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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,* v. HETERO USA INC., HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED, *Defendants.*	C.A. No. 3:24-cv-04852-ZNQ-JBD

HETERO USA INC., HETERO LABS LIMITED UNIT-III, AND HETERO LABS LIMITED'S ANSWER TO PLAINTIFFS' THIRD AMENDED COMPLAINT, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (collectively, "Hetero"), by and through their undersigned attorneys, hereby answer the Third Amended Complaint (D.I. 57) brought by Plaintiffs AbbVie Inc., Allergan Pharmaceuticals International Limited, and Merck Sharp & Dohme LLC (collectively, "Plaintiffs") concerning U.S. Patent Nos.

10,117,836 (the "'836 patent"), 11,717,515 (the "'515 patent"), 11,857,542 (the "'542 patent"), 11,925,709 (the "'709 patent"), 12,070,450 (the "'450 patent"), 12,168,004 (the "'004 patent"), 12,194,030 (the "'030 patent"), 12,220,408 (the "'408 patent"), 12,310,953 (the "'953 patent"), and 12,329,750 (the "'750 patent") (collectively, the "Patents-in-Suit").

GENERAL DENIAL

Hetero denies all allegations in Plaintiffs' Third Amended Complaint except for those specifically admitted below. With respect to the allegations made in the Third Amended Complaint, upon knowledge with respect to Hetero's own acts, and upon information and belief as to other matters, Hetero responds and alleges 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"), 11,925,709 ("the '709 patent"), 12,070,450 ("the '450 patent"), 12,168,004 ("the '004 patent"), 12,194,030 ("the '030 patent"), 12,220,408 ("the '408 patent"), 12,310,953 ("the '953 patent"), and 12,329,750 ("the '750 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.

ANSWER: Paragraph 1 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring an action for patent infringement under the laws of the United States with respect to the Patents-in-Suit. Hetero admits that Hetero USA Inc. submitted ANDA No. 219113 ("Hetero's ANDA") seeking approval to market ubrogepant oral tablets in 50-mg and 100-mg dosage forms ("Hetero's ANDA Product")

prior to the expiration of U.S. Patent Nos. 10,117,836 (the "'836 patent") and 11,717,515 (the "'515 patent"). Hetero also denies any allegations to the extent they suggest that Hetero filed a Paragraph IV certification for U.S. Patent Nos. 11,857,542 (the "'542 patent"), 11,925,709 (the "'709 patent"), 12,070,450 (the "'450 patent"), 12,168,004 (the "'004 patent"), 12,194,030 (the "'030 patent"), 12,220,408 (the "'408 patent"), 12,310,953 (the "'953 patent"), and 12,329,750 (the "'750 patent"). Hetero denies any remaining allegations in Paragraph 1 of the Third Amended Complaint.

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.

ANSWER: Denied.

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.

ANSWER: Hetero admits that AbbVie is listed in the Orange Book as holder of NDA No. 211765 for UBRELVY® Tablets. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 3 of the Third Amended Complaint and therefore denies them.

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.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 4 of the Third Amended Complaint and therefore denies them.

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

ANSWER: Hetero admits that AbbVie is listed in the Orange Book as holder of NDA No. 211765 for UBRELVY® Tablets. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 5 of the Third Amended Complaint and therefore denies them.

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, '542, '450,'030, and '750 patents and the exclusive licensee of the '836, '709, '004, '408, and '953 patents. Allergan is an indirectly wholly owned subsidiary of AbbVie.

ANSWER: Hetero admits that the face of the '515, '542, '450, '030, and '750 patents list Allergan as the "Assignee." Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 6 of the Third Amended Complaint and therefore denies them.

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, '709, '004, '408, and '953 patents.

ANSWER: Hetero admits that the face of the '836, '709, '004, '408, and '953 patents lists Merck as the "Assignee." Hetero lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 7 of the Third Amended Complaint and therefore denies them.

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

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 8 of the Third Amended Complaint and therefore denies them.

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

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of the Third Amended Complaint and therefore denies them.

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.

ANSWER: Hetero admits that Hetero USA is the regulatory agent for ANDA No. 219113. Hetero also admits that Hetero USA is a partially owned subsidiary of Hetero Labs. Hetero denies any remaining allegations in Paragraph 10 of the Third Amended Complaint.

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.

ANSWER: Admitted.

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.

ANSWER: Admitted.

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.

ANSWER: Hetero admits that it is in the business of manufacturing, marketing, importing, distributing, and selling pharmaceutical drug products. Hetero denies any remaining allegations in Paragraph 13 of the Third Amended Complaint.

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.

ANSWER: Hetero admits that Hetero USA submitted Hetero's ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 14 of the Third Amended Complaint.

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.

ANSWER: Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring an action for patent infringement under the laws of the United States. Hetero denies any remaining allegations in Paragraph 15 of the Third Amended Complaint.

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

ANSWER: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero does not contest that this Court has subject matter jurisdiction over this action. Hetero denies any remaining allegations in Paragraph 16 of the Third Amended Complaint.

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.

ANSWER: Paragraph 17 states legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA does not contest personal jurisdiction in this

judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 17 of the Third Amended Complaint.

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.

ANSWER: Paragraph 18 states legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero Unit-III does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 18 of the Third Amended Complaint.

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.

ANSWER: Paragraph 19 states legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero Labs does not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 19 of the Third Amended Complaint.

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.

ANSWER: Paragraph 20 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 20 of the Third Amended Complaint.

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.

ANSWER: Paragraph 21 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 21 of the Third Amended Complaint.

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).

ANSWER: Paragraph 22 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 22 of the Third Amended Complaint.

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).

ANSWER: Paragraph 23 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 23 of the Third Amended Complaint.

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.

ANSWER: Paragraph 24 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of

this action. Hetero denies any remaining allegations in Paragraph 24 of the Third Amended Complaint.

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.

ANSWER: Paragraph 25 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 25 of the Third Amended Complaint.

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.

ANSWER: Paragraph 26 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 26 of the Third Amended Complaint.

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.

ANSWER: Paragraph 27 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-

III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 27 of the Third Amended Complaint.

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.

ANSWER: Paragraph 28 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 28 of the Third Amended Complaint.

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.

ANSWER: Denied.

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).

ANSWER: Paragraph 30 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of

this action. Hetero denies any remaining allegations in Paragraph 30 of the Third Amended Complaint.

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.

ANSWER: Paragraph 31 of the Third Amended Complaint contains legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA, Hetero Unit-III, and Hetero Labs do not contest personal jurisdiction in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 31 of the Third Amended Complaint.

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.

ANSWER: Paragraph 32 states legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero USA does not contest venue in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 32 of the Third Amended Complaint.

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.

ANSWER: Paragraph 33 states legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero Unit-III does not contest venue in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 33 of the Third Amended Complaint.

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.

ANSWER: Paragraph 34 states legal conclusions to which no response is required. To the extent that a response is required, solely for purposes of this action and to conserve the resources of the parties and the Court, Hetero Labs does not contest venue in this judicial district for the purposes of this action. Hetero denies any remaining allegations in Paragraph 34 of the Third Amended Complaint.

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.

ANSWER: Hetero admits that AbbVie is listed in the Orange Book as holder of NDA No. 211765 for UBRELVY® Tablets.

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

ANSWER: Hetero admits that December 23, 2019 is listed in the Orange Book as the approval date for NDA No. 211765.

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; the '542 patent; the '709 patent; the '450 patent; the '004 patent; and the '030 patent.

ANSWER: Admitted that 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; the '542 patent; the '709 patent; the '004 patent; and the '030 patent are listed in the Orange Book for UBRELVY® (ubrogepant) oral tablets, 50 mg. Admitted that the '096 patent, the '210 patent, the '545 patent, the '448 patent, the '836 patent, the '709 patent, the '450 patent, and the '004 patent are listed in the Orange Book for

UBRELVY® (ubrogepant) oral tablets 100 mg. Hetero denies any remaining allegations in Paragraph 37 of the Third Amended Complaint.

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.

ANSWER: Hetero admits that the FDA-approved product label for UBRELVY® Tablets provides that "UBRELVY is a calcitonin gene-related peptide receptor antagonist indicated for the acute treatment of migraine with or without aura in adults." Hetero denies any remaining allegations in Paragraph 38 of the Third Amended Complaint.

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.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 39 of the Third Amended Complaint and therefore denies them.

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.

ANSWER: Hetero admits that the FDA-approved product label for UBRELVY Tablets provides that "[t]he recommended dose of UBRELVY is 50 mg or 100 mg taken orally with or without food. If needed, a second dose may be taken at least 2 hours after the initial dose." Hetero also admits that the FDA-approved product label for UBRELVY Tablets provides that for patients with severe hepatic or severe renal impairment, the "[r]ecommended dose is 50 mg; if needed, a

second 50 mg dose may be taken at least 2 hours after the initial dose." Hetero denies any remaining allegations in Paragraph 40 of the Third Amended Complaint.

41. For patients who concomitantly use weak or moderate CYP3A4 inducers, the recommended dose is 100 mg. If needed, a second 100 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 who concomitantly use weak or moderate CYP3A4 inducers, and information concerning these patients is included in the UBRELVY® Label. For patients who concomitantly use weak CYP3A4 inhibitors, the recommended dose is 50 mg. If needed, a second 50 mg dose may be taken at least 2 hours after the initial dose. For patients who concomitantly use moderate CYP3A4 inhibitors, the recommended dose is 50 mg. The UBRELVY® Label states that those patients should avoid taking a second dose within 24 hours after the initial dose. The FDA approved the inclusion of this safe and effective dosing regimen for UBRELVY® for patients who concomitantly use weak or moderate CYP3A4 inhibitors, and information concerning these patients is included in the UBRELVY® Label. For patients who concomitantly use BCRP and/or P-gp only inhibitors, 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 who concomitantly use BCRP and/or P-gp only inhibitors, and information concerning these patients is included in the UBRELVY® Label.

ANSWER: Hetero admits that the FDA-approved product label for UBRELVY Tablets provides that "[d]osing modifications for concomitant use of specific drugs and for patients with hepatic or renal impairment are provided in Table 1." Hetero also admits that the FDA-approved product label for UBRELVY Tablets provides the following table:

Table 1: Dose Modifications for Drug Interactions and for Specific Populations

Dosage Modifications	Initial Dose	Second Dose[a] (if needed)
Concomitant Drug *[see Drug Interactions (7)]*		
Moderate CYP3A4 Inhibitors *(7.1)*	50 mg	Avoid within 24 hours
Weak CYP3A4 Inhibitors *(7.1)*	50 mg	50 mg
Strong CYP3A4 Inducers *(7.2)*	Avoid concomitant use	
Weak & Moderate CYP3A4 Inducers *(7.2)*	100 mg	100 mg
BCRP and/or P-gp only Inhibitors *(7.3)*	50 mg	50 mg
Specific Populations *[see Use in Specific Populations (8)]*		
Severe Hepatic Impairment (Child-Pugh Class C) *(8.6)*	50 mg	50 mg
Severe Renal Impairment (CLcr 15-29 mL/min) *(8.7)*	50 mg	50 mg
End-Stage Renal Disease (CLcr <15 mL/min) *(8.7)*	Avoid use	

[a] Second dose may be taken at least 2 hours after the initial dose

Hetero denies any remaining allegations in Paragraph 41 of the Third Amended Complaint.

42. 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. The prescribing information for NURTEC® ODT further states that use of the drug should be avoided in patients who concomitantly use moderate CYP3A inducers. 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 and patients who concomitantly use moderate CYP3A inducers.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 42 of the Third Amended Complaint and therefore denies them.

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

ANSWER: Hetero admits that AbbVie is listed in the Orange Book as holder of NDA No. 211765 for UBRELVY® Tablets. Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 43 of the Third Amended Complaint and therefore denies them.

The Patents-in-Suit

44. 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.

ANSWER: Hetero admits that Exhibit A to the Third Amended Complaint appears to be a copy of the '836 patent, which indicates on its face an issue date of November 6, 2018, and is entitled "Tablet Formulation for CGRP Active Compounds." Hetero denies any remaining allegations in Paragraph 44 of the Third Amended Complaint.

45. 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.

ANSWER: Hetero admits that the assignments recorded with the United States Patent and Trademark Office ("USPTO") show Merck as the assignee of the '836 patent as recorded at

Reel 041662, Frame 0851; Reel 041829, Frame 0001; and Reel 061102, Frame 0145. Hetero denies any remaining allegations in Paragraph 45 of the Third Amended Complaint.

46. The '836 patent currently expires on January 30, 2035.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the '836 patent as January 30, 2035. Hetero denies any remaining allegations in Paragraph 46 of the Third Amended Complaint.

47. Allergan is the exclusive licensee of the '836 patent.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 47 of the Third Amended Complaint and therefore denies them.

48. 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.

ANSWER: Admitted.

49. 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.

ANSWER: Hetero admits that Exhibit B to the Third Amended Complaint appears to be a copy of the '515 patent, which indicates on its face an issue date of August 8, 2023, and is entitled "Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 49 of the Third Amended Complaint.

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

ANSWER: Hetero admits that the assignments recorded with the USPTO show Allergan as the assignee of the '515 patent as recorded at Reel 063519, Frame 0307. Hetero denies any remaining allegations in Paragraph 50 of the Third Amended Complaint.

51. The '515 patent currently expires on December 22, 2041.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the '515 patent as December 22, 2041. Hetero denies any remaining allegations in Paragraph 51 of the Third Amended Complaint.

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

ANSWER: Admitted.

53. 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.

ANSWER: Hetero admits that Exhibit C to the Third Amended Complaint appears to be a copy of the '542 patent, which indicates on its face an issue date of January 2, 2024, and is entitled "Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 53 of the Third Amended Complaint.

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

ANSWER: Hetero admits that the assignments recorded with the USPTO show Allergan as the assignee of the '542 patent as recorded at Reel 064076, Frame 0407. Hetero denies any remaining allegations in Paragraph 54 of the Third Amended Complaint.

55. The '542 patent currently expires on December 22, 2041.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the '542 patent as December 22, 2041. Hetero denies any remaining allegations in Paragraph 55 of the Third Amended Complaint.

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

ANSWER: Admitted.

57. 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.

ANSWER: Hetero admits that Exhibit D to the Third Amended Complaint appears to be a copy of the ’709 patent, which indicates on its face an issue date of March 12, 2024, and is entitled “Tablet Formulation for CGRP Active Compounds.” Hetero denies any remaining allegations in Paragraph 57 of the Third Amended Complaint.

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

ANSWER: Hetero admits that the assignments recorded with the USPTO show Merck as the assignee of the ’709 patent as recorded at Reel 061200, Frame 0836. Hetero denies any remaining allegations in Paragraph 58 of the Third Amended Complaint.

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

ANSWER: Hetero admits that the Orange Book lists the expiration date of the ’709 patent as January 30, 2035. Hetero denies any remaining allegations in Paragraph 59 of the Third Amended Complaint.

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

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 60 of the Third Amended Complaint and therefore denies them.

61. 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.

ANSWER: Admitted.

62. The ’450 patent, titled “Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on August 27, 2024. A true and correct copy of the ’450 patent is attached as Exhibit E.

ANSWER: Hetero admits that Exhibit E to the Third Amended Complaint appears to be a copy of the '450 patent, which indicates on its face an issue date of August 27, 2024, and is entitled "Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 62 of the Third Amended Complaint.

63. Allergan is the assignee of the '450 patent through assignment as recorded by the USPTO at Reel 065814, Frame 0254.

ANSWER: Hetero admits that the assignments recorded with the USPTO show Allergan as the assignee of the '450 patent as recorded at Reel 065814, Frame 0254. Hetero denies any remaining allegations in Paragraph 63 of the Third Amended Complaint.

64. The '450 patent currently expires on December 22, 2041.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the '450 patent as December 22, 2041. Hetero denies any remaining allegations in Paragraph 64 of the Third Amended Complaint.

65. The '450 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 100 mg.

ANSWER: Admitted.

66. The '004 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on December 17, 2024. A true and correct copy of the '004 patent is attached as Exhibit F.

ANSWER: Hetero admits that Exhibit F to the Third Amended Complaint appears to be a copy of the '004 patent, which indicates on its face an issue date of December 17, 2024, and is entitled "Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 66 of the Third Amended Complaint.

67. Merck is the assignee of the '004 patent through assignment as recorded by the USPTO at Reel 069116, Frame 0667.

ANSWER: Hetero admits that the assignments recorded with the USPTO show Merck as the assignee of the '004 patent as recorded at Reel 069116, Frame 0667. Hetero denies any remaining allegations in Paragraph 67 of the Third Amended Complaint.

68. The '004 patent currently expires on January 30, 2035.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the '004 patent as January 30, 2035. Hetero denies any remaining allegations in Paragraph 68 of the Third Amended Complaint.

69. Allergan is the exclusive licensee of the '004 patent.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 69 of the Third Amended Complaint and therefore denies them.

70. The '004 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg.

ANSWER: Admitted.

71. The '030 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on January 14, 2025. A true and correct copy of the '030 patent is attached as Exhibit G.

ANSWER: Hetero admits that Exhibit G to the Third Amended Complaint appears to be a copy of the '030 patent, which indicates on its face an issue date of January 14, 2025, and is entitled "Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 71 of the Third Amended Complaint.

72. Allergan is the assignee of the '030 patent through assignment as recorded by the USPTO at Reel 068953, Frame 0640.

ANSWER: Hetero admits that the assignments recorded with the USPTO show Allergan as the assignee of the '030 patent as recorded at Reel 068953, Frame 0640. Hetero denies any remaining allegations in Paragraph 72 of the Third Amended Complaint.

73. The ’030 patent currently expires on December 22, 2041.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the ’030 patent as December 22, 2041. Hetero denies any remaining allegations in Paragraph 73 of the Third Amended Complaint.

74. The ’030 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg.

ANSWER: Admitted.

75. The ’408 patent, titled “Treatment of Migraine,” was duly and legally issued by the United States Patent and Trademark Office on February 11, 2025. A true and correct copy of the ’408 patent is attached as Exhibit H.

ANSWER: Hetero admits that Exhibit H to the Third Amended Complaint appears to be a copy of the ’408 patent, which indicates on its face an issue date of February 11, 2025, and is entitled “Treatment of Migraine.” Hetero denies any remaining allegations in Paragraph 75 of the Third Amended Complaint.

76. Merck is the assignee of the ’408 patent through assignment as recorded by the USPTO at Reel 069185, Frame 0001.

ANSWER: Hetero admits that the assignments recorded with the USPTO show Merck as the assignee of the ’408 patent as recorded at Reel 069185, Frame 0001. Hetero denies any remaining allegations in Paragraph 76 of the Third Amended Complaint.

77. The ’408 patent currently expires on January 30, 2035.

ANSWER: Hetero admits that the Orange Book lists the expiration date of the ’408 patent as January 30, 2035. Hetero denies any remaining allegations in Paragraph 77 of the Third Amended Complaint.

78. The ’408 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Hetero admits that the '408 patent is listed in the FDA Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg. Hetero denies any remaining allegations in Paragraph 78 of the Third Amended Complaint.

79. The '953 patent, titled "Pharmaceutical Formulations for the Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on May 27, 2025. A true and correct copy of the '953 patent is attached as Exhibit I.

ANSWER: Hetero admits that Exhibit I to the Third Amended Complaint appears to be a copy of the '953 patent, which indicates on its face an issue date of May 27, 2025, and is entitled "Pharmaceutical Formulations for the Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 79 of the Third Amended Complaint.

80. Merck is the assignee of the '953 patent through assignment as recorded by the USPTO at Reel 069494, Frame 0051.

ANSWER: Hetero admits that the assignments recorded with the USPTO show Merck as the assignee of the '953 patent as recorded at Reel 069494, Frame 0051. Hetero denies any remaining allegations in Paragraph 80 of the Third Amended Complaint.

81. The '953 patent currently expires on January 30, 2035.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 81 of the Third Amended Complaint and therefore denies them.

82. The '953 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg, 100 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 82 of the Third Amended Complaint and therefore denies them.

83. The '750 patent, titled "Treatment of Migraine," was duly and legally issued by the United States Patent and Trademark Office on June 17, 2025. A true and correct copy of the '750 patent is attached as Exhibit J.

ANSWER: Hetero admits that Exhibit J to the Third Amended Complaint appears to be a copy of the '750 patent, which indicates on its face an issue date of June 17, 2025, and is entitled "Treatment of Migraine." Hetero denies any remaining allegations in Paragraph 83 of the Third Amended Complaint.

84. Allergan is the assignee of the '750 patent through assignment as recorded by the USPTO at Reel 070679, Frame 0475.

ANSWER: Hetero admits that the assignments recorded with the USPTO show Allergan as the assignee of the '750 patent as recorded at Reel 070679, Frame 0475. Hetero denies any remaining allegations in Paragraph 84 of the Third Amended Complaint.

85. The '750 patent currently expires on December 22, 2041.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 85 of the Third Amended Complaint and therefore denies them.

86. The '750 patent covers the UBRELVY® (ubrogepant) oral tablets, 50 mg product, NDA No. 211765, in the FDA Orange Book.

ANSWER: Hetero lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 86 of the Third Amended Complaint and therefore denies them.

Hetero's ANDA No. 219113

87. 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.

ANSWER: Admitted.

88. AbbVie received a letter sent by Hetero ("Hetero's Notice Letter I"), 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."

ANSWER: Hetero admits that pursuant to 21 U.S.C. § 505(j)(2)(B) and 21 C.F.R. § 314.95, Hetero sent a notice letter and detailed statement to AbbVie along with an offer of confidential access to Hetero's ANDA. That notice letter speaks for itself. Hetero admits that AbbVie received the notice letter dated February 26, 2024. Hetero denies any remaining allegations in Paragraph 88 of the Third Amended Complaint.

89. Hetero's Notice Letter I 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.

ANSWER: Hetero admits that pursuant to 21 U.S.C. § 505(j)(2)(B) and 21 C.F.R. § 314.95, Hetero sent a notice letter and detailed statement to AbbVie along with an offer of confidential access to Hetero's ANDA. That letter speaks for itself. Hetero admits that Hetero's ANDA contains a Paragraph IV certification with respect to the '836 and '515 patents. Hetero denies any remaining allegations in Paragraph 89 of the Third Amended Complaint.

90. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding Hetero's ANDA No. 219113 for the '709 patent, the '542 patent, the '450 patent, the '004 patent, the '030 patent, the '408 patent, the '953 patent, and the '750 patent under Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

ANSWER: Hetero admits that ANDA No. 219113 does not contain a Paragraph IV Certification to the '709 patent, the '542 patent, the '450 patent, the '004 patent, the '030 patent, the '408 patent, the '953 patent, and the '750 patent because those patents were not listed in FDA's Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg at the time ANDA No. 219113 was submitted to FDA. Hetero denies any remaining allegations in Paragraph 90 of the Third Amended Complaint.

91. On information and belief, Hetero's Notice Letter I and the information contained therein, coupled with regulatory requirements, demonstrate Hetero's infringement of the '542, '709, '450, '004, '030, '408, '953, and '750 patents.

ANSWER: Denied.

92. 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.

ANSWER: Admitted.

93. 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, '709, '450, '004, '030, '408, '953, and '750 patents.

ANSWER: Paragraph 93 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that ANDA No. 219113 contains a Paragraph IV certification to the '836 and '515 patents. Hetero denies any allegation to the extent they suggest that Hetero filed a Paragraph IV certification for the '542, '709, '450, '004, '030, '408, '953, and '750 patents. Hetero denies any remaining allegations in Paragraph 93 of the Third Amended Complaint.

94. 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.

ANSWER: Paragraph 94 states legal conclusions to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 94 paraphrase or characterize 21 U.S.C. § 355(j)(2)(A)(iv), Hetero denies these allegations to the extent they are inconsistent with 21 U.S.C. § 355(j)(2)(A)(iv). Hetero denies any remaining allegations in Paragraph 94 of the Third Amended Complaint.

95. 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.

ANSWER: Paragraph 95 states legal conclusions to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 95 paraphrase or characterize 21 U.S.C. § 355(j)(2)(A)(i) and 21 C.F.R. § 314.127(a)(7), Hetero denies these allegations to the extent they are inconsistent with 21 U.S.C. § 355(j)(2)(A)(i) and 21 C.F.R. § 314.127(a)(7). Hetero denies any remaining allegations in Paragraph 95 of the Third Amended Complaint.

96. 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.

ANSWER: Paragraph 96 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 96 of the Third Amended Complaint.

97. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 98 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that pursuant to 21 U.S.C. § 505(j)(2)(B)(iv) and 21 C.F.R. § 314.95, Hetero sent a notice letter and detailed statement to AbbVie on or about February 26, 2024, and Plaintiffs filed their original Complaint in this Court on April 11, 2024. Hetero denies the remaining allegations in Paragraph 98 of the Third Amended Complaint.

COUNT I
INFRINGEMENT BY HETERO OF THE '836 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

100. 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.

ANSWER: Admitted.

101. 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.

ANSWER: Admitted.

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

ANSWER: Admitted.

103. 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.

ANSWER: Denied.

104. 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.

ANSWER: Denied.

105. 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.

ANSWER: Denied.

106. 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.

ANSWER: Denied.

107. 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.

ANSWER: Denied.

108. 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.

ANSWER: Denied.

109. 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.

ANSWER: Paragraph 109 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 109 of the Third Amended Complaint.

110. 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.

ANSWER: Denied.

111. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 112 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 112 of the Third Amended Complaint.

113. 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.

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 116 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 116 of the Third Amended Complaint.

117. 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.

ANSWER: Admitted.

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

ANSWER: Admitted.

119. 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.

ANSWER: Denied.

120. 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.

ANSWER: Denied.

121. 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.

ANSWER: Denied.

122. 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.

ANSWER: Denied.

123. 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.

ANSWER: Denied.

124. 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.

ANSWER: Paragraph 124 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 124 of the Third Amended Complaint.

125. 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.

ANSWER: Denied.

126. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 127 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 127 of the Third Amended Complaint.

128. 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).

ANSWER: Denied.

129. 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.

ANSWER: Denied.

130. 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.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT III
INFRINGEMENT BY HETERO OF THE '515 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

133. 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.

ANSWER: Admitted.

134. 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.

ANSWER: Admitted.

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

ANSWER: Admitted.

136. 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.

ANSWER: Denied.

137. 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.

ANSWER: Denied.

138. 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.

ANSWER: Denied.

139. 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.

ANSWER: Denied.

140. 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.

ANSWER: Denied.

141. 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.

ANSWER: Denied.

142. 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.

ANSWER: Paragraph 142 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 142 of the Third Amended Complaint.

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

ANSWER: Paragraph 143 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 143 of the Third Amended Complaint.

144. 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.

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 147 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 147 of the Third Amended Complaint.

148. 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.

ANSWER: Admitted.

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

ANSWER: Admitted.

150. 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.

ANSWER: Denied.

151. 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.

ANSWER: Denied.

152. 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.

ANSWER: Denied.

153. 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.

ANSWER: Denied.

154. 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.

ANSWER: Denied.

155. 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.

ANSWER: Paragraph 155 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 155 of the Third Amended Complaint.

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

ANSWER: Paragraph 156 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 156 of the Third Amended Complaint.

157. 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).

ANSWER: Denied.

158. 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.

ANSWER: Denied.

159. 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.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT V
INFRINGEMENT BY HETERO OF THE '542 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

162. 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.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '542 patent. Hetero denies any remaining allegations in Paragraph 162 of the Third Amended Complaint.

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

ANSWER: Admitted.

164. 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.

ANSWER: Denied.

165. 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.

ANSWER: Denied.

166. 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.

ANSWER: Denied.

167. 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.

ANSWER: Denied.

168. 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.

ANSWER: Denied.

169. 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.

ANSWER: Denied.

170. 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.

ANSWER: Paragraph 170 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 170 of the Third Amended Complaint.

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

ANSWER: Paragraph 171 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 171 of the Third Amended Complaint.

172. 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.

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 175 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 175 of the Third Amended Complaint.

176. 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.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '542 patent. Hetero denies any remaining allegations in Paragraph 176 of the Third Amended Complaint.

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

ANSWER: Admitted.

178. 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.

ANSWER: Denied.

179. 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.

ANSWER: Denied.

180. 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.

ANSWER: Denied.

181. 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.

ANSWER: Denied.

182. 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.

ANSWER: Denied.

183. 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.

ANSWER: Paragraph 183 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 183 of the Third Amended Complaint.

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

ANSWER: Paragraph 184 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 184 of the Third Amended Complaint.

185. 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).

ANSWER: Denied.

186. 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.

ANSWER: Denied.

187. 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.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT VII
INFRINGEMENT BY HETERO OF THE '709 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Denied.

191. 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.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '709 patent. Hetero denies any remaining allegations in Paragraph 191 of the Third Amended Complaint.

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

ANSWER: Admitted.

193. 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.

ANSWER: Denied.

194. 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.

ANSWER: Denied.

195. 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.

ANSWER: Denied.

196. 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.

ANSWER: Denied.

197. 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.

ANSWER: Denied.

198. 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.

ANSWER: Denied.

199. 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.

ANSWER: Paragraph 199 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 199 of the Third Amended Complaint.

200. 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.

ANSWER: Denied.

201. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 202 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 202 of the Third Amended Complaint.

203. 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.

ANSWER: Denied.

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

ANSWER: Denied.

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

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Denied.

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

ANSWER: Paragraph 207 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 207 of the Third Amended Complaint.

208. 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.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '709 patent. Hetero denies any remaining allegations in Paragraph 208 of the Third Amended Complaint.

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

ANSWER: Admitted.

210. 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.

ANSWER: Denied.

211. 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.

ANSWER: Denied.

212. 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.

ANSWER: Denied.

213. 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.

ANSWER: Denied.

214. 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.

ANSWER: Denied.

215. 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.

ANSWER: Paragraph 215 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 215 of the Third Amended Complaint.

216. 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.

ANSWER: Denied.

217. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 218 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 218 of the Third Amended Complaint.

219. 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).

ANSWER: Denied.

220. 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.

ANSWER: Denied.

221. 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.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT IX
INFRINGEMENT BY HETERO OF THE '450 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

224. This Complaint provides notice of the '450 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

225. 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 '450 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '450 patent. Hetero denies any remaining allegations in Paragraph 225 of the Third Amended Complaint.

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

ANSWER: Admitted.

227. 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 '450 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

228. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '450 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 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 '450 patent and any additional periods of exclusivity.

ANSWER: Denied.

229. 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 '450 patent.

ANSWER: Denied.

230. Hetero had knowledge of the '450 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 '450 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

231. 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 '450 patent.

ANSWER: Denied.

232. 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 '450 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '450 patent.

ANSWER: Denied.

233. 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.

ANSWER: Paragraph 233 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 233 of the Third Amended Complaint.

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

ANSWER: Paragraph 234 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 234 of the Third Amended Complaint.

235. 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 '450 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT X
DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF THE '450 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

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

ANSWER: Paragraph 238 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 238 of the Third Amended Complaint.

239. This Complaint provides notice of the '450 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

240. 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 '450 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration

of the ’450 patent. Hetero denies any remaining allegations in Paragraph 240 of the Third Amended Complaint.

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

ANSWER: Admitted.

242. After FDA approval of Hetero’s ANDA, Hetero will infringe one or more claims of the ’450 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 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 ’450 patent and any additional periods of exclusivity.

ANSWER: Denied.

243. 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 ’450 patent.

ANSWER: Denied.

244. Hetero had knowledge of the ’450 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 ’450 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

245. 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 ’450 patent.

ANSWER: Denied.

246. 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 ’450 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the ’450 patent.

ANSWER: Denied.

247. 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.

ANSWER: Paragraph 247 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 247 of the Third Amended Complaint.

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

ANSWER: Paragraph 248 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 248 of the Third Amended Complaint.

249. 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 '450 patent will constitute infringement of one or more claims of the '450 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

250. 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 '450 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

251. 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 '450 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XI
INFRINGEMENT BY HETERO OF THE '004 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

254. This Complaint provides notice of the '004 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

255. 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 '004 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '004 patent. Hetero denies any remaining allegations in Paragraph 255 of the Third Amended Complaint.

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

ANSWER: Admitted.

257. 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 '004 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

258. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '004 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 '004 patent and any additional periods of exclusivity.

ANSWER: Denied.

259. 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 '004 patent.

ANSWER: Denied.

260. Hetero had knowledge of the '004 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 '004 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

261. 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 '004 patent.

ANSWER: Denied.

262. 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 '004 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '004 patent.

ANSWER: Denied.

263. 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.

ANSWER: Paragraph 263 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 263 of the Third Amended Complaint.

264. 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 '004 patent.

ANSWER: Denied.

265. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 266 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 266 of the Third Amended Complaint.

267. 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 '004 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XII
DECLARATORY JUDGMENT OF
INFRINGEMENT BY HETERO OF THE '004 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

270. This Complaint provides notice of the '004 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

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

ANSWER: Paragraph 271 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 271 of the Third Amended Complaint.

272. 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 '004 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '004 patent. Hetero denies any remaining allegations in Paragraph 272 of the Third Amended Complaint.

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

ANSWER: Admitted.

274. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '004 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 '004 patent and any additional periods of exclusivity.

ANSWER: Denied.

275. 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 '004 patent.

ANSWER: Denied.

276. Hetero had knowledge of the '004 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 '004 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

277. 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 '004 patent.

ANSWER: Denied.

278. 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 '004 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '004 patent.

ANSWER: Denied.

279. 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.

ANSWER: Paragraph 279 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 279 of the Third Amended Complaint.

280. 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 '004 patent.

ANSWER: Denied.

281. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 282 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 282 of the Third Amended Complaint.

283. 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 '004 patent will constitute infringement of one or more claims of the '004 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

284. 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 '004 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

285. 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 '004 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XIII
INFRINGEMENT BY HETERO OF THE '030 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

288. This Complaint provides notice of the '030 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

289. 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 '030 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '030 patent. Hetero denies any remaining allegations in Paragraph 289 of the Third Amended Complaint.

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

ANSWER: Admitted.

291. 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 '030 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

292. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '030 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 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 '030 patent and any additional periods of exclusivity.

ANSWER: Denied.

293. 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 '030 patent.

ANSWER: Denied.

294. Hetero had knowledge of the '030 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 '030 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

295. 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 '030 patent.

ANSWER: Denied.

296. 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 '030 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '030 patent.

ANSWER: Denied.

297. 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.

ANSWER: Paragraph 297 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 297 of the Third Amended Complaint.

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

ANSWER: Paragraph 298 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 298 of the Third Amended Complaint.

299. 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 '030 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XIV
DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF THE '030 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

302. This Complaint provides notice of the '030 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

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

ANSWER: Paragraph 303 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 303 of the Third Amended Complaint.

304. 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 '030 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '030 patent. Hetero denies any remaining allegations in Paragraph 304 of the Third Amended Complaint.

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

ANSWER: Admitted.

306. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '030 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 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 '030 patent and any additional periods of exclusivity.

ANSWER: Denied.

307. 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 '030 patent.

ANSWER: Denied.

308. Hetero had knowledge of the '030 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 '030 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

309. 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 '030 patent.

ANSWER: Denied.

310. The offering to sell, sale, making, and/or importation of Hetero's generic products actively induce infringement of at least one of the claims of the '030 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '030 patent.

ANSWER: Denied.

311. 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.

ANSWER: Paragraph 311 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 311 of the Third Amended Complaint.

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

ANSWER: Paragraph 312 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 312 of the Third Amended Complaint.

313. 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 '030 patent will constitute infringement of one or more claims of the '030 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

314. 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 ’030 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

315. 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 ’030 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XV
INFRINGEMENT BY HETERO OF THE ’408 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

318. This Complaint provides notice of the ’408 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

319. 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 ’408 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the ’408 patent. Hetero denies any remaining allegations in Paragraph 319 of the Third Amended Complaint.

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

ANSWER: Admitted.

321. 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 '408 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

322. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '408 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 '408 patent and any additional periods of exclusivity.

ANSWER: Denied.

323. 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 '408 patent.

ANSWER: Denied.

324. Hetero had knowledge of the '408 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 '408 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

325. 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 '408 patent.

ANSWER: Denied.

326. 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 '408 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '408 patent.

ANSWER: Denied.

327. 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.

ANSWER: Paragraph 327 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 327 of the Third Amended Complaint.

328. 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 '408 patent.

ANSWER: Denied.

329. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 330 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 330 of the Third Amended Complaint.

331. 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 '408 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XVI
DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF THE '408 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

334. This Complaint provides notice of the '408 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

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

ANSWER: Paragraph 335 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 335 of the Third Amended Complaint.

336. 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 '408 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '408 patent. Hetero denies any remaining allegations in Paragraph 336 of the Third Amended Complaint.

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

ANSWER: Admitted.

338. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '408 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 '408 patent and any additional periods of exclusivity.

ANSWER: Denied.

339. 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 '408 patent.

ANSWER: Denied.

340. Hetero had knowledge of the '408 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 '408 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

341. 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 '408 patent.

ANSWER: Denied.

342. 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 '408 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '408 patent.

ANSWER: Denied.

343. 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.

ANSWER: Paragraph 343 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 343 of the Third Amended Complaint.

344. 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 '408 patent.

ANSWER: Denied.

345. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 346 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 346 of the Third Amended Complaint.

347. 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 '408 patent will constitute infringement of one or more claims of the '408 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

348. 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 '408 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

349. 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 '408 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XVII
INFRINGEMENT BY HETERO OF THE '953 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

352. This Complaint provides notice of the '953 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

353. 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 '953 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '953 patent. Hetero denies any remaining allegations in Paragraph 353 of the Third Amended Complaint.

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

ANSWER: Admitted.

355. 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 '953 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

356. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '953 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 '953 patent and any additional periods of exclusivity.

ANSWER: Denied.

357. 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 '953 patent.

ANSWER: Denied.

358. Hetero had knowledge of the '953 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 '953 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

359. 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 '953 patent.

ANSWER: Denied.

360. 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 '953 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '953 patent.

ANSWER: Denied.

361. 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.

ANSWER: Paragraph 361 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 361 of the Third Amended Complaint.

362. 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 '953 patent.

ANSWER: Denied.

363. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 364 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 364 of the Third Amended Complaint.

365. 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 '953 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XVIII
DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF THE '953 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

368. This Complaint provides notice of the '953 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

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

ANSWER: Paragraph 369 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 369 of the Third Amended Complaint.

370. 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 '953 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '953 patent. Hetero denies any remaining allegations in Paragraph 370 of the Third Amended Complaint.

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

ANSWER: Admitted.

372. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '953 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 '953 patent and any additional periods of exclusivity.

ANSWER: Denied.

373. 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 '953 patent.

ANSWER: Denied.

374. Hetero had knowledge of the '953 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 '953 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

375. 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 '953 patent.

ANSWER: Denied.

376. 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 '953 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '953 patent.

ANSWER: Denied.

377. 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.

ANSWER: Paragraph 377 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 377 of the Third Amended Complaint.

378. 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 '953 patent.

ANSWER: Denied.

379. 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.

ANSWER: Denied.

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

ANSWER: Paragraph 380 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 380 of the Third Amended Complaint.

381. 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 '953 patent will constitute infringement of one or more claims of the '953 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

382. 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 '953 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

383. 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 '953 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XIX
INFRINGEMENT BY HETERO OF THE '750 PATENT

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

ANSWER: Denied.

386. This Complaint provides notice of the '750 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

387. 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 '750 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration of the '750 patent. Hetero denies any remaining allegations in Paragraph 387 of the Third Amended Complaint.

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

ANSWER: Admitted.

389. 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 '750 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Denied.

390. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '750 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 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 '750 patent and any additional periods of exclusivity.

ANSWER: Denied.

391. 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 '750 patent.

ANSWER: Denied.

392. Hetero had knowledge of the '750 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 '750 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

393. 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 '750 patent.

ANSWER: Denied.

394. 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 '750 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '750 patent.

ANSWER: Denied.

395. 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.

ANSWER: Paragraph 395 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 395 of the Third Amended Complaint.

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

ANSWER: Paragraph 396 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking

approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 396 of the Third Amended Complaint.

397. 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 '750 patent.

ANSWER: Denied.

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

ANSWER: Denied.

COUNT XX
DECLARATORY JUDGMENT OF INFRINGEMENT BY HETERO OF THE '750 PATENT

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

ANSWER: Hetero incorporates by reference the prior paragraphs of this Answer as if fully set forth herein.

400. This Complaint provides notice of the '750 patent to the extent that Hetero did not already have notice of this patent.

ANSWER: Denied.

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

ANSWER: Paragraph 401 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Plaintiffs purport to bring a declaratory judgment claim under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Hetero denies any remaining allegations in Paragraph 401 of the Third Amended Complaint.

402. 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 '750 patent.

ANSWER: Hetero denies that it filed a Paragraph IV certification seeking approval to manufacture, use, import, offer to sell, and/or sell the Hetero ANDA Product before the expiration

of the '750 patent. Hetero denies any remaining allegations in Paragraph 402 of the Third Amended Complaint.

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

ANSWER: Admitted.

404. After FDA approval of Hetero's ANDA, Hetero will infringe one or more claims of the '750 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 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 '750 patent and any additional periods of exclusivity.

ANSWER: Denied.

405. 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 '750 patent.

ANSWER: Denied.

406. Hetero had knowledge of the '750 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 '750 patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

407. 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 '750 patent.

ANSWER: Denied.

408. The offering to sell, sale, making, and/or importation of Hetero's generic products actively induce infringement of at least one of the claims of the '750 patent, either literally or under the doctrine of equivalents. On information and belief, Hetero has knowledge and is aware of the '750 patent.

ANSWER: Denied.

409. 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.

ANSWER: Paragraph 409 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 409 of the Third Amended Complaint.

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

ANSWER: Paragraph 410 states legal conclusions to which no response is required. To the extent a response is required, Hetero admits that Hetero submitted the Hetero ANDA seeking approval to engage in commercial manufacture, use, or sale of the Hetero ANDA Product. Hetero denies any remaining allegations in Paragraph 410 of the Third Amended Complaint.

411. 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 '750 patent will constitute infringement of one or more claims of the '750 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Denied.

412. 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 '750 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

ANSWER: Denied.

413. 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 '750 patent.

ANSWER: Denied.

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

ANSWER: Denied.

REQUEST FOR RELIEF

Hetero denies any and all allegations not expressly admitted herein. Hetero denies that Plaintiffs are entitled to any judgment or relief against Hetero or any relief whatsoever and, therefore, specifically denies Paragraphs A through I of Plaintiffs' Request for Relief. Hetero requests that judgment be entered in its favor, dismissing Plaintiffs' Third Amended Complaint with prejudice, awarding Hetero attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting even further relief as the Court may deem just and proper.

AFFIRMATIVE AND OTHER DEFENSES

Without prejudice to the denials set forth in this **ANSWER**, without admitting any averments of Plaintiffs' Third Amended Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiffs, Hetero avers and asserts the following Defenses to the Third Amended Complaint. Hetero expressly reserves the right to allege additional defenses as they become known through the course of discovery.

FIRST DEFENSE
Failure to State a Claim

The Third Amended Complaint fails to state a claim upon which relief can be granted.

SECOND DEFENSE
Non-Infringement of the '836 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '836 patent.

THIRD DEFENSE
Invalidity of the '836 Patent

The claims of the '836 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code,

including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

FOURTH DEFENSE
Non-Infringement of the '515 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '515 patent.

FIFTH DEFENSE
Invalidity of the '515 Patent

The claims of the '515 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

SIXTH DEFENSE
Non-Infringement of the '542 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '542 patent.

SEVENTH DEFENSE
Invalidity of the '542 Patent

The claims of the '542 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

EIGHTH DEFENSE
Non-Infringement of the '709 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '709 patent.

NINTH DEFENSE
Invalidity of the '709 Patent

The claims of the '709 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TENTH DEFENSE
Costs

Upon information and belief, Plaintiff is barred under 35 U.S.C. § 288 from recovering costs in connection with this action.

ELEVENTH 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.

TWELFTH DEFENSE
Additional Defenses

Any additional defenses that discovery may reveal.

THIRTEENTH DEFENSE
Non-Infringement of the '450 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '450 patent.

FOURTEENTH DEFENSE
Invalidity of the '450 Patent

The claims of the '450 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

FIFTEENTH DEFENSE
Non-Infringement of the '004 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '004 patent.

SIXTEENTH DEFENSE
Invalidity of the '004 Patent

The claims of the '004 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

SEVENTEENTH DEFENSE
Non-Infringement of the '030 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '030 patent.

EIGHTEENTH DEFENSE
Invalidity of the '030 Patent

The claims of the '030 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

NINETEENTH DEFENSE
Non-Infringement of the '408 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '408 patent.

TWENTIETH DEFENSE
Invalidity of the '408 Patent

The claims of the '408 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWENTY-FIRST DEFENSE
Non-Infringement of the '953 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '953 patent.

TWENTY-SECOND DEFENSE
Invalidity of the '953 Patent

The claims of the '953 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

TWENTY-THIRD DEFENSE
Non-Infringement of the '750 Patent

Hetero has not and will not infringe, either directly or indirectly, any valid and enforceable claim of the '750 patent.

TWENTY-FOURTH DEFENSE
Invalidity of the '750 Patent

The claims of the '750 patent are invalid and/or unenforceable for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

RESERVATION OF DEFENSES

Hetero reserves the right to assert additional defenses as may be warranted by discovery or further factual investigation in this action.

COUNTERCLAIMS

Without admitting the allegations of AbbVie Inc., Allergan Pharmaceuticals International Limited, and Merck Sharp & Dohme LLC (collectively, "Plaintiffs/Counterclaim Defendants"), other than those expressly admitted herein, and without prejudice to the right of Hetero USA Inc., Hetero Labs Limited Unit-III, and Hetero Labs Limited (collectively, "Hetero") to plead additional Counterclaims as the facts of the matter warrant, Hetero hereby asserts the following Counterclaims against Plaintiffs/Counterclaim Defendants:

NATURE OF THE ACTION

1. These Counterclaims seek a declaratory judgment that ANDA No. 219113 ("Hetero's ANDA") does not infringe any valid and enforceable claim of U.S. Patent Nos. 10,117,836 (the "'836 patent"), 11,717,515 (the "'515 patent"), 11,857,542 (the "'542 patent"), 11,925,709 (the "'709 patent"), 12,070,450 (the "'450 patent"), 12,168,004 (the "'004 patent"), 12,194,030 (the "'030 patent"), 12,220,408 (the "'408 patent"), 12,310,953 (the "'953 patent"), and 12,329,750 (the "'750 patent") (collectively, the "Asserted Patents") and that each and every claim of the Asserted Patents is invalid for failure to satisfy one or more requirements and/or conditions for patentability under Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

THE PARTIES

2. Hetero USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 1035 Centennial Ave., Piscataway, NJ 08854.

3. Hetero Labs Limited 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.

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

5. Upon information and belief and based on the allegations in the Third Amended Complaint, AbbVie is a corporation organized and existing under the laws of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, IL 60064.

6. Upon information and belief and based on the allegations in the Third Amended Complaint, 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.

7. Upon information and belief and based on the allegations in the Third Amended Complaint, 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 Ave., Rahway, NJ 07065.

JURISDICTION AND VENUE

8. This Court has personal jurisdiction over Plaintiffs/Counterclaim Defendants because they availed themselves of the legal protections of the State of New Jersey by voluntarily submitting to and employing the jurisdiction of this Court as plaintiffs in this matter.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) because Plaintiffs/Counterclaim Defendants voluntarily submitted to the jurisdiction of the Court in this matter.

BACKGROUND

10. According to the United States Food & Drug Administration ("FDA") publication entitled "Approved Drug Products and Therapeutic Equivalence Evaluations" (the "Orange

Book"), and based on the allegations in the Third Amended Complaint, AbbVie holds approved New Drug Application ("NDA") No. 211765 for UBRELVY® Tablets.

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

12. Upon information and belief and based on the allegations of the Third Amended Complaint, Allergan is the assignee of the '515, '542, '450, '030, and '750 patents.

13. Upon information and belief and based on the allegations of the Third Amended Complaint, Merck is the assignee of the '836, '709, '004, '408, and '953 patents.

14. Upon information and belief, Plaintiffs/Counterclaim Defendants caused the '836 patent, the '515 patent, the '542 patent, the '709 patent, the '450 patent, the '004 patent, the '030 patent, and the '408 patent to be listed in the Orange Book as patents associated with UBRELVY® Tablets.

15. Hetero has submitted Hetero's ANDA to FDA, seeking approval to engage in the commercial manufacture, use, or sale of ubrogepant oral tablets in 50-mg and 100-mg dosage forms ("Hetero's ANDA Product") prior to the expiration of the '836 and '515 patents.

16. Hetero's ANDA contained Paragraph IV certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '836 and '515 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Hetero's ANDA Product.

17. Hetero's ANDA does not contain a Paragraph IV Certification to the '709, '542, '450, '004, '030,'408, '953, and '750 patents because those patents were not listed in FDA's Orange Book in connection with NDA No. 211765 for UBRELVY® (ubrogepant) oral tablet, 50 mg, 100 mg at the time ANDA No. 219113 was submitted to FDA.

18. On or around February 26, 2024, Hetero sent Plaintiffs/Counterclaim Defendants a notice letter providing notice of Hetero's submission of Hetero's ANDA to FDA.

19. On or around April 11, 2024, Plaintiffs/Counterclaim Defendants filed this lawsuit alleging that Hetero infringes the '836, '515, '542, and '709 patents.

20. On or around January 24, 2025, Plaintiffs/Counterclaim Defendants amended their complaint to add allegations that Hetero infringes the '450 and '004 patents.

21. On or around March 3, 2025, Plaintiffs/Counterclaim Defendants further amended their complaint to add allegations that Hetero infringes the '030 and '408 patents.

22. On or around June 27, 2025, Plaintiffs/Counterclaim Defendants further amended their complaint to add allegations that Hetero infringes the '953 and '750 patents.

FIRST COUNTERCLAIM
Declaratory Judgment of Non-infringement of the '836 Patent

23. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

24. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '836 patent either directly or indirectly.

25. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '836 patent and is not liable for such infringement.

26. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '836 patent, and that the manufacture, use,

sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '836 patent.

SECOND COUNTERCLAIM
Declaratory Judgment of Invalidity of the '836 Patent

27. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

28. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '836 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '836 patent.

29. Each and every claim of the '836 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

30. For at least the reasons stated in Hetero's notice letter, which is hereby incorporated by reference in its entirety, the claims of the '836 patent are not infringed by Hetero's ANDA Product and are invalid.

31. Hetero is entitled to a judicial declaration that all claims of the '836 patent are invalid.

THIRD COUNTERCLAIM
Declaratory Judgment on Non-Infringement of the '515 Patent

32. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

33. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the

United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '515 patent either directly or indirectly.

34. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '515 patent and is not liable for such infringement.

35. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '515 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '515 patent.

FOURTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '515 Patent

36. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

37. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '515 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '515 patent.

38. Each and every claim of the '515 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

39. For at least the reasons stated in Hetero's notice letter, which is hereby incorporated by reference in its entirety, the claims of the '515 patent are not infringed by Hetero's ANDA Product and are invalid.

40. Hetero is entitled to a judicial declaration that all claims of the '515 patent are invalid.

FIFTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '542 Patent

41. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

42. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '542 patent either directly or indirectly.

43. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '542 patent and is not liable for such infringement.

44. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '542 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '542 patent.

SIXTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '542 Patent

45. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

46. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '542 patent, based

on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '542 patent.

47. Each and every claim of the '542 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

48. Hetero is entitled to a judicial declaration that all claims of the '542 patent are invalid.

SEVENTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '709 Patent

49. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

50. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '709 patent either directly or indirectly.

51. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '709 patent and is not liable for such infringement.

52. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '709 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '709 patent.

EIGHTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '709 Patent

53. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

54. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '709 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '709 patent.

55. Each and every claim of the '709 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

56. Hetero is entitled to a judicial declaration that all claims of the '709 patent are invalid.

NINTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '450 Patent

57. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

58. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '450 patent either directly or indirectly.

59. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '450 patent and is not liable for such infringement.

60. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '450 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '450 patent.

TENTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '450 Patent

61. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

62. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '450 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '450 patent.

63. Each and every claim of the '450 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

64. Hetero is entitled to a judicial declaration that all claims of the '450 patent are invalid.

ELEVENTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '004 Patent

65. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

66. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the

United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '004 patent either directly or indirectly.

67. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '004 patent and is not liable for such infringement.

68. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '004 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '004 patent.

TWELFTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '004 Patent

69. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

70. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '004 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '004 patent.

71. Each and every claim of the '004 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

72. Hetero is entitled to a judicial declaration that all claims of the '004 patent are invalid.

THIRTEENTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '030 Patent

73. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

74. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '030 patent either directly or indirectly.

75. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '030 patent and is not liable for such infringement.

76. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '030 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '030 patent.

FOURTEENTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '030 Patent

77. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

78. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '030 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '030 patent.

79. Each and every claim of the ’030 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

80. Hetero is entitled to a judicial declaration that all claims of the ’030 patent are invalid.

FIFTEENTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the ’408 Patent

81. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

82. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero’s submission of Hetero’s ANDA and/or Hetero’s manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero’s ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the ’408 patent either directly or indirectly.

83. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the ’408 patent and is not liable for such infringement.

84. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the ’408 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero’s ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the ’408 patent.

SIXTEENTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the ’408 Patent

85. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

86. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '408 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '408 patent.

87. Each and every claim of the '408 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

88. Hetero is entitled to a judicial declaration that all claims of the '408 patent are invalid.

SEVENTEENTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '953 Patent

89. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

90. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '953 patent either directly or indirectly.

91. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '953 patent and is not liable for such infringement.

92. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '953 patent, and that the manufacture, use,

sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '953 patent.

EIGHTEENTH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '953 Patent

93. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

94. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '953 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '953 patent.

95. Each and every claim of the '953 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

96. Hetero is entitled to a judicial declaration that all claims of the '953 patent are invalid.

NINETEENTH COUNTERCLAIM
Declaratory Judgment of Non-Infringement of the '750 Patent

97. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

98. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding whether Hetero's submission of Hetero's ANDA and/or Hetero's manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product infringes, has infringed, or will infringe any valid and enforceable claim of the '750 patent either directly or indirectly.

99. Hetero has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '750 patent and is not liable for such infringement.

100. Hetero is entitled to a judicial declaration that it has not infringed, contributed to the infringement of, or induced the infringement of the '750 patent, and that the manufacture, use, sale, offer for sale, or importation of Hetero's ANDA Product has not infringed, does not infringe, and will not infringe any valid and enforceable claims of the '750 patent.

TWENTIETH COUNTERCLAIM
Declaratory Judgment of Invalidity of the '750 Patent

101. Hetero incorporates by reference the prior paragraphs of these Counterclaims as if fully set forth herein.

102. There is an actual, substantial, continuing, and justiciable controversy between Hetero and Plaintiffs/Counterclaim Defendants regarding the invalidity of the '750 patent, based on Plaintiffs/Counterclaim Defendants' allegations in the Third Amended Complaint that Hetero has infringed or will infringe the '750 patent.

103. Each and every claim of the '750 patent is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 101, 102, 103, and/or 112, as well as obviousness-type double patenting.

104. Hetero is entitled to a judicial declaration that all claims of the '750 patent are invalid.

PRAYER FOR RELIEF

Wherefore, Hetero respectfully requests that this Court enter judgment against Plaintiffs/Counterclaim Defendants and issue an order:

a) Dismissing the Third Amended Complaint with prejudice and denying each request for relief made by Plaintiffs/Counterclaim Defendants therein;

b) Declaring all claims of the Asserted Patents invalid;

c) Declaring that the filing of Hetero's ANDA has not infringed, does not, and will not infringe any valid and enforceable claim, if any, of the Asserted Patents;

d) Declaring that Hetero has not directly or indirectly infringed, induced infringement of, or contributed to the infringement of any valid and enforceable claim, if any, of the Asserted Patents;

e) Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Hetero's ANDA Product has not, does not, and will not, if marketed, directly or indirectly infringe any valid and enforceable claim, if any, of the Asserted Patents;

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

g) Declaring Hetero the prevailing party and awarding costs and attorney fees to Hetero; and

h) Awarding Hetero such other and further relief as the Court deems just and equitable.

Dated: July 11, 2025

By: /s Jakob B. Halpern

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