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

ABBVIE INC., ALLERGAN PHARMACEUTICALS INTERNATIONAL LIMITED, and MERCK SHARP & DOHME LLC,	)	
Plaintiffs,	)	Civil Action No. _____
v.	)	
HETERO USA INC., HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AbbVie Inc. ("AbbVie"), Allergan Pharmaceuticals International Limited ("Allergan"), and Merck Sharp & Dohme LLC ("Merck") (collectively, "Plaintiffs"), by its attorneys, bring this action against Defendants Hetero USA Inc. ("Hetero USA"), Hetero Labs

Limited Unit-III ("Hetero Unit-III"), and Hetero Labs Limited ("Hetero Labs") (collectively "Hetero"), and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), and 11,925,709 ("the '709 patent") (collectively, "the Patents-in-Suit") arising under the United States Patent Laws, Title 35, United States Code, § 1, *et seq.*, and in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to Hetero's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market generic versions of Plaintiffs' commercial pharmaceutical product UBRELVY® (ubrogepant) oral tablets in 50 mg and 100 mg dosage forms ("UBRELVY® Tablets") submitted under New Drug Application ("NDA") No. 211765, prior to the expiration of patents listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for UBRELVY® Tablets. Hetero has submitted ANDA No. 219113 ("Hetero's ANDA"), which seeks approval to market its generic version of UBRELVY® Tablets, ubrogepant oral tablets, 50 mg, 100 mg ("Hetero's generic products"), prior to the expiration of the Patents-in-Suit.

2. Hetero has infringed one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(e)(2)(A) by virtue of its filing of ANDA No. 219113 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Hetero's generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof. Hetero will infringe one or more claims of the Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or

importation into the United States of Hetero's generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof.

THE PARTIES

3. Plaintiff AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie holds NDA No. 211765 for UBRELVY® Tablets.

4. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including migraine treatment.

5. AbbVie markets, distributes, and sells therapeutic drug products, including UBRELVY® Tablets, in this judicial district and throughout the United States.

6. Plaintiff Allergan is a corporation organized and existing under the laws of Ireland, with a principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400. Allergan is the assignee of the '515 and '542 patents. Allergan is an indirectly wholly owned subsidiary of AbbVie.

7. Plaintiff Merck is a limited liability company organized and existing under the laws of the State of New Jersey, having a principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065. Merck is the assignee of the '836 and '709 patents.

8. Merck is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets a broad range of innovative products to improve health.

9. Plaintiffs allege the following about Hetero on information and belief formed after a reasonable inquiry.

10. 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. On information and belief, Hetero USA is the U.S. Regulatory Agent for Hetero Unit-III, a division of Hetero Labs, including for ANDA No. 219113. Hetero USA is a partially owned subsidiary of Hetero Labs.

11. Hetero Unit-III is a corporation organized and existing under the laws of India, having a principal place of business at 22-110, IDA Jeedimetla, Hyderabad – 500 055, Telangana, India. On information and belief, Hetero Unit-III is a division of Hetero Labs.

12. Hetero Labs is a corporation organized and existing under the laws of India, having a principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad 500 018, Andhra Pradesh, India.

13. Hetero is in the business of, *inter alia*, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in this judicial district.

14. Following any FDA approval of Hetero's ANDA, Hetero will distribute and sell the proposed Hetero generic products described in Hetero's ANDA throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

15. This action arises under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

16. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Defendant Hetero USA. On information and belief, Hetero USA is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Hetero USA directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero USA has purposefully conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products upon approval of Hetero's ANDA.

18. This Court has personal jurisdiction over Defendant Hetero Unit-III. On information and belief, Hetero Unit-III is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Hetero Unit-III directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Unit-III has purposefully conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products upon approval of Hetero's ANDA.

19. This Court has personal jurisdiction over Defendant Hetero Labs. On information and belief, Hetero Labs is in the business of manufacturing, marketing, importing, and selling pharmaceutical drug products, including generic drug products. On information and belief, Hetero Labs directly, or indirectly, develops, manufactures, markets, and sells generic drugs throughout the United States and in this judicial district. On information and belief, Hetero Labs has

purposefully conducted and continues to conduct business in this judicial district, and this judicial district is a likely destination of Hetero's generic products upon approval of Hetero's ANDA.

20. On information and belief, Hetero USA is a United States agent for Hetero Labs. Hetero USA claims that it is "a group company of Hetero" and "the sales and marketing arm of Hetero's Active Pharmaceutical Ingredients (API) and Custom Pharmaceutical Services (CPS) business in [the] USA." *Global Presence of Hetero Across the World*, https://hetero.com/presence (last visited Apr. 11, 2024). Hetero USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0400362826. Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

21. On information and belief, Hetero USA, Hetero Unit-III, and Hetero Labs hold themselves out as a unitary entity and operate as a single integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this judicial district.

22. On information and belief, Hetero USA, Hetero Unit-III, and Hetero Labs each directly or indirectly currently sells significant quantities of generic drug products and derives substantial revenue from the sale of those products in the United States and in this judicial district. Hetero claims to be "[a]mong India's leading generic pharmaceutical companies." *About Us*, https://hetero.com/about-us (last visited Apr. 11, 2024). Hetero claims that it "[has] over 38 strategically located manufacturing facilities, catering to diverse market requirements on demand – including . . . [the] USA." Hetero, *Corporate Presentation, October, 2023*, 4 (2023), https://www.hetero.com/pdf/hetero_corporate_ppt_october_2023.pdf (last visited Apr. 11, 2024) ("Hetero Corporate Presentation"). Hetero claims to be "manufacturing branded and non-branded

generics," with "200+ products across various therapeutic categories." *Id.* at 6. Hetero claims that it "[is] among the largest supplier of therapeutic drugs to markets in . . . [the] US." *Key Therapies at Hetero*, https://www.hetero.com/key-therapies (last visited Apr. 11, 2024).

23. Hetero is engaged in the submission and approval of ANDAs for the United States market. *See, e.g.*, *2022 First Generic Drug Approvals*, U.S. Food & Drug Administration (Mar. 3, 2023), https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2022-first-generic-drug-approvals (last visited Apr. 11, 2024) (listing the approval of Hetero Lab's ANDA No. 204787 and Hetero Unit-III's ANDA No. 203347); *Original Abbreviated New Drug Application (ANDA) Approvals, October 2023*, U.S. Food & Drug Administration https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process&rptName=3&reportSelectMonth=10&reportSelectYear=2023&nav#navigation (last visited Apr. 11, 2024) (listing the approval of Hetero Unit-III's ANDA Nos. 091475, 216749, and 214571).

24. On information and belief, the acts of Hetero USA and Hetero Unit-III complained of herein were done with the cooperation, participation, and assistance of Hetero Labs.

25. Hetero's ANDA filing regarding the Patents-in-Suit relates to this litigation and is substantially connected with this judicial district because it predicts Hetero's intent to market and sell Hetero's generic products in this judicial district.

26. On information and belief, Hetero USA, Hetero Unit-III, and Hetero Labs have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 219113.

27. Following FDA approval of ANDA No. 219113, Hetero will act in concert to import, market, distribute, offer for sale, and/or sell Hetero's generic products described in ANDA

No. 219113 throughout the United States, including in New Jersey and will derive substantial revenue from the use, consumption, or sale of Hetero's generic products in the state of New Jersey.

28. If ANDA No. 219113 is approved, Hetero's generic products will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by healthcare providers practicing in New Jersey; administered by healthcare providers located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

29. If ANDA No. 219113 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Hetero's generic products, including in New Jersey.

30. This Court also has personal jurisdiction over Hetero because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. Hetero has been sued multiple times in this district without challenging personal jurisdiction. *See, e.g.*, Defs.' Answer to Pls.' Compl., *Axsome Malta Ltd. v. Alkem Lab'ys Ltd.*, No. 2:23-cv-20354-MCA-JBC (D.N.J. Nov. 17, 2023); Defs.' Answer to Pl.'s Compl., *Merck Sharp & Dohme LLC v. Hetero USA, Inc.*, No. 2:22-cv-06820-ES-CLW (D.N.J. Feb. 10, 2023); Defs.' Answer to Pl.'s Compl., *Rigel Pharms., Inc. v. Annora Pharma Priv., Ltd.*, No. 2:22-cv-04732 (D.N.J. Sept. 21, 2022); Defs.' Answer to Pls.' Compl., *Aragon Pharms., Inc. v. Hetero Labs Ltd. Unit V*, No. 2:22-cv-03212 (D.N.J. Aug. 5, 2022).

31. For these reasons and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Hetero.

32. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Hetero USA has a principal place of business in New Jersey.

33. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Hetero Unit-III is incorporated in the Republic of India and may be sued in any judicial district in the United States.

34. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), because Hetero Labs is incorporated in the Republic of India and may be sued in any judicial district in the United States.

FACTUAL BACKGROUND

UBRELVY® and the NDA

35. AbbVie is the holder of the New Drug Application ("NDA") No. 211765 for UBRELVY® (ubrogepant) tablets in 50 mg and 100 mg dosages forms.

36. The FDA approved NDA No. 211765 on December 23, 2019.

37. The FDA Orange Book for NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg, lists U.S. Patent No. 8,754,096 ("the '096 patent"); U.S. Patent No. 8,912,210 ("the '210 patent"); U.S. Patent No. 9,499,545 ("the '545 patent"); U.S. Patent No. 9,833,448 ("the '448 patent"); the '836 patent; the '515 patent; and the '542 patent.

38. UBRELVY® Tablets are approved for the acute treatment of migraine attacks with or without aura in adults. Ubrogepant is the active ingredient of UBRELVY® Tablets. Ubrogepant is a calcitonin gene-related (CGRP) receptor antagonist.

39. Migraine is a debilitating disease. Migraine impacts more than 37 million men, women, and children in the United States. Migraine costs millions of dollars each year in the United States due to direct medical expenses and lost productivity. Migraine is also associated with other illnesses.

40. The recommended dose of UBRELVY® Tablets is 50 mg or 100 mg taken orally with or without food. If needed, a second dose may be administered at least 2 hours after the initial dose. For patients with severe hepatic impairment or severe renal impairment, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients with severe hepatic impairment or severe renal impairment, and information concerning these patients is included in the UBRELVY® Label.

41. To date, only two orally available CGRP receptor antagonists have been approved by FDA for acute treatment of migraine. UBRELVY® Tablets were the first. The prescribing information for the other, NURTEC® ODT, states that use of the drug should be avoided in patients with severe hepatic impairment. Thus, UBRELVY® Tablets are the only orally available CGRP receptor antagonist in the United States indicated for acute treatment of migraine in patients with severe hepatic impairment.

42. UBRELVY® Tablets are marketed and sold in the United States by AbbVie.

The Patents-in-Suit

43. The ’836 patent, titled “Tablet Formulation for CGRP Active Compounds,” was duly and legally issued by the United States Patent and Trademark Office (“USPTO”) on November 6, 2018. A true and correct copy of the ’836 patent is attached as Exhibit A.

44. Merck is the assignee of the ’836 patent through assignment as recorded by the USPTO at Reel 041662, Frame 0851; Reel 041829, Frame 0001; and Reel 061102, Frame 0145.

45. The ’836 patent currently expires on January 30, 2035.

46. Allergan is the exclusive licensee of the ’836 patent.

47. The ’836 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg.

48. The ’515 patent, titled “Treatment of Migraine,” was duly and legally issued by the USPTO on August 8, 2023. A true and correct copy of the ’515 patent is attached as Exhibit B.

49. Allergan is the assignee of the ’515 patent through assignment as recorded by the USPTO at Reel 063519, Frame 0307.

50. The ’515 patent currently expires on December 22, 2041.

51. The ’515 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

52. The ’542 patent, titled “Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on January 2, 2024. A true and correct copy of the ’542 patent is attached as Exhibit C.

53. Allergan is the assignee of the ’542 patent through assignment as recorded by the USPTO at Reel 064076, Frame 0407.

54. The ’542 patent currently expires on December 22, 2041.

55. The ’542 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

56. The ’709 patent, titled “Tablet Formulation for CGRP Active Compounds,” was duly and legally issued by the United States Patent and Trademark Office on March 12, 2024. A true and correct copy of the ’709 patent is attached as Exhibit D.

57. Merck is the assignee of the ’709 patent through assignment as recorded by the USPTO at Reel 061200, Frame 0836.

58. The ’709 patent currently expires on January 30, 2035.

59. Allergan is the exclusive licensee of the ’709 patent.

60. The ’709 patent was submitted for listing in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg.

Hetero’s ANDA No. 219113

61. On information and belief, Hetero filed ANDA No. 219113 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of ubrogepant oral tablets, 50 mg, 100 mg, which are generic versions of AbbVie’s UBRELVY® Tablets.

62. AbbVie received a letter sent by Hetero (“Hetero’s Notice Letter”), dated February 26, 2024, purporting to be a notice letter “[u]nder 21 U.S.C. § 355(j)(2)(B)(ii) (§ 505(j)(2)(B)(ii) of the Federal Food, Drug and Cosmetic Act) and 21 C.F.R. § 314.95.”

63. Hetero’s Notice Letter represents that Hetero’s ANDA No. 219113 contains a Paragraph IV certification, alleging that the claims of the ’836 and ’515 patents are invalid, unenforceable, and/or will not be infringed by Hetero’s generic products.

64. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding Hetero’s ANDA No. 219113 for the ’709 patent (“’709 Patent Notice Letter”) under Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

65. On information and belief, Hetero’s Notice Letter and the information contained therein, coupled with regulatory requirements, demonstrate Hetero’s infringement of the ’709 patent.

66. Hetero’s Notice Letter does not state or otherwise indicate that Hetero submitted a Paragraph IV certification for the ’096, ’210, ’545, and ’448 patents, each of which is listed in the FDA Orange Book for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Accordingly, on

information and belief, Hetero submitted a Paragraph III certification for the '096, '210, '545, and '448 patents, and informed the FDA that it would not launch at least before December 23, 2033.

67. Hetero's purpose in submitting ANDA No. 219113 and a Paragraph IV certification is to market Hetero's generic products before the expiration of the '836 and '515 patents. Hetero intends to market Hetero's generic products before the expiration of the '542 and '709 patents.

68. To obtain approval of an ANDA for a generic drug, an ANDA applicant must show, *inter alia*, that the generic drug is bioequivalent to its reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(iv). If approved, Hetero's generic products will be bioequivalent to AbbVie's UBRELVY® Tablets.

69. To obtain approval of an ANDA for a generic drug, an ANDA applicant must also show, *inter alia*, that the conditions of use prescribed, recommended, or suggested in the proposed labeling have been previously approved for its reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(i). Further, the FDA will refuse to approve an ANDA if the labeling proposed for a generic drug product differs from the labeling approved for its reference listed drug product and such differences make the proposed generic drug product less safe or effective. *See* 21 C.F.R. § 314.127(a)(7). On information and belief, if approved, Hetero's generic products will have the same indication and safety and efficacy information as AbbVie's UBRELVY® Tablets.

70. Hetero's Notice Letter purported to offer confidential access to Hetero's ANDA No. 219113 on terms and conditions set forth in Hetero's Notice Letter ("Hetero's Offer of Confidential Access"). Outside counsel for AbbVie, Allergan, and Merck negotiated in good faith with counsel for Hetero in an attempt to reach agreement on reasonable terms of confidential access to Hetero's ANDA No. 219113. The parties engaged in multiple rounds of negotiation. As

of April 11, 2024, the parties were unable to reach agreement. To date, AbbVie, Allergan, and Merck have not received access to Hetero's ANDA No. 219113.

71. Following FDA approval of Hetero's ANDA No. 219113, Hetero will make, use, sell, and/or offer to sell Hetero's generic products throughout the United States, or import such generic products into the United States before the Patents-in-Suit expire. The manufacture, use, offer for sale, sale, and/or importation of Hetero's generic products will directly infringe the Patents-in-Suit.

72. Following FDA approval of Hetero's ANDA No. 219113, Hetero will actively induce or contribute to the manufacture, use, offer for sale, and/or sale of Hetero's generic products in a manner that infringes the Patents-in-Suit.

73. Plaintiffs commenced this action within 45 days of receiving Hetero's Notice Letter.

COUNT I
INFRINGEMENT BY HETERO OF THE '836 PATENT

74. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

75. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '836 patent.

76. Hetero's Notice Letter states that Hetero submitted to the FDA, pursuant to 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), a certification that the claims of the '836 patent are purportedly invalid, unenforceable, and/or will not be infringed.

77. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

78. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's generic products before the expiration date of the '836 patent, constitutes infringement, either literally or under the doctrine of equivalents.

79. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '836 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

80. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '836 patent.

81. Hetero had knowledge of the '836 patent, as evidenced by Hetero's Notice Letter, and, by its promotional activities and proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents.

82. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

83. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '836 patent, either literally or

under the doctrine of equivalents. Hetero has knowledge and is aware of the '836 patent, as evidenced by Hetero's Notice Letter.

84. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

85. Hetero should have had and/or has had and continues to have knowledge that Hetero's generic products are especially adapted for a use that infringes the '836 patent.

86. Hetero should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's generic products.

87. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

88. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '836 patent.

89. Plaintiffs do not have an adequate remedy at law.

COUNT II
DECLARATORY JUDGMENT OF
INFRINGEMENT BY HETERO OF THE '836 PATENT

90. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

91. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

92. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '836 patent.

93. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

94. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '836 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

95. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '836 patent.

96. Hetero had knowledge of the '836 patent, as evidenced by Hetero's Notice Letter, and, by its promotional activities and proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents.

97. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

98. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '836 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '836 patent, as evidenced by Hetero's Notice Letter.

99. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

100. Hetero should have had and/or has had and continues to have knowledge that Hetero's generic products are especially adapted for a use that infringes the '836 patent.

101. Hetero should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's generic products.

102. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

103. On information and belief, Hetero's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Hetero's generic products in the United States, will begin immediately after FDA approves Hetero's generic products. Such activity before the expiration of the '836 patent will constitute infringement of one or more claims of the '836 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

104. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero concerning liability for the infringement of the '836 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

105. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '836 patent.

106. Plaintiffs do not have an adequate remedy at law.

COUNT III
INFRINGEMENT BY HETERO OF THE '515 PATENT

107. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

108. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '515 patent.

109. Hetero's Notice Letter states that Hetero submitted to the FDA, pursuant to 21 U.S.C. §§ 355(j)(2)(A)(vii)(IV), a certification that the claims of the '515 patent are purportedly invalid, unenforceable, and/or will not be infringed.

110. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

111. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's generic products before the expiration date of the '515 patent, constitutes infringement, either literally or under the doctrine of equivalents.

112. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '515 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

113. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '515 patent.

114. Hetero had knowledge of the '515 patent, as evidenced by Hetero's Notice Letter, and, by its promotional activities and proposed package insert for Hetero's generic products,

knows or should know that it will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents.

115. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

116. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '515 patent, as evidenced by Hetero's Notice Letter.

117. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

118. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

119. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '515 patent.

120. Plaintiffs do not have an adequate remedy at law.

COUNT IV
DECLARATORY JUDGMENT OF
INFRINGEMENT BY HETERO OF THE '515 PATENT

121. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

122. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

123. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '515 patent.

124. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

125. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '515 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

126. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '515 patent.

127. Hetero had knowledge of the '515 patent, as evidenced by Hetero's Notice Letter, and, by its promotional activities and proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents.

128. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

129. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '515 patent, either literally or under the doctrine of equivalents. Hetero has knowledge and is aware of the '515 patent, as evidenced by Hetero's Notice Letter.

130. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

131. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

132. On information and belief, Hetero's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Hetero's generic products in the United States, will begin immediately after FDA approves Hetero's generic products. Such activity before the expiration of the '515 patent will constitute infringement of one or more claims of the '515 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

133. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero concerning liability for the infringement of the '515 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

134. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '515 patent.

135. Plaintiffs do not have an adequate remedy at law.

COUNT V
INFRINGEMENT BY HETERO OF THE '542 PATENT

136. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

137. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '542 patent.

138. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

139. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero's ANDA seeking approval for the commercial manufacture, use, or sale of Hetero's generic products before the expiration date of the '542 patent, constitutes infringement, either literally or under the doctrine of equivalents.

140. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '542 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

141. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '542 patent.

142. Hetero had knowledge of the '542 patent and, by its promotional activities and proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents.

143. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

144. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '542 patent.

145. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

146. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

147. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '542 patent.

148. Plaintiffs do not have an adequate remedy at law.

COUNT VI
DECLARATORY JUDGMENT OF
INFRINGEMENT BY HETERO OF THE '542 PATENT

149. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

150. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

151. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '542 patent.

152. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

153. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '542 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, by actively inducing infringement by others under § 271(b), and/or by contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

154. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '542 patent.

155. Hetero had knowledge of the '542 patent and, by its promotional activities and proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents.

156. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

157. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '542 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '542 patent.

158. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

159. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

160. On information and belief, Hetero's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Hetero's generic products in the United States, will begin immediately after FDA approves Hetero's generic products. Such activity before the expiration of the '542 patent will constitute infringement of one or more claims of the '542 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

161. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero concerning liability for the infringement of the '542 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

162. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '542 patent.

163. Plaintiffs do not have an adequate remedy at law.

COUNT VII
INFRINGEMENT BY HETERO OF THE '709 PATENT

164. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

165. This Complaint provides notice of the ’709 patent to the extent that Hetero did not already have notice of this patent.

166. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero’s generic products in the United States before the expiration of the ’709 patent.

167. On information and belief, Hetero represented to the FDA that Hetero’s generic products are pharmaceutically and therapeutically equivalent to AbbVie’s UBRELVY® Tablets.

168. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of Hetero’s ANDA seeking approval for the commercial manufacture, use, or sale of Hetero’s generic products before the expiration date of the ’709 patent, constitutes infringement, either literally or under the doctrine of equivalents.

169. After FDA approval of Hetero’s ANDA, Hetero will infringe one or more claims of the ’709 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero’s generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero’s ANDA shall be no earlier than the expiration of the ’709 patent and any additional periods of exclusivity.

170. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero’s generic products for which approval is sought in Hetero’s ANDA, and therefore will infringe at least one claim in the ’709 patent.

171. Hetero had knowledge of the ’709 patent and, by its promotional activities and proposed package insert for Hetero’s generic products, knows or should know that it will induce

direct infringement of at least one of the claims of the ’709 patent, either literally or under the doctrine of equivalents.

172. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero’s generic products according to the instructions in the proposed package insert in a way that directly infringes the ’709 patent.

173. The offering to sell, sale, making, and/or importation of Hetero’s generic products will actively induce infringement of at least one of the claims of the ’709 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the ’709 patent.

174. If Hetero’s ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero’s generic products.

175. Hetero should have had and/or has had and continues to have knowledge that Hetero’s generic products are especially adapted for a use that infringes the ’709 patent.

176. Hetero should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Hetero’s generic products.

177. Hetero’s actions relating to Hetero’s ANDA complained of herein were done by and for the benefit of Hetero.

178. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the ’709 patent.

179. Plaintiffs do not have an adequate remedy at law.

COUNT VIII
DECLARATORY JUDGMENT OF
INFRINGEMENT BY HETERO OF THE '709 PATENT

180. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

181. This Complaint provides notice of the '709 patent to the extent that Hetero did not already have notice of this patent.

182. Plaintiffs' claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

183. Hetero filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero's generic products in the United States before the expiration of the '709 patent.

184. On information and belief, Hetero represented to the FDA that Hetero's generic products are pharmaceutically and therapeutically equivalent to AbbVie's UBRELVY® Tablets.

185. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '709 patent, either literally or under the doctrine of equivalents under § 271(a) by making, using, offering to sell, selling, and/or importing Hetero's generic products, and by actively inducing infringement by others under § 271(b) and/or contributing to infringement under § 271(c), unless this Court orders that the effective date of any FDA approval of Hetero's ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

186. Hetero knows or should know, and intends that healthcare providers will prescribe and patients will take Hetero's generic products for which approval is sought in Hetero's ANDA, and therefore will infringe at least one claim in the '709 patent.

187. Hetero had knowledge of the '709 patent and, by its promotional activities and proposed package insert for Hetero's generic products, knows or should know that it will induce direct infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents.

188. Hetero is aware and/or has knowledge that it will advertise an infringing use and/or instruct how to engage in an infringing use because healthcare professionals and/or patients will use Hetero's generic products according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

189. The offering to sell, sale, making, and/or importation of Hetero's generic products will actively induce infringement of at least one of the claims of the '709 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '709 patent.

190. If Hetero's ANDA is approved, Hetero intends to and will offer to sell, sell, and/or import in the United States Hetero's generic products.

191. Hetero should have had and/or has had and continues to have knowledge that Hetero's generic products are especially adapted for a use that infringes the '709 patent.

192. Hetero should have had and/or has had and continues to have knowledge that there is no substantial non-infringing use for Hetero's generic products.

193. Hetero's actions relating to Hetero's ANDA complained of herein were done by and for the benefit of Hetero.

194. On information and belief, Hetero's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of Hetero's generic products in the United States, will begin immediately after FDA approves Hetero's generic products. Such activity before the expiration of

the ’709 patent will constitute infringement of one or more claims of the ’709 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

195. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Hetero concerning liability for the infringement of the ’709 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

196. Plaintiffs will be irreparably harmed if Hetero is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the ’709 patent.

197. Plaintiffs do not have an adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that Hetero has infringed at least one claim of the Patents-in-Suit through Hetero’s submission of ANDA No. 219113 to the FDA to obtain approval to manufacture, use, import, offer to sell, and/or sell Hetero’s generic products in the United States before the expiration of the Patents-in-Suit;

B. The entry of judgment that Hetero’s making, using, offering to sell, selling, or importing Hetero’s generic products prior to the expiration of the Patents-in-Suit will infringe, actively induce infringement, and/or contribute to the infringement of Patents-in-Suit under 35 U.S.C. § 271(a), (b), and/or (c);

C. A declaration under 28 U.S.C. § 2201 that if Hetero, its officers, agents, employees, parents, affiliates, and subsidiaries, and all persons and entities acting in concert with it or on its behalf, engage in the commercial manufacture, use, offer for sale, sale or importation of Hetero’s

generic products prior to the expiration of the Patents-in-Suit, it will constitute an act of infringement pursuant to 35 U.S.C. § 271(a), (b), and/or (c);

D. The issuance of an order that the effective date of any FDA approval of Hetero's generic products shall be no earlier than the expiration date of the Patents-in-Suit and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. The entry of a permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from commercially manufacturing, using, offering for sale, or selling Hetero's generic products within the United States, or importing Hetero's generic products into the United States, until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. The entry of a permanent injunction, enjoining Hetero and all persons acting in concert with Hetero from seeking, obtaining, or maintaining approval of the ANDA until the expiration of the Patents-in-Suit, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

G. The issuance of a declaration that this is an exceptional case and an award to Plaintiffs of costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

H. An award to Plaintiffs of any further appropriate relief under 35 U.S.C. § 271(e)(4); and

I. An award to Plaintiffs of any further and additional relief that this Court deems just and proper.

Dated: April 11, 2024

/s/ Jose L. Linares
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