRH) agonist.

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

124. Defendants will induce infringement of at least claims 1 and 19 of the RE353 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating a male human with non-metastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of an anti-androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide, wherein said method further comprises administering a gonadotropin releasing hormone (GnRH) agonist.

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

125. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the RE353 Patent, including at least claims 1 and 19, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the RE353 Patent, including at least claims 1

and 19, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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

126. The 2023 Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the RE353 Patent. The 2023 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the RE353 Patent.

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

127. On information and belief, Defendants have actual knowledge of the RE353 Patent, at least as shown by the 2023 Notice Letter.

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

128. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the RE353 Patent, including at least claims 1 and 19, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the RE353 Patent.

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

129. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of

the RE353 Patent, including at least claims 1 and 19, under at least one of 35 U.S.C. § 271(a), (b), or (c).

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

130. On information and belief, physicians and/or patients will directly infringe the claims of the RE353 Patent, including at least claims 1 and 19, by the use of the Proposed ANDA Product upon approval.

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

131. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the RE353 Patent, including at least claims 1 and 19, for the pecuniary benefit of Defendants.

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

132. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the RE353 Patent, including at least claims 1 and 19. On information and belief, Defendants will actively induce the infringement of the claims of the RE353 Patent, including at least claims 1 and 19.

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

133. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the RE353 Patent, including at least claims 1 and 19. On information and belief, Defendants will thus contribute to the infringement of the claims of the RE353 Patent, including at least claims 1 and 19.

ANSWER: Paragraph 133 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 133.

134. On information and belief, the actions described in this Complaint relating to the ANDA and the RE353 Patent were done by and for the benefit of Defendants.

ANSWER: Paragraph 134 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 134.

135. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 135 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 135.

COUNT V – CLAIM FOR INFRINGEMENT OF THE 508 PATENT

136. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to Paragraphs 1-135, as if fully set forth herein.

137. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7.

ANSWER: Admitted.

138. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 1 and 2 of the 508 Patent because physicians and/or patients will practice a method of

improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human, an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein the median metastasis free survival is about 40.5 months.

ANSWER: Paragraph 138 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 138.

139. On information and belief, Defendants will induce infringement of at least claims 1 and 2 of the 508 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human, an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein the median metastasis free survival is about 40.5 months.

ANSWER: Paragraph 139 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 139.

140. On information and belief, the use of the Proposed ANDA Product will infringe claims at least 5 and 7 of the 508 Patent because physicians and/or patients will practice a method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human, an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein a drug product label for a reference listed drug for such approved drug product comprises metastasis free survival data, wherein the

metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months.

ANSWER: Paragraph 140 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 140.

141. On information and belief, Defendants will induce infringement of at least claims 5 and 7 of the 508 Patent by actively inducing the use of the Proposed ANDA Product as a method of improving metastasis free survival in a male human with nonmetastatic castration-resistant prostate cancer, said method comprising administering, causing to be administered, or directing the administration of, to said male human, an approved drug product comprising apalutamide in combination with androgen deprivation therapy, wherein a drug product label for a reference listed drug for such approved drug product comprises metastasis free survival data, wherein the metastasis free survival data for apalutamide in combination with androgen deprivation therapy arm has a median of about 40.5 months.

ANSWER: Paragraph 141 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 141.

142. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Paragraph 142 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 142.

143. The 2022 Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 508 Patent. The 2022 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 508 Patent.

ANSWER: Paragraph 143 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 143.

144. On information and belief, Defendants have actual knowledge of the 508 Patent, at least as shown by the 2022 Notice Letter.

ANSWER: Paragraph 144 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 144.

145. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 508 Patent.

ANSWER: Paragraph 145 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 145.

146. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 508 Patent, including at least claims 1, 2, 5, and 7, under at least one of 35 U.S.C. § 271(a), (b), or (c).

ANSWER: Paragraph 146 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 146.

147. On information and belief, physicians and/or patients will directly infringe the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, by the use of the Proposed ANDA Product upon approval.

ANSWER: Paragraph 147 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 147.

148. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7, for the pecuniary benefit of Defendants.

ANSWER: Paragraph 148 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 148.

149. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 508 Patent, including at least claims 1, 2, 5, and 7. On information and belief, Defendants will actively induce the infringement of the claims of the 508 Patent, including at least claims 1, 2, 5, and 7.

ANSWER: Paragraph 149 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 149.

150. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 508 Patent, including at least claims

1, 2, 5, and 7. On information and belief, Defendants will thus contribute to the infringement of the claims of the 508 Patent, including at least claims 1, 2, 5, and 7.

ANSWER: Paragraph 150 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 150.

151. On information and belief, the actions described in this Complaint relating to the ANDA and the 508 Patent were done by and for the benefit of Defendants.

ANSWER: Paragraph 151 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 151.

152. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 152 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 152.

COUNT VI – CLAIM FOR INFRINGEMENT OF THE 888 PATENT

153. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to Paragraphs 1-152, as if fully set forth herein.

154. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 888 Patent, including at least claims 1 and 8.

ANSWER: Admitted.

155. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 1 and 8 of the 888 Patent because physicians and/or patients will practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of an anti-

androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide and wherein said method further comprises orchiectomy.

ANSWER: Paragraph 155 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 155.

156. On information and belief, Defendants will induce infringement of at least claims 1 and 8 of the 888 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating non-metastatic castration-resistant prostate cancer in a male human, said method comprising administering, causing to be administered, or directing the administration of an anti-androgen at a dose of about 240 mg per day to a male human in need of such treatment, wherein the anti-androgen is apalutamide and wherein said method further comprises orchiectomy.

ANSWER: Paragraph 156 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 156.

157. On information and belief, if the FDA approves the ANDA, Defendants will sell or offer to sell the Proposed ANDA Product specifically labeled for use in practicing the claims of the 888 Patent, including at least claims 1 and 8, wherein the Proposed ANDA Product is a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the Proposed ANDA Product in accordance with the instructions or label provided by Defendants in practicing the claims of the 888 Patent, including at least claims 1 and 8, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Paragraph 157 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 157.

158. The 2022 Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 888 Patent. The 2022 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 888 Patent.

ANSWER: Paragraph 158 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 158.

159. On information and belief, Defendants have actual knowledge of the 888 Patent, at least as shown by the 2022 Notice Letter.

ANSWER: Paragraph 159 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 159.

160. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 888 Patent, including at least claims 1 and 8, by submitting or causing to be submitted to the FDA, the ANDA seeking approval to manufacture, use, import, offer to sell or sell the Proposed ANDA Product before the expiration date of the 888 Patent.

ANSWER: Paragraph 160 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 160.

161. On information and belief, the use of the Proposed ANDA Product, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim of the 888 Patent, including at least claims 1 and 8, under at least one of 35 U.S.C. § 271(a), (b), or (c).

ANSWER: Paragraph 161 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 161.

162. On information and belief, physicians and/or patients will directly infringe the claims of the 888 Patent, including at least claims 1 and 8, by the use of the Proposed ANDA Product upon approval.

ANSWER: Paragraph 162 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 162.

163. On information and belief, upon approval, Defendants will take active steps to encourage the use of the Proposed ANDA Product by physicians and/or patients with the knowledge and intent that the Proposed ANDA Product will be used by physicians and/or patients, in a manner that infringes the claims of the 888 Patent, including at least claims 1 and 8, for the pecuniary benefit of Defendants.

ANSWER: Paragraph 163 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 163.

164. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 888 Patent, including at least claims 1 and 8. On information and belief, Defendants will actively induce the infringement of the claims of the 888 Patent, including at least claims 1 and 8.

ANSWER: Paragraph 164 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 164.

165. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 888 Patent, including at least claims 1 and 8. On information and belief, Defendants will thus contribute to the infringement of the claims of the 888 Patent, including at least claims 1 and 8.

ANSWER: Paragraph 165 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 165.

166. On information and belief, the actions described in this Complaint relating to the ANDA and the 888 Patent were done by and for the benefit of Defendants.

ANSWER: Paragraph 166 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 166.

167. Plaintiffs will be irreparably harmed by these infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

ANSWER: Paragraph 167 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 167.

* * *

Hetero denies all allegations not expressly admitted herein. Hetero further denies that Plaintiffs are entitled to any of the relief requested, and requests that the First Amended Complaint be dismissed with prejudice and that Hetero be awarded its fees and costs under 35 U.S.C. § 285 for defending this suit.

HETERO'S DEFENSES

Without prejudice to the denials set forth in its **ANSWER**, without admitting allegations of the First Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Hetero avers and asserts the following separate defenses to the First Amended Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '507 PATENT)

One or more claims of the '507 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '507 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '507 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '507 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '507 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '663 PATENT)

One or more claims of the '663 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '663 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '663 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '663 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '663 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '054 PATENT)

One or more claims of the '054 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

EIGHTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '054 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '054 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '054 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '054 Patent.

TENTH SEPARATE DEFENSE
(INVALIDITY OF THE RE353 PATENT)

One or more claims of the RE353 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

ELEVENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE RE353 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE353 Patent.

TWELFTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE RE353 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the RE353 Patent.

THIRTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '508 PATENT)

One or more claims of the '508 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FOURTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '508 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '508 Patent.

FIFTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '508 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '508 Patent.

SIXTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE '888 PATENT)

One or more claims of the '888 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SEVENTEENTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '888 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '888 Patent.

EIGHTEENTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '888 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 217185 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '888 Patent.

NINETEENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

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

TWENTIETH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiffs' Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

TWENTY-FIRST SEPARATE DEFENSE
(PROSECUTION HISTORY ESTOPPEL)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '507, '663, and '054, RE353, '508, and '888 patents, Plaintiff is estopped from maintaining that any valid or enforceable claim of the '507, '663,'054, RE353, '508, and '888 patents is infringed by the product that is the subject of ANDA No. 217185.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

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

COUNTERCLAIMS

1. For its counterclaims against Counterclaim-Defendants Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), The Regents of the University of California ("Regents"), and Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering") (collectively, "Counterclaim-Defendants"), Counterclaim-Plaintiffs Hetero Labs Limited Unit V and Hetero USA, Inc. (collectively, "Counterclaim-Plaintiffs" or "Hetero"), state as follows:

THE PARTIES

2. On information and belief, Aragon is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 10990 Wilshire Boulevard, Suite 440, Los Angeles, California 90024.

3. On information and belief, JBI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 800/850 Ridgeview Drive, Horsham, Pennsylvania 19044.

4. On information and belief, Regents is a California non-profit constitutional corporation and the governing body of an educational institution, having its principal place of business at 1111 Franklin Street, Oakland, California 94607.

5. On information and belief, Sloan-Kettering is a corporation organized and existing under the laws of the State of New York, having its principal place of business at 1275 York Avenue, New York, New York 10065.

6. Counterclaim-Plaintiff Hetero Labs Limited 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.

7. Counterclaim-Plaintiff Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854.

NATURE OF THE ACTION

9. Hetero seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 8,445,507 ("the '507 Patent"), 9,481,663 ("the '663 Patent"), 9,884,054 ("the '054 Patent"), RE49,353 ("the RE353 Patent"), 10,702,508 ("the '508 Patent"), and 10,849,888 ("the '888 Patent") (collectively, the "Patents-In-Suit") are invalid and/or not infringed.

JURISDICTION AND VENUE

10. This Court has jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

11. This Court has personal jurisdiction over Plaintiffs because, among other reasons, Plaintiffs subjected themselves to the jurisdiction of this Court by filing its complaint here.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiffs' choice of forum.

13. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patents-in-Suit.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

14. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

15. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

16. An NDA must include, among other things, the number of any patent that allegedly claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

17. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

18. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly

submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

19. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

20. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

21. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

22. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

23. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

24. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

25. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

26. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Hetero's ANDA and Plaintiffs' Complaint

27. Hetero submitted Abbreviated New Drug Application ("ANDA") No. 217185 ("Hetero's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of 60 mg apalutamide tablets ("Hetero's ANDA Product").

28. On information and belief, JBI holds approved New Drug Application ("NDA") No. 210951 for Erleada® under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

29. Hetero's ANDA shows that Hetero's ANDA Product are bioequivalent to the products that are the subject of NDA No. 210951.

30. On information and belief, Plaintiffs caused the Patents-in-Suit to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which Plaintiffs submitted, NDA No. 210951.

31. The ’507 patent is entitled “Androgen Receptor Modulator for the Treatment of Prostate Cancer and Androgen Receptor-Associated Diseases”; the issue date identified on the cover of the ’507 patent is May 21, 2013; and Regents is identified as the assignee of the ’507 patent.

32. The ’663 patent is entitled “Crystalline Forms of an Androgen Receptor Modulator”; the issue date identified on the cover of the ’663 patent is November 1, 2016; and Aragon and Sloan-Kettering is identified as the assignee of the ’663 patent.

33. The ’054 patent is entitled “Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer”; the issue date identified on the cover of the ’054 patent is February 6, 2018; and Aragon is identified as the assignee of the ’054 patent.

34. The RE353 patent is entitled “Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer”; the issue date identified on the cover of the RE353 patent is January 3, 2023; the RE353 Patent is a reissue of U.S. Patent No. 10,052,314 (“the 314 Patent”); and Aragon is identified as the assignee of the RE353 patent.

35. The ’508 patent is entitled “Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer”; the issue date identified on the cover of the ’508 patent is July 7, 2020; and Aragon is identified as the assignee of the ’508 patent.

36. The ’888 patent is entitled “Anti-androgens for the Treatment of Non-metastatic Castrate-resistant Prostate Cancer”; the issue date identified on the cover of the ’888 patent is December 1, 2020; and Aragon is identified as the assignee of the ’888 patent.

37. Hetero’s ANDA contains “Paragraph IV” certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero’s ANDA Product.

38. On April 18, 2022, Hetero sent Plaintiffs' written notice of Hetero's Paragraph IV Certifications ("Hetero's First Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's First Notice Letter asserted that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

39. Hetero's First Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Hetero's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

40. On September 11, 2023, Hetero sent Plaintiffs' written notice of Hetero's Paragraph IV Certifications ("Hetero's Second Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's Second Notice Letter asserted that the claims of the RE353 Patent are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

41. Hetero's Second Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Hetero's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

42. On May 27, 2022, Plaintiffs filed the present lawsuit alleging infringement of the Patents-in-Suit. On October 18, 2023, Plaintiffs filed a first amended complaint alleging infringement of the Patents-in-Suit. There has been and now is an actual and justiciable controversy between Hetero and Plaintiffs as to whether Hetero's ANDA Product infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '507 PATENT

43. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

44. There is an actual, substantial, continuing, and justiciable controversy between Plaintiffs and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '507 patent.

45. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the '507 patent is not infringed by Hetero's ANDA or the products or activities described therein.

46. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '507 patent and is not liable for such infringement.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '507 PATENT

47. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

48. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the '507 patent are invalid.

49. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '507 patent are invalid.

50. Hetero is entitled to a declaration that all claims of the '507 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT III: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’663 PATENT

51. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

52. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the filing of Hetero’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero’s ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the ’663 patent.

53. Hetero incorporates by reference Hetero’s First Notice Letter, which contains exemplary and nonlimiting explanations that the ’663 patent is not infringed by Hetero’s ANDA or the products or activities described therein.

54. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’663 patent and is not liable for such infringement.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’663 PATENT

55. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

56. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the ’663 patent are invalid.

57. Hetero incorporates by reference Hetero’s First Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the ’663 patent are invalid.

58. Hetero is entitled to a declaration that all claims of the ’663 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT V: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’054 PATENT

59. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

60. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the filing of Hetero’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero’s ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the ’054 patent.

61. Hetero incorporates by reference Hetero’s First Notice Letter, which contains exemplary and nonlimiting explanations that the ’054 patent is not infringed by Hetero’s ANDA or the products or activities described therein.

62. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’054 patent and is not liable for such infringement.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’054 PATENT

63. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

64. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the ’054 patent are invalid.

65. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '054 patent are invalid.

66. Hetero is entitled to a declaration that all claims of the '054 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT VII: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE RE353 PATENT

67. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

68. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the RE353 patent.

69. Hetero incorporates by reference Hetero's Second Notice Letter, which contains exemplary and nonlimiting explanations that the RE353 patent is not infringed by Hetero's ANDA or the products or activities described therein.

70. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the RE353 patent and is not liable for such infringement.

COUNT VIII: DECLARATORY JUDGMENT OF INVALIDITY OF THE RE353 PATENT

71. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

72. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the RE353 patent are invalid.

73. Hetero incorporates by reference Hetero's Second Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the RE353 patent are invalid.

74. Hetero is entitled to a declaration that all claims of the RE353 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT IX: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '508 PATENT

75. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

76. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '508 patent.

77. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the '508 patent is not infringed by Hetero's ANDA or the products or activities described therein.

78. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '508 patent and is not liable for such infringement.

COUNT X: DECLARATORY JUDGMENT OF INVALIDITY OF THE '508 PATENT

79. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

80. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the '508 patent are invalid.

81. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '508 patent are invalid.

82. Hetero is entitled to a declaration that all claims of the '508 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

COUNT XI: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '888 PATENT

83. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

84. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the filing of Hetero's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringe, have infringed, and/or will infringe any valid and enforceable claim of the '888 patent.

85. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the '888 patent is not infringed by Hetero's ANDA or the products or activities described therein.

86. Hetero is entitled to a declaration that it has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '888 patent and is not liable for such infringement.

COUNT XII: DECLARATORY JUDGMENT OF INVALIDITY OF THE '888 PATENT

87. Hetero incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

88. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the '888 patent are invalid.

89. Hetero incorporates by reference Hetero's First Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the '888 patent are invalid.

90. Hetero is entitled to a declaration that all claims of the '888 patent are invalid under the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially-created bases for invalidity.

PRAYER FOR RELIEF

8. WHEREFORE, Hetero respectfully requests that this Court enter a judgment in its favor and against Plaintiffs as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Hetero;

(b) Declaring that no valid claim of the patents-in-suit would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Products pursuant to ANDA No. 217185;

(c) Declaring that the claims of the patents-in-suit are invalid;

(d) Entering judgment for Hetero on its affirmative defenses and any and all additional defenses and counterclaims that discovery may reveal;

(e) Enjoining Counterclaim-Defendants, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendants from threatening to assert or otherwise attempting to enforce the patents-in-suit against Hetero, its customers, suppliers, or anyone in privity with Hetero;

(f) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Hetero its reasonable attorneys' fees and costs incurred in this action;

(g) Awarding Hetero its costs and expenses incurred in this action; and

(h) Awarding Hetero such other and further relief as this Court may deem proper.

Respectfully Submitted,

Dated: November 1, 2023

/s/ Rebekah R. Conroy
Rebekah R. Conroy
Surinder K. Aggarwal
STONE CONROY LLC
25A Hanover Road, Suite 301
Florham Park, New Jersey 07932
Tel: (973) 400-181
rconroy@stoneconroy.com
saggawaral@stoneconroy.com

OF COUNSEL:

Neal Seth *(pro hac vice forthcoming)*
Wesley E. Weeks *(pro hac vice forthcoming)*
WILEY REIN LLP
2050 M Street NW
Washington, DC 20036
Tel: (202) 719-7000
nseth@wiley.law
wweeks@wiley.law

Attorneys for Defendants Hetero Labs Limited Unit V and Hetero USA, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 1st day of November, 2023, a true and accurate copy of the above and foregoing copy of DEFENDANTS HETERO LABS LIMITED UNIT V AND HETERO USA, INC.'S ANSWER TO THE FIRST AMENDED COMPLAINT, DEFENSES AND COUNTERCLAIMS was served on lead counsel for Plaintiff via CM/ECF.

/s/ *Rebekah Conroy*
Rebekah Conroy