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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.	Civil Action No. 2:25cv11924

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

Defendants Hetero Labs Limited Unit-V ("Hetero Labs") and Hetero USA, Inc. ("Hetero USA") (collectively, "Hetero" or "Defendants"), by their undersigned attorneys, 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"), 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), 9,987,261 ("the 261 Patent"), 9,481,663 ("the 663 Patent"), 9,884,054 ("the 054 Patent"), RE49,353 ("the RE353 Patent"), 10,849,888 ("the 888 Patent"), 10,702,508 ("the 508 Patent"), and 11,963,952 ("the 952 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"), 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), 9,987,261 ("the 261 Patent"), 9,481,663 ("the 663 Patent"), 9,884,054 ("the 054 Patent"), RE49,353 ("the RE'353 Patent"), 10,849,888 ("the 888 Patent"), 10,702,508 ("the 508 Patent"), and 11,963,952 ("the 952 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. 220525 ("the ANDA") by Defendants to the United States Food and Drug Administration ("FDA") seeking approval to market a proposed generic version of Erleada® 240 mg tablets ("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. 220525 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"), 8,802,689 ("the 689 Patent"), 9,388,159 ("the 159 Patent"), 9,987,261 ("the 261 Patent"), 9,481,663 ("the 663 Patent"), 9,884,054 ("the 054 Patent"), RE49,353 ("the RE'353 Patent"), 10,849,888 ("the 888 Patent"), 10,702,508 ("the 508 Patent"), and 11,963,952 ("the 952 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, Polepally Village, Jadcherla Mandal, Mahabubnagar (District), Telangana, India 509301.

ANSWER: Denied.

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. 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.

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

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 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 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, 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 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 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, *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-24-cv-06784.

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

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 the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 21.

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

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 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 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 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 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 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 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, 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 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 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, *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-24-cv-06784.

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 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 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 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 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. 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 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, Hetero USA has committed an act of infringement in this judicial district by submitting the ANDA with the FDA on or about March 20, 2025.

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

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 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 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. 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 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 the propriety of venue in this District. Hetero denies all remaining allegations of Paragraph 35.

ERLEADA®

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

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

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. 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 60 mg and 240 mg 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.

39. 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

40. 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 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 '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 40 of the Complaint.

41. 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 B.

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 '689 patent is attached to the Complaint as Exhibit B; 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 41 of the Complaint.

42. 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 C.

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 '159 patent is attached to the Complaint as Exhibit C; 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 42 of the Complaint.

43. 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 D.

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 '261 patent is attached to the Complaint as Exhibit D; 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 42 of the Complaint.

44. 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 E.

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 '663 patent is attached to the Complaint as Exhibit E; 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 44 of the Complaint.

45. 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 F.

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 '054 patent is attached to the Complaint as Exhibit F; 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 45 of the Complaint.

46. 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. A copy of the RE353 Patent is attached as Exhibit G.

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 RE'353 patent is attached to the Complaint as Exhibit G; that the RE'353 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 RE'353 patent is January 3, 2023; and that Aragon is identified as the assignee of the RE'353 patent. Hetero denies that the RE'353 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 46 of the Complaint.

47. 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 H.

ANSWER: Paragraph 47 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 H; 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 47 of the Complaint.

48. 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 I.

ANSWER: Paragraph 48 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 I; 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 48 of the Complaint.

49. On April 23, 2024, the 952 Patent, titled "Anti-Androgens for the Treatment of Metastatic Castration-Sensitive Prostate Cancer" was duly and legally issued to Aragon as assignee. A copy of the 952 Patent is attached as Exhibit J.

ANSWER: Paragraph 49 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 '952 patent is attached to the Complaint as Exhibit J; that the '952 patent is entitled "Anti-Androgens for the Treatment of Metastatic Castration-Sensitive Prostate Cancer"; that the issue date identified on the cover of the '952 patent is April 23, 2024; and that Aragon is identified as the assignee of the '952 patent. Hetero denies that the '952 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 4 9of the Complaint.

50. 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 50 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.

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

ANSWER: Paragraph 51 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

52. By letter dated May 8, 2025, addressed to JBI, Sloan-Kettering, Aragon, and Regents ("2025 Notice Letter"), Defendants notified Plaintiffs that they had submitted ANDA No. 220525 to the FDA under § 505(j)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The 2025 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 2025 Notice

Letter as "Apalutamide Tablets; Oral, 240 mg" prior to the expiration of the 507 Patent, the 689 Patent, the 159 Patent, the 261 Patent, the 663 Patent, the 054 Patent, the RE353 Patent, the 888 Patent, the 508 Patent, and the 952 Patent.

ANSWER: Hetero admits to sending a Notice Letter 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 52 are denied.

53. The 2025 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.

54. The ANDA includes a Paragraph IV Certification that the claims of the 507 Patent, the 689 Patent, the 159 Patent, the 261 Patent, the 663 Patent, the 054 Patent, the RE353 Patent, the 888 Patent, the 508 Patent, and the 952 Patent are invalid, unenforceable, or not infringed.

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

55. The 2025 Notice Letter included an Offer for Confidential Access ("OCA") to the ANDA. The parties agreed on revised terms for the OCA. On June 6, 2025, 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.

56. 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 2025 Notice Letter. Additionally, in prior proceedings involving Defendants' proposed generic version of Erleada® 60 mg tablets, Plaintiffs asserted infringement of the 507 Patent, the 663 Patent, the 054 Patent, the RE353 Patent, the 508 Patent, and the 888 Patent in *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-22-cv-03212 (D.N.J.) and Plaintiffs asserted infringement of the 689 Patent, the 159 Patent, the 261 Patent in *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2-24-cv-06784 (D.N.J.).

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 56.

57. 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 Patents-in-Suit. All remaining allegations are denied.

58. Plaintiffs are commencing this action within 45 days of the date of receipt of the 2025 Notice Letter.

ANSWER: Admitted.

COUNT I – CLAIM FOR INFRINGEMENT OF THE 507 PATENT

59. 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.

60. 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.

61. 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 61 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 61.

62. 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 62 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 62.

63. 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 63 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 63.

64. 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 64 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 64.

65. 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 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, 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 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. The 2025 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 2025 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 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, Defendants have actual knowledge of the 507 Patent, at least as shown by the 2025 Notice Letter.

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

COUNT II – CLAIM FOR INFRINGEMENT OF THE 689 PATENT

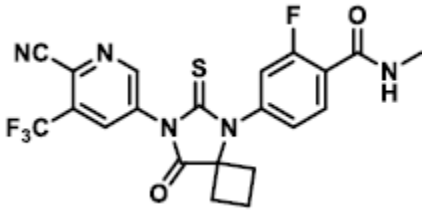
78. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

79. 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.

80. 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 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, 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 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, 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 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, 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 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. The 2025 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 2025 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 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, Defendants have actual knowledge of 689 Patent, at least as shown by the 2025 Notice Letter.

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

COUNT III – CLAIM FOR INFRINGEMENT OF THE 159 PATENT

95. 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.

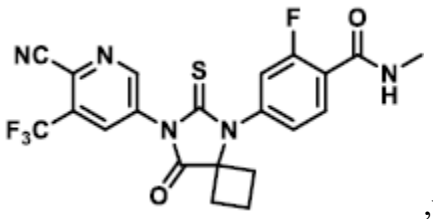
96. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 159 Patent, including at least claims 1, 12, and 17.

ANSWER: Admitted.

97. 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 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 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 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 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 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, 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 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. The 2025 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 2025 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 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 have actual knowledge of the 159 Patent, at least as shown by the 2025 Notice Letter.

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

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

COUNT IV – CLAIM FOR INFRINGEMENT OF THE 261 PATENT

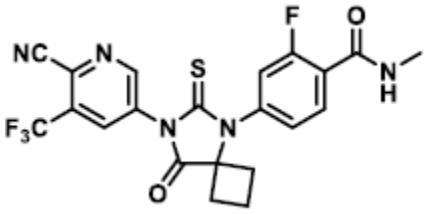
112. Plaintiffs re-allege each of the foregoing paragraphs as if fully set forth herein.

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

113. 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.

114. 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 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, 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 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, 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 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. The 2025 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 2025 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 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 have actual knowledge of the 261 Patent, at least as shown by the 2025 Notice Letter.

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

121. 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 121 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 121.

122. 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 122 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 122.

123. On information and belief, upon approval, Defendants will tae 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 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. 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 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, 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 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. 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 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. 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 127 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 127.

COUNT V – CLAIM FOR INFRINGEMENT OF THE 261 PATENT

128. 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.

129. 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

130. 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 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, 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 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, 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 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, 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 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, 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 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. 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 135 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 135.

136. The 2025 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 2025 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 136 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 136.

137. On information and belief, Defendants have actual knowledge of the 663 Patent, at least as shown by the 2025 Notice Letter.

ANSWER: Paragraph 137 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 137.

138. 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 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, 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 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 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 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, 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 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, 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 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. 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 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, 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 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, 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 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. 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 146 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 146.

COUNT VI –CLAIM FOR INFRINGEMENT OF THE 054 PATENT

147. 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.

148. 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.

149. 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 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 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 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, 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 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. The 2025 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 2025 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 152 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 152.

153. On information and belief, Defendants have actual knowledge of the 054 Patent, at least as shown by the 2025 Notice Letter.

ANSWER: Paragraph 153 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 153.

154. 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 154 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 154.

155. 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 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, 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 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, 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 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. 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 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' 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 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, 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 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. 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 161 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 161.

COUNT VII – CLAIM FOR INFRINGEMENT OF THE RE353 PATENT

162. 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.

163. 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.

164. 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 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. 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 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, 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 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. The 2025 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 2025 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 167 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 167.

168. On information and belief, Defendants have actual knowledge of the RE353 Patent, at least as shown by the 2025 Notice Letter.

ANSWER: Paragraph 168 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 168.

169. 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 169 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 169.

170. 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 170 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 170.

171. 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 171 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 171.

172. 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 172 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 172.

173. 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 173 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 173.

174. 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 174 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 174.

175. 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 175 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 175.

176. 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 176 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 176.

COUNT VIII – CLAIM FOR INFRINGEMENT OF THE 888 PATENT

177. 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.

178. 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.

179. 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 179 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 179.

180. 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 180 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 180.

181. 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 181 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 181.

182. The 2025 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 2025 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 182 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 182.

183. On information and belief, Defendants have actual knowledge of the 888 Patent, at least as shown by the 2025 Notice Letter.

ANSWER: Paragraph 183 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 183.

184. 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 184 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 184.

185. 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 185 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 185.

186. 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 186 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 186.

187. 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 187 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 187.

188. 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 188 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 188.

189. 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 189 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 189.

190. 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 190 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 190.

191. 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 191 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 191.

COUNT IX – CLAIM FOR INFRINGEMENT OF THE 508 PATENT

192. 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.

193. 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.

194. 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 194 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 194.

195. 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 195 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 195.

196. 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 196 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 196.

197. 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 197 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 197.

198. 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 198 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 198.

199. The 2025 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 2025 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 199 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 199.

200. On information and belief, Defendants have actual knowledge of the 508 Patent, at least as shown by the 2025 Notice Letter.

ANSWER: Paragraph 200 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 200.

201. 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 201 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 201.

202. 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 202 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 202.

203. 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 203 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 203.

204. 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 204 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 204.

205. 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 205 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 205.

206. 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 206 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 206.

207. 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 207 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 207.

208. 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 208 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 208.

COUNT X – CLAIM FOR INFRINGEMENT OF THE 952 PATENT

209. 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.

210. An actual controversy exists between the parties as to whether Defendants' proposed sale of the Proposed ANDA Product infringes the claims of the 952 Patent, including at least claims 6, 7, and 8.

ANSWER: Admitted.

211. On information and belief, the use of the Proposed ANDA Product will infringe at least claims 6, 7, and 8 of the 952 Patent because physicians and/or patients will practice a method

of treating metastatic castration-sensitive prostate cancer in a male human, said method consisting essentially of administering a therapeutically effective amount of an anti-androgen to a male human with metastatic castration-sensitive prostate cancer, wherein the anti-androgen is apalutamide, wherein its dosage is decreased to 180 mg per day or 120 mg per day if the male human experiences a greater than or equal to Grade 3 toxicity.

ANSWER: Paragraph 211 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 211.

212. On information and belief, Defendants will induce infringement of at least claims 6, 7, and 8 of the 952 Patent by actively inducing the use of the Proposed ANDA Product to practice a method of treating metastatic castration-sensitive prostate cancer in a male human, said method consisting essentially of administering a therapeutically effective amount of an anti-androgen to a male human with metastatic castration-sensitive prostate cancer, wherein the anti-androgen is apalutamide, wherein its dosage is decreased to 180 mg per day or 120 mg per day if the male human experiences a greater than or equal to Grade 3 toxicity.

ANSWER: Paragraph 212 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 212.

213. 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 952 Patent, including at least claims 6, 7, 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 952 Patent, including at least claims 6, 7,

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 213 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 213.

214. The 2025 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 2025 Notice Letter did not include a detailed and supported statement of allegations of invalidity, unenforceability, or non-infringement for every claim of the 952 Patent.

ANSWER: Paragraph 214 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 214.

215. On information and belief, Defendants have actual knowledge of the 952 Patent, at least as shown by the 2025 Notice Letter.

ANSWER: Paragraph 215 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 215.

216. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed the claims of the 952 Patent, including at least claims 6, 7, 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 952 Patent.

ANSWER: Paragraph 216 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 216.

217. 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 952 Patent, including at least claims 6, 7, and 8, under at least one of 35 U.S.C. § 271(a), (b), or (c).

ANSWER: Paragraph 217 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 217.

218. On information and belief, physicians and/or patients will directly infringe the claims of the 952 Patent, including at least claims 6, 7, and 8, by their use of the Proposed ANDA Product upon approval.

ANSWER: Paragraph 218 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 218.

219. 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 952 Patent, including at least claims 6, 7, and 8, for the pecuniary benefit of Defendants.

ANSWER: Paragraph 219 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 219.

220. On information and belief, Defendants specifically intend the Proposed ANDA Product to be used in a manner that infringes the claims of the 952 Patent, including at least claims 6, 7, and 8. On information and belief, Defendants will actively induce the infringement of the claims of the 952 Patent, including at least claims 6, 7, and 8.

ANSWER: Paragraph 220 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 220.

221. On information and belief, Defendants' Proposed ANDA Product is specifically designed for use in a manner that infringes the claims of the 952 Patent, including at least claims 6, 7, and 8. On information and belief, Defendants will thus contribute to the infringement of the claims of the 952 Patent, including at least claims 6, 7, and 8.

ANSWER: Paragraph 221 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 221.

222. On information and belief, the actions described in this Complaint relating to the ANDA and the 952 Patent were done by and for the benefit of Defendants.

ANSWER: Paragraph 222 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 222.

223. 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 223 contains legal conclusions to which no answer is required. To the extent an answer is required, Hetero denies the allegations of Paragraph 223.

* * *

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 '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. 220525 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. 220525 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 '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.

FIFTH 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '689 Patent.

SIXTH 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. 220525 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.

SEVENTH 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.

EIGHTH 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '159 Patent.

NINTH 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. 220525 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.

TENTH 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.

ELEVENTH 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '261 Patent.

TWELFTH 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. 220525 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.

THIRTEENTH 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.

FOURTEENTH 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '663 Patent.

FIFTEENTH 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. 220525 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.

SIXTEENTH 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.

SEVENTEENTH 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '054 Patent.

EIGHTEENTH 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. 220525 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.

NINTEENTH SEPARATE DEFENSE
(INVALIDITY OF THE RE'353 PATENT)

One or more claims of the RE'353 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.

TWENTIETH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE RE'353 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the RE'353 Patent.

TWENTY-FIRST SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE RE'353 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220525 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 RE'353 Patent.

TWENTY-SECOND 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.

TWENTY-THIRD 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '888 Patent.

TWENTY-FOURTH 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. 220525 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.

TWENTY-FIFTH 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.

TWENTY-SIXTH 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. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '508 Patent.

TWENTY-SEVENTH 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. 220525 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.

TWENTY-EIGHTH SEPARATE DEFENSE
(INVALIDITY OF THE '952 PATENT)

One or more claims of the '952 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.

TWENTY-NINTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '952 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220525 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '952 Patent.

THIRTIETH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '952 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220525 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 '952 Patent.

THIRTY-FIRST 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.

THIRTY-SECOND 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).

THIRTY-THIRD 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, '689, '159, '261, '663, '054, RE'353, '888, '508, and '952 patents, Plaintiffs are estopped from maintaining that any valid or enforceable claim of the '507, '689, '159, '261, '663, '054, RE'353, '888, '508, and '952 patents is infringed by the product that is the subject of ANDA No. 220525.

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.

Dated: September 18, 2025

/s/ Rebekah R. Conroy
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CERTIFICATE 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. 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: September 18, 2025

Respectfully Submitted,

/s/ Rebekah Conroy
Rebekah Conroy