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

ASTELLAS PHARMA, INC., et al.,	:	
Plaintiff,	:	Civil Action No. 3:25-cv-15434-MAS-RLS
v.	:	
HETERO USA, INC., et al.,	:	
Defendant.	:	*Electronically Filed*

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

Defendants Hetero Labs Limited, Hetero Labs Limited Unit V, and Hetero USA, Inc (collectively "Hetero" or "Defendants"), hereby answer Plaintiffs Astellas Pharma Inc. ("API"), Astellas US LLC ("AUS"), and Astellas Pharma US, Inc. ("APUS") (collectively, "Astellas"), and Medivation LLC and Medivation Prostate Therapeutics LLC ("MPT") (collectively, "Medivation") (all collectively, "Plaintiffs") Complaint, and present their affirmative defenses and counterclaims, as follows:

THE PARTIES

1. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

2. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

3. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

4. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

5. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

6. Admitted.

7. Denied.

8. Defendant Hetero Labs is a company organized and existing under the laws of India, with a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

9. Denied.

10. Defendant Hetero Unit-V is a company organized and existing under the laws of India, with a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Telangana, India.

11. Denied.

12. Admitted.

13. Hetero USA is a wholly owned subsidiary of Hetero Labs Limited, and Hetero USA is the U.S. Regulatory Agent for Hetero Labs. Hetero denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

14. Denied.

15. Denied.

NATURE OF THE ACTION

16. Paragraph 16 contains conclusions of law to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring this action under the patent laws of the United States, pursuant to title 35 of the United States Code. Hetero admits that Hetero filed Abbreviated New Drug Application No. 220481 ("Hetero's ANDA") to FDA, seeking approval of the products described therein prior to expiration of U.S. Patent Nos. 11,839,689 ("the '689 patent") and 12,161,628 ("the '628 patent") (collectively, the "Patents-in-Suit"). Hetero denies all further allegations in this paragraph of the Complaint. Allegations not expressly admitted are denied.

JURISDICTION AND VENUE

17. Paragraph 17 contains conclusions of law for which no response is required. To the extent a response is required, Hetero states it will not contest subject matter jurisdiction for

the limited purpose of this action under 28 U.S.C. §§ 1331 and 1338(a) only. Hetero denies the remaining allegations in this paragraph.

18. Paragraph 18 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states it will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Hetero's ANDA No. 220481. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

19. Paragraph 19 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states it will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Hetero's ANDA No. 220481. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

20. Paragraph 20 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states it will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Hetero's ANDA No. 220481. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

21. Paragraph 21 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states it will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case

under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Hetero's ANDA No. 220481. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

22. Paragraph 22 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, Hetero states it will not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Hetero in this case under 35 U.S.C. § 271(e)(2) and solely as they apply to the proposed products described in Hetero's ANDA No. 220481. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

23. Paragraph 23 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, solely for the purpose of this litigation, Hetero states it does not contest venue. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

24. Paragraph 24 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, solely for the purpose of this litigation, Hetero states it does not contest venue. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

25. Paragraph 25 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, solely for the purpose of this litigation, Hetero states it does not contest venue. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

26. Paragraph 26 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, solely for the purpose of this litigation, Hetero

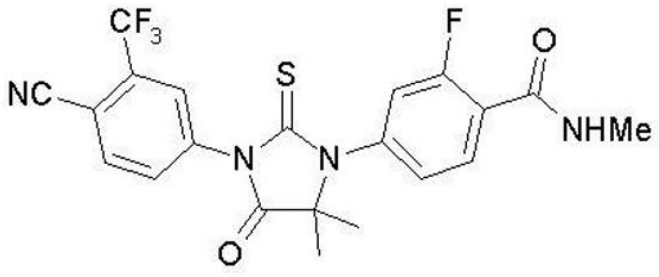
states it does not contest venue. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

27. Paragraph 27 of the Complaint states a legal conclusion to which no response is required. To the extent a response is required, solely for the purpose of this litigation, Hetero states it does not contest venue. Hetero denies all remaining allegations in this paragraph. Allegations not expressly admitted are denied.

THE XTANDI® TABLET NDA

28. On information and belief, Hetero admits that the August 4, 2020 FDA-approved label for Xtandi® 40 mg and 80 mg tablets states that Xtandi® is an androgen receptor inhibitor indicated for the treatment of patients with: castration-resistant prostate cancer and metastatic castration-sensitive prostate cancer. Hetero also admits that the November 16, 2023 FDA-approved label for Xtandi® 40 mg and 80 mg tablets expanded the indications for the use of Xtandi® 40 mg and 80 mg tablets to include patients with non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis. Hetero is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph of the Complaint and therefore deny the same.

29. Hetero admits that enzalutamide has the chemical name 4-{3-[4-cyano-3-(trifluoromethyl)phenyl]-5,5 dimethyl-4-oxo-2-sulfanylideneimidazolidin-1-yl}-2-fluoro-N-methylbenzamide and the chemical structure:



Hetero is without knowledge or information sufficient to form a belief as to the truth of the remaining allegations of this paragraph of the Complaint and therefore deny the same.

THE PATENTS-IN-SUIT

30. Paragraph 30 contains conclusions of law to which no response is required. To the extent a response is required, on information and belief, Hetero admits the '689 Patent, titled "Formulations of Enzalutamide" lists Astellas Pharma Inc. and Medivation Prostate Therapeutics LLC as assignees and applicants and that a purported copy of the '689 patent is attached to the Complaint as Exhibit A.

31. Paragraph 31 contains conclusions of law to which no response is required. To the extent a response is required, on information and belief, Hetero admits that on the Orange Book, provided by the FDA on its website, the '689 patent is listed for Xtandi® 40 mg and 80 mg tablets.

32. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

33. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

34. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

35. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

36. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

37. Hetero lacks knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

38. Paragraph 38 contains conclusions of law to which no response is required. To the extent a response is required, on information and belief, Hetero admits the '628 Patent, titled "Combination Therapy" lists Medivation Prostate Therapeutics LLC and Astellas Pharma Inc. as assignees and applicants and that a purported copy of the '628 patent is attached to the Complaint as Exhibit B.

39. Paragraph 39 contains conclusions of law to which no response is required. To the extent a response is required, on information and belief, Hetero admits that on the Orange Book, provided by the FDA on its website, the '628 patent is listed for Xtandi® 40 mg and 80 mg tablets.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

40. Hetero admits that it served on Plaintiffs a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii)" for ANDA No. 220481 pursuant to § 505(j)(2)(b)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95 as to the '689 patent and the '628 patent dated July 28, 2025, advising Plaintiffs that Hetero sought FDA approval for enzalutamide 40 mg and 80 mg tablets ("Hetero's ANDA Products") prior to the expiration of the '689 patent and the '628 patent. ("Hetero's Notice Letter"). Except as otherwise expressly admitted, Hetero denies the remaining allegations in this paragraph.

41. Hetero admits that ANDA No. 220481 was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A) and contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") to obtain approval to engage in the commercial manufacture, use, or sale of Hetero's ANDA Products before the expiration of the '689 patent and the '628 patent.

Except as otherwise expressly admitted, Hetero denies the remaining allegations in this paragraph.

42. Hetero admits that it filed Hetero's ANDA and that Hetero's ANDA speaks for itself. Hetero denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of Hetero's ANDA.

43. Hetero admits that ANDA No. 220481 was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A) and contains a Paragraph IV certification that, in Hetero's opinion and to the best of its knowledge, the '689 patent and the '628 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of proposed products described in Hetero's ANDA. Except as otherwise expressly admitted, Hetero denies the remaining allegations in this paragraph.

44. Hetero admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Hetero denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

45. Denied.

46. Hetero admits that it sent the Notice Letter and that the Notice Letter speaks for itself. Hetero denies the allegations of this paragraph inasmuch as they do not accurately reflect the content of the Notice Letter.

47. Denied.

48. Paragraph 48 contains conclusions of law to which no response is required.

49. Hetero admits that it sent the Notice Letter on July 28, 2025, and Plaintiffs filed this action on September 10, 2025. Except as otherwise expressly admitted, Hetero lacks

knowledge or information sufficient to form a belief as to the truth of Plaintiffs' allegations and therefore denies them.

COUNT I
(Infringement of the '689 Patent)

50. Hetero incorporates each of the preceding paragraphs 1 to 49 as if fully set forth herein.

51. Denied.

52. Paragraph 52 contains conclusions of law to which no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

53. Paragraph 53 contains conclusions of law to which no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

54. Denied.

55. Denied.

56. Denied.

57. Paragraph 57 contains conclusions of law to which no response is required. To the extent a response is required, Hetero admits that it filed Hetero's ANDA and that Hetero's ANDA speaks for itself. Except as otherwise expressly admitted, Hetero denies the remaining allegations in this paragraph.

58. Denied.

59. Paragraph 59 contains conclusions of law to which no response is required. To the extent a response is required, Hetero admits that the Notice Letter provided a detailed explanation of the factual and legal bases why the claims of the '689 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of

Hetero's ANDA Products. Except as otherwise expressly admitted, Hetero denies the remaining allegations in this paragraph.

60. Denied.

61. Denied.

62. Denied.

COUNT II
(Infringement of the '628 Patent)

63. Hetero incorporates each of the preceding paragraphs 1 to 62 as if fully set forth herein.

64. Denied.

65. Paragraph 65 contains conclusions of law to which no response is required. To the extent a response is required, Hetero admits that the Notice Letter provided a detailed explanation of the factual and legal bases why the claims of the '628 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Products. Except as otherwise expressly admitted, Hetero denies the remaining allegations in this paragraph.

66. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

67. Paragraph 67 contains conclusions of law to which no response is required. To the extent a response is required, Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph and therefore denies them.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

75. Denied.

76. Denied.

RESPONSE FOR REQUEST FOR RELIEF

All allegations in Plaintiffs' Complaint not expressly admitted by Hetero are hereby denied. Having answered Plaintiffs' Complaint, Hetero denies Plaintiffs are entitled to any of the relief requested in the Complaint or any relief whatsoever.

RESERVATION OF DEFENSES

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

WHEREFORE, Hetero hereby demands judgment in their favor based on a finding of non-infringement and/or invalidity and/or unenforceability of the Patents-in-Suit, an award of all costs and fees incurred in defense of this Action and for such other relief as the Court may deem just and proper.

First Affirmative Defense
(Failure to State a Claim)

Plaintiffs fail to state a claim upon which relief can be granted.

Second Affirmative Defense
(Noninfringement of U.S. Patent No. 11,839,689)

For at least the reasons set forth in Hetero's Notice Letter, Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within,

and/or importation into, the United States of the products that are the subject Hetero's ANDA No. 220481 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '689 patent.

Third Affirmative Defense
(Invalidity of U.S. Patent No. 11,839,689)

Upon information and belief, the claims of the '689 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Fourth Affirmative Defense
(Noninfringement of U.S. Patent No. 12,161,628)

For at least the reasons set forth in Hetero's Notice Letter, Plaintiffs will not and cannot meet the burden of proof required to show that the manufacture, use, sale, or offer to sell within, and/or importation into, the United States of the products that are the subject Hetero's ANDA No. 220481 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '628 patent.

Fifth Affirmative Defense
(Invalidity of U.S. Patent No. 12,161,628)

For at least the reasons set forth in Hetero's Notice Letter, the claims of the '628 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112.

Sixth Affirmative Defense
(No Injunctive Relief)

Plaintiffs may not seek injunctive relief under 35 U.S.C. §§ 274(e)(4)(B) against Hetero because Plaintiffs' alleged damages are not irreparable, and Plaintiffs have an adequate remedy at law.

Seventh Affirmative Defense
(No Costs)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering costs associated with this suit.

Eighth Affirmative Defense
(No Exceptional Case)

Hetero's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

Nineth Affirmative Defense
(Equitable Defenses)

Hetero reserves the right to amend its Answer to include additional equitable defenses, such as additional inequitable conduct, unclean hands, laches, estoppel and/or patent misuse, if information obtained in discovery provides support for such a defense.

COUNTERCLAIMS

For their counterclaims against Plaintiffs Astellas Pharma Inc. ("API"), Astellas US LLC ("AUS"), and Astellas Pharma US, Inc. ("APUS") (collectively, "Astellas"), and Medivation LLC and Medivation Prostate Therapeutics LLC ("MPT") (collectively, "Medivation") (collectively, "Counterclaim Defendants"), Defendants/Counterclaim-Plaintiffs Hetero Labs Limited ("Hetero Labs"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero USA Inc. ("Hetero USA") (collectively "Hetero" or "Counterclaim Plaintiffs"), state as follows:

BACKGROUND AND PARTIES

1. This is an action for declaratory judgment of non-infringement and invalidity of Patent Nos. 11,839,689 ("the '689 patent") and 12,161,628 ("the '628 patent") ("the Counterclaim Patents-in-Suit"), pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; the patent laws of the United States, 35 U.S.C. § 1, *et seq.*; and the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j)(5)(C) and 35 U.S.C. § 271(e)(5)).

2. Counterclaim Plaintiff Hetero Labs is a company organized and existing under the laws of India, with a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Telangana, India.

3. Counterclaim Plaintiff Hetero Unit-V is a company organized and existing under the laws of India, with a principal place of business at Polepally, Jadcherla, Mahabubnagar, 509301, Telangana, India.

4. Counterclaim Plaintiff Hetero USA is a corporation organized and existing under the laws of Delaware, with its principal place of business at 1035 Centennial Avenue, Piscataway, New Jersey 08854.

5. On information and belief, Counterclaim Defendant API is a corporation organized and existing under the laws of Japan having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan.

6. On information and belief, Counterclaim Defendant AUS is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

7. On information and belief, Counterclaim Defendant APUS is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 2375 Waterview Drive, Northbrook, Illinois 60062, United States.

8. On information and belief, Counterclaim Defendant Medivation LLC is a limited liability company organized and existing under the laws of the State of Delaware having its

principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States.

9. On information and belief, Counterclaim Defendant Plaintiff MPT is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 66 Hudson Boulevard East, New York, New York 10001-2192, United States

JURISDICTION AND VENUE

10. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

11. This Court has subject matter jurisdiction over these counterclaims under 28 U.S.C. §§ 1331 and 1338(a) and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

12. This Court has personal jurisdiction over Counterclaim Defendants because, among other reasons, they subjected themselves to the jurisdiction of this Court by filing this action here and because, on information and belief, either directly or through agents, they transact business in and derive substantial revenue from the State of New Jersey.

13. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Counterclaim Defendants commenced the underlying action in this venue.

14. Because of Counterclaim Defendants' Complaint against Hetero, there is an actual, substantial, and justiciable controversy between the parties as to the infringement, validity, and/or enforceability of the Counterclaim Patents-in-Suit.

FACTUAL BACKGROUND

A. FDA Approval of Brand Name Pharmaceuticals

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

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

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

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

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

B. FDA Approval of Brand Name Pharmaceuticals

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

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

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

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

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

25. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the Paragraph IV certifications because doing so, regardless of merit,

automatically prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

26. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the product proposed in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id*. If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, "including any substantive determination that there is no cause of action for patent infringement or invalidity," the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. NDA No. 213674 and The Counterclaim Patents-In-Suit

27. According to the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book"), Astellas Pharma US Inc. is the holder of New Drug Application ("NDA") No. 213674, under which the FDA granted approval for enzalutamide 40 mg and 80 mg tablets, marketed in the United States as XTANDI® ("XTANDI®").

28. NDA holders are required to disclose to the FDA the patent number of patents claiming the drug or the method of using such drug for which the NDA is submitted. The FDA lists these patents in the Orange Book.

29. The Orange Book lists, *inter alia*, the '689 patent and the '628 patent in association with NDA No. 213674 for XTANDI®.

30. On information and belief, Astellas Pharma US Inc. caused the '689 and '628 patents to be listed in the Orange Book in connection with NDA No. 213674.

The ’689 Patent

31. Upon information and belief, the United States Patent and Trademark Office (“USPTO”) issued the ’689 patent, titled “Formulations of Enzalutamide” on or about December 12, 2023.

32. The ’689 patent on its face lists Counterclaim Defendants Astellas Pharma Inc. and Medivation Prostate Therapeutics LLC as the assignees, and upon information and belief, a copy of the ’689 patent is attached as Exhibit A to the Complaint.

33. Counterclaim Defendants averred in the underlying action that the USPTO issued the ’689 Patent to Astellas Pharma Inc. and Medivation Prostate Therapeutics LLC, that Astellas Pharma Inc. is an exclusive licensee of the patent, and that Astellas US LLC and Astellas Pharma US, Inc. have sublicenses to the ’689 patent.

The ’628 Patent

34. Upon information and belief, the USPTO issued the ’628 patent, titled “Combination Therapy” on or about December 10, 2024.

35. The ’628 patent on its face lists Counterclaim Defendants Astellas Pharma Inc. and Medivation Prostate Therapeutics LLC as the assignees, and upon information and belief, a copy of the ’628 patent is attached as Exhibit B to the Complaint.

36. Counterclaim Defendants averred in the underlying action that the USPTO issued the ’628 Patent to Astellas Pharma Inc. and Medivation Prostate Therapeutics LLC.

D. Hetero’s ANDA No. 220481

37. Hetero USA filed Abbreviated New Drug Application (“ANDA”) No. 220481 (“Hetero’s ANDA”) with the FDA, seeking approval for enzalutamide tablets, oral, 40 mg and 80 mg (“Hetero’s ANDA Products”) prior to expiration of the ’689 patent and ’628 patent.

38. Hetero's ANDA included a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), that, in Hetero's opinion and to the best of its knowledge, Hetero's ANDA Products would not infringe any valid claim of the '689 patent and the '628 patent.

39. Pursuant to 21 U.S.C. § 355(j)(2)(B), Hetero sent, or caused to be sent, to Counterclaim-Defendants a letter dated July 28, 2025, detailing the legal and factual bases for Hetero's Paragraph IV certification that Hetero's ANDA Products would not infringe any valid claim of the '689 and '628 patents (the "Detailed Statement"), detailing bases for Hetero's certification as to each claim of the '689 and '628 patents, and including an Offer of Confidential Access in accordance with 21 U.S.C. § 355(j)(5)(C)(i)(III) to allow Counterclaim-Defendants to inspect relevant portions of Hetero's ANDA.

40. Counterclaim Defendants did not agree to the terms and conditions of Hetero's Offer of Confidential Access.

41. Counterclaim Defendants initiated the present litigation by filing a complaint against Hetero on September 10, 2025, alleging that Hetero's ANDA infringes one or more claims of the '689 and '628 patents.

42. Counterclaim Defendants have alleged in the present action that Hetero has infringed and will infringe the '689 and '628 patents by filing Hetero's ANDA with the FDA and/or by manufacturing, using, importing, offering to sell, or selling Hetero's ANDA Products.

43. Counterclaim Defendants did not review Hetero's ANDA in the instant action prior to filing suit.

44. Counterclaim Defendants did not perform a prefiling infringement investigation of Hetero's ANDA Products.

45. As a consequence of the foregoing, there is an actual and justiciable controversy between Counterclaim Defendants and Hetero as to whether Hetero's ANDA infringes the '689 and '628 patents, or whether the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Products would infringe the '689 and '628 patents.

COUNT I
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,839,689)

46. Hetero restates and realleges each of the foregoing paragraphs 1-45 of the Counterclaims as if fully set forth herein.

47. Counterclaim Defendants allege that Hetero's filing of ANDA No. 220481 infringes the '689 patent and that the manufacture, use, offer for sale, sale or importation of Hetero's ANDA Products would infringe the '689 patent.

48. As evidenced by Counterclaim Defendants' Complaint and Hetero's Answer thereto, there is an actual, substantial, and continuing justiciable case or controversy between Hetero and Counterclaim Defendants regarding the validity of the claims of the '689 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

49. Hetero is entitled to a judicial determination that the claims of the '689 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT II
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 11,839,689)

50. Hetero restates and realleges each of the foregoing paragraphs 1-49 of the Counterclaims as if fully set forth herein.

51. Counterclaim Defendants allege that Hetero's filing of ANDA No. 220481 infringes the '689 patent and that the manufacture, use, offer for sale, sale or importation of Hetero's ANDA Products would infringe the '689 patent.

52. As evidenced by Counterclaim Defendants' Complaint and Hetero's Answer thereto, there is an actual, substantial, and continuing justiciable case or controversy between Hetero and Counterclaim Defendants regarding the infringement of the claims of the '689 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

53. The manufacture, use, offer for sale, sale, and/or import of Hetero's ANDA Products would not infringe any valid or enforceable claim of the '689 patent, either directly or indirectly.

54. Hetero is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claim of the '689 patent.

COUNT III
(Declaratory Judgment of Invalidity of U.S. Patent No. 12,161,628)

55. Hetero restates and realleges each of the foregoing paragraphs 1-54 of the Counterclaims as if fully set forth herein.

56. Counterclaim Defendants allege that Hetero's filing of ANDA No. 220481 infringes the '628 patent and that the manufacture, use, offer for sale, sale or importation of Hetero's ANDA Products would infringe the '628 patent.

57. As evidenced by Counterclaim Defendants' Complaint and Hetero's Answer thereto, there is an actual, substantial, and continuing justiciable case or controversy between Hetero and Counterclaim Defendants regarding the validity of the claims of the '628 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

58. Hetero is entitled to a judicial determination that the claims of the '628 patent are invalid for failure to comply with one or more of the requirements for patentability set forth in Title 35 of the U.S. Code, including §§ 102, 103 and/or 112.

COUNT IV
(Declaratory Judgment of Non-Infringement of U.S. Patent No. 12,161,628)

59. Hetero restates and realleges each of the foregoing paragraphs 1-58 of the Counterclaims as if fully set forth herein.

60. Counterclaim Defendants allege that Hetero's filing of ANDA No. 220481 infringes the '628 patent and that the manufacture, use, offer for sale, sale or importation of Hetero's ANDA Products would infringe the '628 patent.

61. As evidenced by Counterclaim Defendants' Complaint and Hetero's Answer thereto, there is an actual, substantial, and continuing justiciable case or controversy between Hetero and Counterclaim Defendants regarding the infringement of the claims of the '628 patent under 21 U.S.C. § 355(j)(5)(C)(ii).

62. The manufacture, use, offer for sale, sale, and/or import of Hetero's ANDA Products would not infringe any valid or enforceable claim of the '628 patent, either directly or indirectly.

63. Hetero is entitled to a declaration that it has not infringed, is not infringing, and will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid or enforceable claims of the '628 patent.

PRAYER FOR RELIEF

WHEREFORE, Hetero respectfully requests that this Court enter a judgment in its favor and against Counterclaim Defendants as follows:

a. Declaring that the filing of Hetero's ANDA did not infringe any valid and enforceable claim of the '689 patent or the '628 patent;

b. Declaring that the manufacture, use, sale, offer for sale, and/or importation of Hetero's ANDA Products described in Hetero's ANDA has not infringed, does not infringe, and would not – if made, used, sold, offered for sale, imported, or marketed – infringe, either directly or indirectly, any valid and enforceable claim of the '689 patent or the '628 patent, either literally or under the doctrine of equivalents;

c. Declaring that the claims of the '689 patent and the '628 patent are invalid;

d. Ordering that the Complaint be dismissed with prejudice and judgment entered in favor of Hetero;

e. Denying Plaintiffs/Counterclaim Defendants any of the relief requested in the Complaint;

f. Declaring this case exceptional in favor of Hetero pursuant to 35 U.S.C. § 285;

g. Awarding costs and attorneys' fees to Hetero; and,

h. Awarding Hetero such other and further relief the Court may deem just and proper.

Dated: November 11, 2025

By: *s/ Eric I. Abraham*

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Attorneys for Defendants/Counterclaim Plaintiffs Hetero Labs Limited, Hetero Labs Limited Unit-V and Hetero USA Inc.

LOCAL CIVIL RULE 11.2 and 40.1 CERTIFICATION

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

Dated: November 11, 2025

s/ Eric I. Abraham
Eric I. Abraham

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, injunctive and declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: June 2, 2025

s/ Eric I. Abraham
Eric I. Abraham

CERTIFICATE OF SERVICE

I certify that on November 11, 2025, a true and correct copy of the foregoing was served on Plaintiffs' counsel of record by way of the CM/ECF System and via email.

s/ Eric I. Abraham
Eric I. Abraham