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

ARAGON PHARMACEUTICALS, INC., JANSSEN BIOTECH, INC., and THE REGENTS OF THE UNIVERSITY OF CALIFORNIA, Plaintiffs, v. HETERO LABS LIMITED UNIT V, and HETERO USA, INC., Defendants.	Civil Action No. 2-24-cv-06784 **(Filed Electronically)**

DEFENDANTS HETERO LABS LIMITED UNIT V AND HETERO USA, INC.'S ANSWER, DEFENSES AND COUNTERCLAIMS

Defendants Hetero Labs Limited Unit V ("Hetero Labs") and Hetero USA, Inc. ("Hetero USA") (collectively, "Hetero" or "Defendants"), by their undersigned attorney, for their Answer to the Complaint for Patent Infringement filed by Plaintiffs Aragon Pharmaceuticals, Inc. ("Aragon"), Janssen Biotech, Inc. ("JBI"), and The Regents of the University of California ("Regents") (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. 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), and 9,987,261 ("the 261 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. 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), and 9,987,261 ("the 261 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. 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), and 9,987,261 ("the 261 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. 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 6 of the Complaint.

7. 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

8. 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 8 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 8 of the Complaint.

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

ANSWER: Paragraph 9 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 9.

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

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 the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 10.

11. 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.

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

ANSWER: Paragraph 12 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 12.

13. 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 13 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 13.

14. 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 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 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; *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-22-cv-03212.

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

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 the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 20.

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

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. 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 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 personal jurisdiction 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, 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 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 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 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, 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 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 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; *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-22-cv-03212.

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. 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 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. 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 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. 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 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. 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, and subsequently amending its ANDA on or about April 26, 2024, to contain a Paragraph IV certification for the 689 Patent, the 159 Patent, and the 261 Patent.

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. 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 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 acts or caused acts to be committed in preparation for and submission of the ANDA in this judicial district.

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, 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 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. 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 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 the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 34.

ERLEADA®

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

ANSWER: Paragraph 35 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.

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

ANSWER: Paragraph 36 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.

37. 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.

38. 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

39. On August 12, 2014, the 689 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 689 Patent is attached as Exhibit A.

ANSWER: Paragraph 39 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 '689 patent is attached to the Complaint as Exhibit A; that the '689 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 '689 patent is August 12, 2014; and that Regents is identified as the assignee of the '689 patent. Hetero denies that the '689 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 39 of the Complaint.

40. On July 12, 2016, the 159 Patent, titled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators" was duly and legally issued to Regents as assignee. A copy of the 159 Patent is attached as Exhibit B.

ANSWER: Paragraph 40 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 '159 patent is attached to the Complaint as Exhibit B; that the '159 patent is entitled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators"; that the issue date identified on the cover of the '159 patent is July 12, 2016; and that Regents is identified as the assignee of the '159 patent. Hetero denies that the '159 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 40 of the Complaint.

41. On June 5, 2018, the 261 Patent, titled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators" was duly and legally issued to Regents as assignee. A copy of the 261 Patent is attached as Exhibit C.

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 '261 patent is attached to the Complaint as Exhibit C; that the '261 patent is entitled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators"; that the issue date identified on the cover of the '261 patent is June 5, 2018; and that Regents is identified as the assignee of the '261 patent. Hetero denies that the '261 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 41 of the Complaint.

42. 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 42 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.

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

ANSWER: Paragraph 43 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

44. By letter dated April 18, 2022, addressed to JBI, Sloan-Kettering Institute for Cancer Research ("Sloan-Kettering"),[1] 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 8,445,507 ("507 Patent"), 9,481,663 ("the 663 Patent"), 9,884,054 ("the 054 Patent"), 10,052,314 ("the 314 Patent"), 10,702,508 ("the 508 Patent"), and 10,849,888 ("the 888 Patent"), which are asserted in *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, Civil Action No. 2:22-cv-03212 (D.N.J.) ("2022 Matter").

[1] Sloan-Kettering is not a party to the filing of the present complaint.

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 44 are denied.

45. 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.

46. 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.

47. 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.

48. Plaintiffs commenced an action within 45 days of the date of receipt of the 2022 Notice Letter. *See* 2022 Matter at D.I. 1.

ANSWER: Admitted.

49. 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 49 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 RE353 Patent in connection with New Drug Application ("NDA") No. 210951 for Erleada®. All remaining allegations are denied.

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

ANSWER: Admitted.

51. 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 51 are denied.

52. 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.

53. 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.

54. The 2023 Notice Letter included an OCA to the ANDA.

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

55. Plaintiffs timely amended the pleadings in the 2022 Matter to include allegations of infringement of the RE353 Patent. *See* 2022 Matter at D.I. 68.

ANSWER: Hetero admits that D.I. 68 speaks for itself. All remaining allegations are denied.

56. By letter dated April 26, 2024, addressed to JBI, Aragon, and Regents ("2024 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 2024 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 2024 Notice Letter as "Apalutamide Tablets; Oral 60 mg" prior to the expiration of the 689 Patent, the 159 Patent, and the 261 Patent. The 689 Patent, the 159 Patent, and the 261 Patent have each been listed in the Orange Book as covering Erleada® since before the date of Defendants' 2022 Notice Letter.

ANSWER: Hetero admits to sending a Notice Letter dated April 26, 2024 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 '689, '159, and '261 Patents. All other allegations of Paragraph 56 are denied.

57. The 2024 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.

58. The ANDA includes a Paragraph IV Certification that the claims of the 689 Patent, the 159 Patent, and the 261 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.

59. The 2024 Notice Letter included an OCA to the ANDA. Defendants agreed that Plaintiffs could access the ANDA documents produced in the 2022 Matter.

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

60. 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, 2023 Notice Letter, and 2024 Notice Letter.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 60.

61. 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: Hetero admits that it 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 ’689, ’159, and ’261 Patents. All other allegations of Paragraph 61

are denied.

62. Plaintiffs are commencing this action within 45 days of the date of receipt of the 2024 Notice Letter.

ANSWER: Admitted.

COUNT I – CLAIM FOR INFRINGEMENT OF THE 689 PATENT

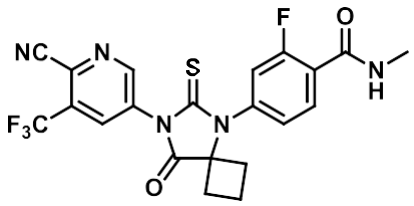
63. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to the foregoing paragraphs as if fully set forth herein.

64. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 689 Patent, including at least claim 2.

ANSWER: Admitted.

65. On information and belief, the Proposed ANDA Product contains apalutamide, which is a compound having the formula:



, which will infringe the genus of compounds claimed in at least claim 2 of the 689 Patent.

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, the use of the Proposed ANDA Product will infringe at least claim 2 of the 689 Patent because physicians and/or patients will practice a method for treating prostate cancer in a subject, specifically a patient, said method comprising

administering, causing to be administered, or directing the administration of the compound apalutamide to the patient in need of such treatment.

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

67. On information and belief, Defendants will induce infringement of at least claim 2 of the 689 Patent by actively inducing the use of the Proposed ANDA Product to practice a method for treating prostate cancer in a subject, specifically a patient, said method comprising administering, causing to be administered, or directing the administration of the compound apalutamide to the patient in need of such treatment.

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

68. 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 689 Patent, including at least claim 2, 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 689 Patent, including at least claim 2, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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

69. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 689 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for

every claim of the 689 Patent.

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

70. On information and belief, Defendants have actual knowledge of 689 Patent, at least as shown by the Notice Letter.

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, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 689 Patent, including at least claim 2, 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 689 Patent.

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 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 689 Patent, including at least claim 2, under at least one of 35 U.S.C. § 271(a), (b), or (c).

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 manufacture, use, import, offer to sell, or sale of the Proposed ANDA Product will directly infringe the claims of the 689 Patent, including at least claim 2.

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, physicians and/or patients will directly infringe the claims of the 689 Patent, including at least claim 2, by the use of the Proposed ANDA Product upon approval.

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, 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 689 Patent, including at least claim 2, for the pecuniary benefit of Defendants.

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. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 689 Patent, including at least claim 2. On information and belief, Defendants will actively induce the infringement of the claims of the 689 Patent, including at least claim 2.

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, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 689 Patent, including at least claim 2. On information and belief, Defendants will thus contribute to the infringement of the claims of the 689 Patent, including at least claim 2.

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, the actions described in this Complaint relating to the ANDA and the 689 Patent were done by and for the benefit of Defendants.

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

COUNT II – CLAIM FOR INFRINGEMENT OF THE 159 PATENT

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

ANSWER: Hetero incorporates its answers to the foregoing paragraphs as if fully set forth herein.

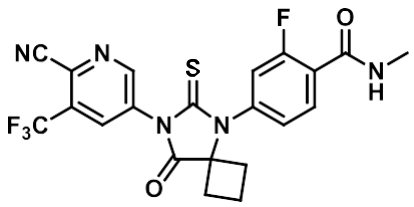
81. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 159 Patent, including at least claims 1, 12, and 17.

ANSWER: Admitted.

82. 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, 12, and 17 of the 159 Patent.

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, the Proposed ANDA Product contains apalutamide, which is a compound having the formula:



, which will infringe the genus of compounds claimed in at least claim 1 of the 159 Patent.

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 infringes at least claims 12 and 17 of the 159 Patent because it is a pharmaceutical composition comprising a therapeutically effective amount of the compound apalutamide formulated in an oral dosage form and a pharmaceutically acceptable carrier, diluent, or adjuvant.

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, 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 159 Patent, including at least claims 1, 12, 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 159 Patent, including at least claims 1, 12, 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 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. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 159 Patent. The Notice Letter did not include a detailed

and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 159 Patent.

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.

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

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

88. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 159 Patent, including at least claims 1, 12, 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 159 Patent.

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

89. 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 159 Patent, including at least claims 1, 12, and 17, under at least one of 35 U.S.C. § 271(a), (b), or (c).

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 manufacture, use, import, offer to sell, or sale of the Proposed ANDA Product will directly infringe the claims of the 159 Patent, including at least claims 1, 12, and 17.

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, physicians and/or patients will directly infringe the claims of the 159 Patent, including at least claims 1, 12, and 17, by the use of the Proposed ANDA Product upon approval.

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, 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 159 Patent, including at least claims 1, 12, and 17, for the pecuniary benefit of Defendants.

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 specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 159 Patent, including at least claims 1, 12, and 17. On information and belief, Defendants will actively induce the infringement of the claims of the 159 Patent, including at least claims 1, 12, and 17.

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, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 159 Patent, including at least claims 1, 12, and 17. On information and belief, Defendants will thus contribute to the infringement of the claims of the 159 Patent, including at least claims 1, 12, and 17.

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. On information and belief, the actions described in this Complaint relating to the ANDA and the 159 Patent were done by and for the benefit of Defendants.

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

COUNT III – CLAIM FOR INFRINGEMENT OF THE '261 PATENT

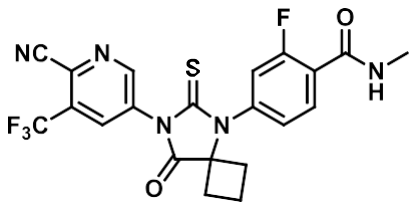
97. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

ANSWER: Hetero incorporates its answers to the foregoing paragraphs as if fully set forth herein.

98. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 261 Patent, including at least claims 10 and 12.

ANSWER: Admitted.

99. On information and belief, the Proposed ANDA Product contains apalutamide, which is a compound having the formula:



. Thus, the Proposed ANDA Product and the use of the Proposed ANDA Product will infringe at least claims 10 and 12 of the 261 Patent.

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, the Proposed ANDA Product infringes at least claims 10 and 12 of the 261 Patent because it is a tablet comprising the compound apalutamide in a range of from 0.0005 to 500 mg and a pharmaceutically acceptable carrier, diluent, or adjuvant.

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, 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 261 Patent, including at least claims 10 and 12, 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 261 Patent, including at least claims 10 and 12, and wherein the Proposed ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use.

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. The Notice Letter purports to include a Notice of Certification for the ANDA under 37 C.F.R. § 314.95(c)(6) as to the 261 Patent. The Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 261 Patent.

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, Defendants have actual knowledge of the 261 Patent, at least as shown by the Notice Letter.

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, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 261 Patent, including at least claims 10 and 12, 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 261 Patent.

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. 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 261 Patent, including at least claims 10 and 12, under at least one of 35 U.S.C. § 271(a), (b), or (c).

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.

106. 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 261 Patent, including at least claims 10 and 12.

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

107. On information and belief, physicians and/or patients will directly infringe the claims of the 261 Patent, including at least claims 10 and 12, by the use of the Proposed ANDA Product upon approval.

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

108. 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 261 Patent, including at least claims 10 and 12, for the pecuniary benefit of Defendants.

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 specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 261 Patent, including at least claims 10 and 12. On information and belief, Defendants will actively induce the infringement of the claims of the 261 Patent, including at least claims 10 and 12.

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, the Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 261 Patent, including at least claims 10 and 12. On information and belief, Defendants will thus contribute to the infringement of the claims of the 261 Patent, including at least claims 10 and 12.

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. On information and belief, the actions described in this Complaint relating to the ANDA and the 261 Patent were done by and for the benefit of Defendants.

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

* * *

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 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 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 Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '689 PATENT)

One or more claims of the '689 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 '689 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 '689 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '689 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 '689 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '159 PATENT)

One or more claims of the '159 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 '159 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 '159 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '159 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 '159 Patent.

SEVENTH SEPARATE DEFENSE
(INVALIDITY OF THE '261 PATENT)

One or more claims of the '261 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 '261 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 '261 Patent.

NINTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '261 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 '261 Patent.

TENTH 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.

ELEVENTH 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).

TWELFTH 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 '689, '159, and '261 patents, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the '689, '159, and '261 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

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

THE PARTIES

1. 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.

2. 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.

3. 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.

4. 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.

5. 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

6. 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. 88,802,689 ("the '689 Patent"), 9,388,159 ("the '159 Patent"), and 9,987,261 ("the '261 Patent") are invalid and/or not infringed.

JURISDICTION AND VENUE

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

8. 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.

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

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

BACKGROUD

A. FDA Approval of New Brand Name Drugs

11. 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.

12. 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.

13. 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).

14. 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).

15. 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

16. 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.

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

18. 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).

19. 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).

20. 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).

21. 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).

22. 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).

23. 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

24. 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").

25. 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").

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

27. On information and belief, Plaintiffs caused the '689, '159, and '261 Patents 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.

28. The '689 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 August 12, 2014; and Regents is identified as the assignee of the '689 patent.

29. The '159 patent is entitled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators"; the issue date identified on the cover of the '159 patent is July 12, 2016; and Regents is identified as the assignee of the '159 patent.

30. The '261 patent is entitled "Substituted Diazaspiroalkanes as Androgen Receptor Modulators"; the issue date identified on the cover of the '261 patent is June 5, 2018; and Regents is identified as the assignee of the '261 patent.

31. Hetero's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '689, '159, and '261 Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product.

32. On April 26, 2024, Hetero sent Plaintiffs' written notice of Hetero's Paragraph IV Certifications ("Hetero's 2024 Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Hetero's 2024 Notice Letter asserted that the claims of the '689, '159, and '261 Patents are invalid, unenforceable, and/or will not be infringed by Hetero's ANDA or the products or activities described therein.

33. Hetero's 2024 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).

34. On June 6, 2024, Plaintiffs filed the present lawsuit alleging infringement of the 689, '159, and '261 Patents. 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 '689, '159, and '261 Patents.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '689 PATENT

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

36. 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 '689 patent.

37. Hetero incorporates by reference Hetero's 2024 Notice Letter, which contains exemplary and nonlimiting explanations that the '689 patent is not infringed by Hetero's ANDA or the products or activities described therein.

38. 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 ’689 patent and is not liable for such infringement.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’689 PATENT

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

40. There is an actual, substantial, continuing and justiciable controversy between Plaintiffs and Hetero regarding whether the claims of the ’689 patent are invalid.

41. Hetero incorporates by reference Hetero’s 2024 Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the ’689 patent are invalid.

42. Hetero is entitled to a declaration that all claims of the ’689 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 ’159 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 ’159 patent.

45. Hetero incorporates by reference Hetero’s 2024 Notice Letter, which contains exemplary and nonlimiting explanations that the ’159 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 ’159 patent and is not liable for such infringement.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’159 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 ’159 patent are invalid.

49. Hetero incorporates by reference Hetero’s 2024 Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the ’159 patent are invalid.

50. Hetero is entitled to a declaration that all claims of the ’159 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 ’261 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 ’261 patent.

53. Hetero incorporates by reference Hetero’s 2024 Notice Letter, which contains exemplary and nonlimiting explanations that the ’261 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 ’261 patent and is not liable for such infringement.

COUNT VI: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’261 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 ’261 patent are invalid.

57. Hetero incorporates by reference Hetero’s 2024 Notice Letter, which contains exemplary and nonlimiting explanations that the claims of the ’261 patent are invalid.

58. Hetero is entitled to a declaration that all claims of the ’261 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

WHEREFORE, Hetero respectfully request that this Court enter 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 689, ’159, and ’261 Patents 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 ’689, ’159, and ’261 Patents 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, their 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 689, '159, and '261 Patents 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: July 1, 2024

/s/ Rebekah R. Conroy

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

CERTIFICATION PURSUANT TO RULES 11.2 AND 40.1

I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that Aragon, JBI, and/or Regents have asserted one or more of the patents in this case in the pending matters in this Judicial District: *Aragon Pharmaceuticals, Inc. et al. v. Zydus Worldwide DMCC et al.*, Civil Action No. 2:22-cv-02964-SRC-LDW (Consolidated) and *Aragon Pharmaceuticals, Inc. et al. v. Sandoz Inc.*, Civil Action No. 2:22-cv-03044-SRC-LDW. Further, there are not any non-parties known to Hetero that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: July 1, 2024

Respectfully Submitted,

/s/ Rebekah Conroy
Rebekah Conroy