Gregory D. Miller
Timothy P. Gonzalez
RIVKIN RADLER LLP
25 Main Street
Court Plaza North, Suite 501
Hackensack, New Jersey 07601
T: (201) 287-2460
Gregory.Miller@rivkin.com
Timothy.Gonzalez@rivkin.com

Richard J. Berman (admitted *pro hac vice*)
Janine A. Carlan (admitted *pro hac vice*)
Bradford C. Frese (admitted *pro hac vice*)
Saukshmya Trichi (admitted *pro hac vice*)
Michael J. Baldwin (admitted *pro hac vice*)
ARENTFOX SCHIFF LLP
1717 K St. NW
Washington, DC 20006
T: (202) 857-6000
richard.berman@afslaw.com
janine.carlan@afslaw.com
bradford.frese@afslaw.com
saukshmya.trichi@afslaw.com
michael.baldwin@afslaw.com

Attorneys for Defendants, MSN Pharmaceuticals Inc., MSN Laboratories Private Limited and MSN Life Sciences Private Limited.

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. MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, and MSN LIFE SCIENCES PRIVATE LIMITED, *Defendants*.	Civil Action No. 3:24-cv-04662-ZNQ-JBD

DEFENDANTS MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, AND MSN LIFE SCIENCES PRIVATE LIMITED'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Defendants MSN Pharmaceuticals Inc., ("MSN Pharmaceuticals"), MSN Laboratories Private Limited ("MSN Labs"), and MSN Life Sciences Private Limited ("MSN Life Sciences") (collectively, "MSN"), by and through their undersigned counsel, hereby submit the following Answer, Separate Defenses, and Counterclaims ("Answer") in response to the Third Amended Complaint ("TAC" or "Complaint") filed by Plaintiffs AbbVie Inc. ("AbbVie"), Allergan Pharmaceuticals International Limited ("Allergan"), and Merck Sharp & Dohme LLC ("Merck") (collectively, "Plaintiffs").

Pursuant to Federal Rules of Civil Procedure 8(b)(3), MSN denies all allegations in the TAC, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts.

RESPONSE TO "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 MSN'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. MSN has submitted ANDA No. 219218 ("MSN's ANDA"), which seeks approval to market its generic version of UBRELVY® Tablets, ubrogepant oral tablets, 50 mg, 100 mg ("MSN's generic products"), prior to the expiration of the Patents-in-Suit.

ANSWER: MSN admits that, on its face, the Complaint advances an action for alleged infringement of the Patents-in-Suit stemming from the filing of ANDA No. 219218 with the FDA.

MSN denies all allegations of infringement of the Patents-in-Suit. MSN admits to filing ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN otherwise denies the remaining allegations in Paragraph 1.

2. MSN 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. 219218 seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of MSN's generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof. MSN 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 MSN's generic products prior to the expiration of the Patents-in-Suit, or any extensions thereof.

ANSWER: Paragraph 2 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations in Paragraph 2.

RESPONSE TO "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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 3, and therefore denies the same.

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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 4, and therefore denies the same.

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

ANSWER: Upon information and belief, MSN admits that AbbVie markets, distributes, and sells UBRELVY® products in the United States. MSN lacks sufficient knowledge or information to form an opinion or belief as to the remaining allegations of Paragraph 5, and therefore denies the same.

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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 6, and therefore denies the same.

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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 7, and therefore denies the same.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 8, and therefore denies the same.

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

ANSWER: Paragraph 9 does not contain an allegation requiring a response. To the extent a response is required, MSN denies the allegations of Paragraph 9.

10. MSN Pharmaceuticals is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854. MSN Pharmaceuticals is a fully owned subsidiary of MSN Labs.

ANSWER: Admitted.

11. MSN Labs is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanath Nagar, Hyderabad, 500 018, Telangana, India.

ANSWER: Admitted.

12. MSN Life is a corporation organized and existing under the laws of India, having a principal place of business at Sy No- 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India. MSN Life is a wholly owned subsidiary of MSN Labs.

ANSWER: MSN admits that MSN Life is a corporation organized and existing under the laws of India, having a principal place of business at Sy No-21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India. MSN denies the remaining allegations of Paragraph 12.

13. MSN 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: MSN states that MSN is in, non-exclusively, the business of the development, manufacture, and importation of generic drug products for marketing, sale, and distribution. MSN otherwise denies the remaining allegations of Paragraph 13.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN otherwise denies the remaining allegations in Paragraph 14.

RESPONSE TO "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 contains a legal conclusion to which no response is required. To the extent a response is required, MSN admits that the Complaint on its face appears to be for an action arising under the patent laws of the United States. MSN otherwise denies the allegations of Paragraph 15.

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

ANSWER: Paragraph 16 contains a legal conclusion to which no response is required. To the extent a response is required, MSN is not contesting this Court's subject matter jurisdiction over this action. MSN denies any remaining allegations in Paragraph 16.

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

ANSWER: Paragraph 17 contains a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals does not contest this Court's personal jurisdiction over MSN Pharmaceuticals in this action and reserves the right to contest personal jurisdiction in any other case or action. MSN otherwise denies the remaining allegations of Paragraph 17.

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

ANSWER: Paragraph 18 contains a legal conclusion to which no response is required. To the extent a response is required, MSN Labs does not contest this Court's personal jurisdiction over MSN Labs in this action and reserves the right to contest personal jurisdiction in any other case or action. MSN otherwise denies the remaining allegations of Paragraph 18.

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

ANSWER: Paragraph 19 contains a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 19.

20. On information and belief, MSN Pharmaceuticals is a United States agent for MSN Labs. MSN Pharmaceuticals claims that it is a "[p]harmaceutical [g]eneric development and manufacturing facility based out of Piscataway, New Jersey." *MSN Pharmaceuticals Inc. – An MSN Company*, https://msnpi.com/msnpi-index.html (last visited Apr. 8, 2024). MSN Pharmaceuticals claims that it "is a fully owned subsidiary of the MSN group of companies," and "develops and manufacture[s] products for MSN group." *Id.* MSN Pharmaceuticals 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. 0400627791. MSN Pharmaceuticals is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under the registration number 5006107.

ANSWER: Admitted.

21. On information and belief, MSN Life is the holder of FDA Drug Master File No. 38576 for ubrogepant.

ANSWER: Admitted.

22. On information and belief, MSN Pharmaceuticals, MSN Labs, and MSN Life 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 22 contains a legal conclusion to which no response is required. MSN denies the allegations of Paragraph 22.

23. MSN Pharmaceuticals, MSN Labs, and MSN Life 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. MSN claims that "[a]t present, [MSN's] growing portfolio consists of 1085 DMFs, 2400+ dossiers and 160+ ANDAs registered," and that "[its] reach is now global - not just in markets, but we also have offices in New Jersey - USA." *Research & Development – MSN Laboratories*, https://www.msnlabs.com/r-and-d.html (last visited Apr. 8, 2024). MSN claims that it "[r]ank[s] 1st in active Drug Master Files in the US," with "[a] total of 1000+ DMFs filed and counting." *Formulation Development – MSN Laboratories*, https://www.msnlabs.com/formulations.html (last visited Apr. 8, 2024).

ANSWER: MSN admits that the website at https://www.msnlabs.com/r-and-d.html states that "[a]t present, our growing portfolio consists of 1085 DMFs, 2400+ dossiers and 160+ ANDAs registered. Pioneers in developing complex products, our reach is now global - not just in markets, but we also have offices in New Jersey - USA, Brazil, Chile, Nairobi, Vietnam and a few other international locations." MSN further admits that the website at

https://www.msnlabs.com/formulations.html states, "The MSN Group's DMFs filing has significantly increased over the years and our major accomplishments have been: Rank 1st in active Drug Master Files in the US; A total of 1000+ DMFs filed and counting." MSN denies the remaining allegations of Paragraph 23. MSN avers that it engages in the business of, among others, the development of generic pharmaceutical drug products, including the submission and approval of generic pharmaceutical drug products in the United States. MSN otherwise denies the allegations of Paragraph 23.

24. On information and belief, MSN is engaged in the submission and approval of ANDAs for the United States market. *See, e.g.*, *2023 First Generic Drug Approvals*, U.S. Food & Drug Administration (Mar. 8, 2024), https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/2023-first-generic-drug-approvals (last visited Apr. 8, 2024) (listing the approval of MSN's ANDA Nos. 211901 and 215017); *Original Abbreviated New Drug Application (ANDA) Approvals, January 2024*, U.S. Food & Drug Administration, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=reportsSearch.process&rptName=3&reportSelectMonth=1&reportSelectYear=2024&nav#navigation (last visited Apr. 8, 2024) (listing the approval of MSN's ANDA No. 214925). MSN claims that it "has to its credit: . . . 160+ ANDAs." *Quality – MSN Laboratories*, https://www.msnlabs.com/quality.html (last visited Apr. 8, 2024).

ANSWER: MSN states that it engages in the business of, among others, the development of generic pharmaceutical drug products, including the submission and approval of ANDAs for sale of drug product in the United States. MSN admits that the website https;//www.msnlabs.com/quality.html states, "Apart from global accreditations and international regulatory standards, MSN has to its credit: ANDA – 160+ ANDAs[.]" MSN otherwise denies the allegations of Paragraph 24.

25. On information and belief, the acts of MSN Pharmaceuticals and MSN Life complained of herein were done with the cooperation, participation, and assistance of MSN Labs.

ANSWER: MSN Pharmaceuticals and MSN Labs admit to filing ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836, '515, '542, and '709 patents. MSN otherwise denies the remaining allegations in Paragraph 25.

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

ANSWER: Paragraph 26 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals and MSN Labs do not contest personal jurisdiction in this Court solely for the purposes of this action and reserves the right to contest personal jurisdiction in any other action or case. MSN denies the remaining allegations of Paragraph 26.

27. On information and belief, MSN Pharmaceuticals, MSN Labs, and MSN Life have thus been, and continue to be, joint and prime actors in the drafting, submission, approval and maintenance of ANDA No. 219218.

ANSWER: MSN Pharmaceuticals and MSN Labs admit to filing ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836, '515, '542, and '709 patents. MSN otherwise denies the remaining allegations in Paragraph 27.

28. Following FDA approval of ANDA No. 219218, MSN will act in concert to import, market, distribute, offer for sale, and/or sell MSN's generic products described in ANDA No. 219218 throughout the United States, including in New Jersey and will derive substantial revenue from the use, consumption, or sale of MSN's generic products in the state of New Jersey.

ANSWER: MSN Pharmaceuticals and MSN Labs admit to filing ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836, '515, '542, and '709 patents. MSN otherwise denies the remaining allegations in Paragraph 28.

29. If ANDA No. 219218 is approved, MSN'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: MSN Pharmaceuticals and MSN Labs admit to filing ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836, '515, '542, and '709 patents. MSN otherwise denies the remaining allegations in Paragraph 29.

30. If ANDA No. 219218 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of MSN's generic products, including in New Jersey.

ANSWER: MSN denies that Plaintiffs will be harmed as a legal conclusion, as this is vague and speculative of future events. MSN otherwise denies the remaining allegations in Paragraph 30.

31. This Court also has personal jurisdiction over MSN because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. MSN has been sued multiple times in this district without challenging personal jurisdiction. *See, e.g.*, MSN's Answer, *GW Rsch. Ltd. v. Teva Pharms., Inc.*, No. 2:23-cv-03914 (D.N.J. Sept. 21, 2023); Defs.' Answer to Compl., *Catalyst Pharms., Inc. v. MSN Lab'ys Priv. Ltd.*, No. 1:23-cv-01945-KMW-SAK (D.N.J. June 9, 2023); MSN's Answer, *GW Rsch. Ltd. v. Teva Pharms., Inc.*, No. 2:23-cv-00018-KM-AME (D.N.J. Mar. 14, 2023); Defs.' Answer, *Janssen Prods., L.P. v. MSN Pharms. Inc.*, No. 3:21-cv-14622-ZNQ-LHG (D.N.J. Dec. 17, 2021).

ANSWER: Paragraph 31 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals and MSN Labs do not contest personal jurisdiction in this Court solely for the purposes of this action and reserve the right to contest personal jurisdiction in any other action or case. MSN otherwise denies the remaining allegations in Paragraph 31.

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

ANSWER: Paragraph 32 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals and MSN Labs do not contest personal jurisdiction in this Court solely for the purposes of this action and reserve the right to contest personal jurisdiction in any other action or case. MSN denies the remaining allegations of Paragraph 32.

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

ANSWER: Paragraph 33 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals and MSN Labs do not contest venue solely for the purposes of this action and reserve the right to contest venue in any other action or case. MSN denies the remaining allegations of Paragraph 33.

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

ANSWER: Paragraph 34 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals and MSN Labs do not contest venue solely for the purposes of this action and reserve the right to contest venue in any other action or case. MSN denies the remaining allegations of Paragraph 34.

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

ANSWER: Paragraph 35 states a legal conclusion to which no response is required. To the extent a response is required, MSN Pharmaceuticals and MSN Labs do not contest venue solely for the purposes of this action and reserve the right to contest venue in any other action or case. MSN denies the remaining allegations of Paragraph 35.

RESPONSE TO "UBRELVY® AND THE NDA"

36. 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: Upon information and belief, admitted.

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

ANSWER: MSN admits, upon information and belief, that the Food and Drug Administration approved NDA No. 211765 on December 23, 2019.

38. 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: MSN admits that the FDA Orange Book for NDA No. 211765, 100 mg tablets lists the '096 patent, the '210 patent, the '545 patent, the '448 patent, the '836 patent, '709 patent, '450 patent, and '004 patent for the 100 mg tablet. MSN admits the FDA Orange Book for

NDA No. 211765, 50 mg tablets lists the '096 patent, the '210 patent, the '545 patent, the '448 patent, the '836 patent, the '515 patent, the '542 patent, '709 patent, '004 patent, and the '030 patent. MSN denies the remaining allegations of paragraph 38.

39. 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: Upon information and belief, admitted.

40. 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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 40, and therefore denies the same.

41. 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: Upon information and belief, MSN admits that Paragraph 41 recites the dosing and administration section of the FDA-approved prescribing information for UBRELVY® tablets. MSN denies the remaining allegations in Paragraph 41.

42. 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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 42, and therefore denies the same.

43. 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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 43, and therefore denies the same.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 44, and therefore denies the same.

RESPONSE TO "THE PATENTS-IN-SUIT"

45. 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: MSN admits that, on its face, the '836 patent is titled "Tablet Formulations for CGRP Active Compounds" and purports to have been issued on November 6, 2018. MSN further admits that what appears to be a copy of the '836 patent appears to be attached as Exhibit A to Plaintiff's Complaint. MSN further admits that on its face, the '836 patent issued on November 6, 2018. MSN denies that the '836 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 45.

46. 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: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 46, and therefore denies the same.

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

ANSWER: MSN, upon information and belief, admits that the Orange Book lists the expiration date of the ’836 patent as January 30, 2035. MSN does not have sufficient information to admit or deny the remaining allegations in Paragraph 47, and therefore denies the same.

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

ANSWER: MSN does not have sufficient knowledge or information to admit or deny the allegations of Paragraph 48, and therefore denies the same.

49. 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.

50. 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: MSN admits that, on its face, the ’515 patent is titled “Treatment of Migraine” and purports to have been issued on August 8, 2023. MSN further admits that a copy of the ’515 patent appears to be attached as Exhibit B to Plaintiff’s Complaint. MSN denies that the ’515 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 50.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 51, and therefore denies the same.

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

ANSWER: MSN admits that the Orange Book lists the expiration of the ’515 patent as December 22, 2041. MSN does not have sufficient information to confirm or deny the remaining allegations of Paragraph 52, and therefore denies the same.

53. 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.

54. 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: MSN admits that on its face, the ’542 patent is titled “Treatment of Migraine” and purports to have been issued on January 2, 2024, and that a copy of the ’542 patent appears to be attached as Exhibit C to Plaintiff’s Complaint. MSN denies that the ’542 patent was duly and legally issued. MSN denies the remaining allegations of Paragraph 54.

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

ANSWER: MSN does not have sufficient knowledge or information to admit or deny the allegations of Paragraph 55, and therefore denies the same.

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

ANSWER: MSN admits that the Orange Book lists the expiration date of the ’542 patent as December 22, 2041. MSN does not have sufficient information to admit or deny the remaining allegations in Paragraph 56, and therefore denies the same.

57. 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.

58. 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: MSN admits that, on its face, the ’709 patent is titled “Tablet Formulation for CGRP Active Compounds” and purports to have been issued on March 12, 2024. MSN further admits that a copy of the ’709 patent appears to be attached as Exhibit D to Plaintiff’s Complaint. MSN denies that the ’709 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 58.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 59, and therefore denies the same.

60. The '709 patent currently expires on January 30, 2035.

ANSWER: MSN admits that the Orange Book lists the expiration date of the '709 patent as January 30, 2035. MSN does not have sufficient information to confirm or deny the remaining allegations in Paragraph 60, and therefore denies the same.

61. Allergan is the exclusive licensee of the '709 patent.

ANSWER: MSN lacks sufficient information to admit or deny that Plaintiffs are the exclusive licensee of the '709 patent. MSN therefore denies the allegations of Paragraph 61.

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

ANSWER: Denied.

63. 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: MSN admits that, on its face, the '450 patent is titled "Treatment of Migraine" and purports to have been issued on August 27, 2024. MSN further admits that a copy of the '450 patent appears to be attached as Exhibit E to Plaintiff's Third Amended Complaint. MSN denies that the '450 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 63.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 64, and therefore denies the same.

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

ANSWER: MSN admits that the Orange Book lists the expiration date of the '450 patent as December 22, 2041. MSN does not have sufficient information to admit or deny the remaining allegations in Paragraph 65, and therefore denies the same.

66. 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.

67. 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: MSN admits that, on its face, the '004 patent is titled "Treatment of Migraine" and purports to have been issued on December 17, 2024. MSN further admits that a copy of the '004 patent appears to be attached as Exhibit F to Plaintiff's Third Amended Complaint. MSN denies that the '004 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 67.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 68, and therefore denies the same.

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

ANSWER: MSN admits that the Orange Book lists the expiration date of the '004 patent as January 30, 2035. MSN does not have sufficient information to confirm or deny the remaining allegations in Paragraph 69, and therefore denies the same.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 70, and therefore denies the same.

71. 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.

72. 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: MSN admits that, on its face, the ’030 patent is titled “Treatment of Migraine” and purports to have been issued on January 14, 2025. MSN further admits that what appears to be a copy of the ’030 patent appears to be attached as Exhibit G to Plaintiff’s Third Amended Complaint. MSN denies that the ’030 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 72.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 73, and therefore denies the same.

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

ANSWER: MSN, upon information and belief, admits that the Orange Book lists the expiration date of the ’030 patent as December 22, 2041. MSN does not have sufficient information to admit or deny the remaining allegations in Paragraph 74, and therefore denies the same.

75. 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.

76. 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: MSN admits that, on its face, the ’408 patent is titled “Treatment of Migraine” and purports to have been issued on February 11, 2025. MSN further admits that what appears to be a copy of the ’408 patent appears to be attached as Exhibit H to Plaintiff’s Third Amended Complaint. MSN denies that the ’408 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 76.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 77, and therefore denies the same.

78. The '408 patent currently expires on January 30, 2035.

ANSWER: Paragraph 78 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN does not have sufficient information to admit or deny the allegations in Paragraph 78, and therefore denies the same.

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

ANSWER: Paragraph 79 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN does not have sufficient information to admit or deny the allegations in Paragraph 79, and therefore denies the same.

80. 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: MSN admits that, on its face, the '953 patent is titled "Pharmaceutical Formulations for the Treatment of Migraine" and purports to have been issued on May 27, 2025. MSN further admits that what appears to be a copy of the '953 patent appears to be attached as Exhibit I to Plaintiff's Third Amended Complaint. MSN denies that the '953 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 80.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 81, and therefore denies the same.

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

ANSWER: Paragraph 82 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN does not have sufficient information to admit or deny the allegations in Paragraph 82, and therefore denies the same.

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

ANSWER: Paragraph 83 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN does not have sufficient information to admit or deny the allegations in Paragraph 83, and therefore denies the same.

84. 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: MSN admits that, on its face, the '750 patent is titled "Treatment of Migraine" and purports to have been issued on June 17, 2025. MSN further admits that what appears to be a copy of the '750 patent appears to be attached as Exhibit J to Plaintiff's Third Amended Complaint. MSN denies that the '750 patent was duly and legally issued. MSN denies any remaining allegations of Paragraph 84.

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

ANSWER: MSN does not have sufficient knowledge or information to form an opinion or belief as to the allegations of Paragraph 85, and therefore denies the same.

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

ANSWER: Paragraph 86 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN does not have sufficient information to admit or deny the allegations in Paragraph 86, and therefore denies the same.

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

ANSWER: Paragraph 87 calls for a legal conclusion to which no response is required. To the extent a response is required, MSN denies that the '750 patent is listed in the FDA Orange Book for UBRELVY® (ubrogepant) oral tablets, 50 mg.

RESPONSE TO "MSN'S ANDA NO. 219218"

88. On information and belief, MSN filed ANDA No. 219218 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: MSN admits that it submitted ANDA No. 219218 to the FDA seeking approval to market MSN's 50 and 100 mg ubrogepant ANDA tablets in the United States. MSN denies the remaining allegations of Paragraph 88.

89. AbbVie received a letter sent by MSN ("MSN's Notice Letter I"), dated February 23, 2024, purporting to be a notice letter "pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act ('the Act') and 21 U.S.C. § 355(j)(2)(B)(iv) and § 314.95 of Title 21 of the Code of Federal Regulations."

ANSWER: Upon information and belief, MSN admits that AbbVie received MSN's Notice Letter I.

90. MSN's Notice Letter I represents that MSN's ANDA No. 219218 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 MSN's generic products.

ANSWER: Admitted.

91. AbbVie received a letter sent by MSN ("MSN's Notice Letter II"), dated June 21, 2024, purporting to be a notice letter "pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug and Cosmetic Act ('the Act') and 21 U.S.C. § 355(j)(2)(B)(iv) and § 314.95 of Title 21 of the Code of Federal Regulations."

ANSWER: Upon information and belief, MSN admits that AbbVie received MSN's Notice Letter II.

92. MSN's Notice Letter II represents that MSN's ANDA No. 219218 contains a Paragraph IV certification, alleging that the claims of the '542 and '709 patents are invalid, unenforceable, and/or will not be infringed by MSN's generic products.

ANSWER: Admitted.

93. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding MSN's ANDA No. 219218 for the '450 patent, '004 patent, '030 patent, '408 patent, '953 patent,

and ’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: As of this time, admitted.

94. On information and belief, MSN’s Notice Letters I and II and the information contained therein, coupled with regulatory requirements, demonstrate MSN’s infringement of the ’450, ’004, ’030, ’408, ’953, and ’750 patents.

ANSWER: Paragraph 94 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 94.

95. MSN’s Notice Letters I or II do not state or otherwise indicate that MSN 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, MSN 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: Paragraph 95 contains a legal conclusion to which no response is required. To the extent a response is required, MSN admits that it presently has submitted to the FDA a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(III) for the ’096, ’210, ’545, and ’448 patents. MSN denies the remaining allegations of Paragraph 95.

96. MSN’s purpose in submitting ANDA No. 219218 and a Paragraph IV certification is to market MSN’s generic products before the expiration of the ’836, ’515, ’542, and ’709 patents MSN intends to market MSN’s generic products before the expiration of the ’450, ’004, ’030, ’408, ’953, and ’750 patents.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the ’836, ’515, ’542, and ’709 patents. MSN denies the remaining allegations of Paragraph 96.

97. 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, MSN’s generic products will be bioequivalent to AbbVie’s UBRELVY® Tablets.

ANSWER: Paragraph 97 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that ANDA No. 219218 contains information

demonstrating the bioequivalence of MSN's ubrogepant tablets, 50 and 100 mg, to the reference-listed drug, which is UBRELVY® tablets. MSN denies the remaining allegations of Paragraph 97.

98. 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, MSN's generic products will have the same indication and safety and efficacy information as AbbVie's UBRELVY® Tablets.

ANSWER: Paragraph 98 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 98.

99. Following FDA approval of MSN's ANDA No. 219218, MSN will make, use, sell, and/or offer to sell MSN'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 MSN's generic products will directly infringe the Patents-in-Suit.

ANSWER: Paragraph 99 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 99.

100. Following FDA approval of MSN's ANDA No. 219218, MSN will actively induce or contribute to the manufacture, use, offer for sale, and/or sale of MSN's generic products in a manner that infringes the Patents-in-Suit.

ANSWER: Paragraph 100 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 100.

101. Plaintiffs commenced this action within 45 days of receiving MSN's Notice Letter.

ANSWER: Admitted.

RESPONSE TO "COUNT I: INFRINGEMENT BY MSN OF THE '836 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836 patent. MSN denies the remaining allegations of Paragraph 103.

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

ANSWER: Admitted.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 105.

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

ANSWER: Paragraph 106 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 106.

107. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

ANSWER: Paragraph 107 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 107.

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

ANSWER: Paragraph 108 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 108.

109. MSN had knowledge of the '836 patent, as evidenced by MSN's Notice Letter, and, by its promotional activities and proposed package insert for MSN'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: Paragraph 109 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that it had knowledge of the '836 patent as of the time it sent its Notice Letter. MSN denies the remaining allegations of Paragraph 109.

110. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

ANSWER: Paragraph 110 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 110.

111. The offering to sell, sale, making, and/or importation of MSN'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. MSN has knowledge and is aware of the '836 patent, as evidenced by MSN's Notice Letter.

ANSWER: Paragraph 111 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 111.

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

ANSWER Paragraph 112 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market the 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 112.

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

ANSWER: Paragraph 113 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 113.

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

ANSWER: Paragraph 114 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 114.

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

ANSWER: Paragraph 115 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 115.

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

ANSWER: Paragraph 116 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 116.

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

ANSWER: Paragraph 117 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 117.

RESPONSE TO "COUNT II: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '836 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 119 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that this action purports to arise under the Declaratory Judgment Act, and denies any remaining allegation of Paragraph 119.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836 patent. MSN denies the remaining allegations of Paragraph 120.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies any remaining allegation of Paragraph 121.

122. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '836 patent and any additional periods of exclusivity.

ANSWER: Paragraph 122 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 122.

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

ANSWER: Paragraph 123 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 123.

124. MSN had knowledge of the '836 patent, as evidenced by MSN's Notice Letter, and, by its promotional activities and proposed package insert for MSN'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: Paragraph 124 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that it had knowledge of the '836 patent as of the time it sent it Notice Letter. MSN denies the allegations of Paragraph 124.

125. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '836 patent.

ANSWER: Paragraph 125 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 125.

126. The offering to sell, sale, making, and/or importation of MSN'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. MSN has knowledge and is aware of the '836 patent, as evidenced by MSN's Notice Letter.

ANSWER: Paragraph 126 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 126.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '836 patent. MSN denies the remaining allegations of Paragraph 127.

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

ANSWER: Paragraph 128 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 128.

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

ANSWER: Paragraph 129 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 129.

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

ANSWER: Paragraph 130 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 130.

131. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 131 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 131.

132. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 132 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

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

ANSWER: Paragraph 133 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

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

ANSWER: Paragraph 134 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 134.

RESPONSE TO "COUNT III: INFRINGEMENT BY MSN OF THE '515 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg ubrogepant tablets prior to the expiration of the '515 patent.

MSN denies the remaining allegations of Paragraph 136.

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

ANSWER: Admitted.

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

ANSWER: Paragraph 138 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 138.

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

ANSWER: Paragraph 139 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 139.

140. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

ANSWER: Paragraph 140 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 140.

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

ANSWER: Paragraph 141 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 141.

142. MSN had knowledge of the '515 patent, as evidenced by MSN's Notice Letter, and, by its promotional activities and proposed package insert for MSN'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: Paragraph 142 states a legal conclusion to which no response is required. To the extent a response is required, MSN states that it had knowledge of the '515 patent as of the time it sent its Notice Letter. MSN denies the allegations of Paragraph 142.

143. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

ANSWER: Paragraph 143 contains speculation of future events and a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 143.

144. The offering to sell, sale, making, and/or importation of MSN'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. MSN has knowledge and is aware of the '515 patent, as evidenced by MSN's Notice Letter.

ANSWER: Paragraph 144 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 144.

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

ANSWER: Paragraph 145 contains a legal conclusion to which no response is required. To the extent that a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 145.

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

ANSWER: The allegations of Paragraph 146 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 146.

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

ANSWER: Paragraph 147 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 147.

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

ANSWER: Paragraph 148 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 148.

RESPONSE TO "COUNT IV: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '515 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: MSN admits that it submitted ANDA No. 219218 to the FDA seeking approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 151.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 152.

153. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '515 patent and any additional periods of exclusivity.

ANSWER: Paragraph 153 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 153.

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

ANSWER: Paragraph 154 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 154.

155. MSN had knowledge of the '515 patent, as evidenced by MSN's Notice Letter, and, by its promotional activities and proposed package insert for MSN'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: Paragraph 155 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits it had knowledge of the '515 patent as of the time it sent its Notice Letter. MSN denies the allegations of Paragraph 155.

156. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '515 patent.

ANSWER: Paragraph 156 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 156.

157. The offering to sell, sale, making, and/or importation of MSN'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. MSN has knowledge and is aware of the '515 patent, as evidenced by MSN's Notice Letter.

ANSWER: Paragraph 157 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits it had knowledge of the '515 patent of the time it sent its Notice Letter. MSN denies the allegations of Paragraph 157.

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

ANSWER: MSN admits that it submitted ANDA No. 219218 to the FDA seeking approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 158.

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

ANSWER: The allegations of Paragraph 159 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 159.

160. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 160 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 160.

161. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 161 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

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

ANSWER: Paragraph 162 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 162.

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

ANSWER: Paragraph 163 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 163.

RESPONSE TO "COUNT V: INFRINGEMENT BY MSN OF THE '542 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg ubrogepant tablets prior to the expiration of the '542 patent, for which the Orange Book states an expiration date of December 22, 2041. MSN denies the remaining allegations of Paragraph 165.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 166.

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

ANSWER: Paragraph 167 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 167.

168. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

ANSWER: Paragraph 168 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 168.

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

ANSWER: Paragraph 169 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 169.

170. MSN had knowledge of the '542 patent, as evidenced by MSN's Notice Letter, and, by its promotional activities and proposed package insert for MSN'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: Paragraph 170 states a legal conclusion to which no response is required.

To the extent a response is required, MSN admits it had knowledge of the '542 patent as of the time it sent its Notice Letter. MSN denies the remaining allegations of Paragraph 170.

171. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

ANSWER: Paragraph 171 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 171.

172. The offering to sell, sale, making, and/or importation of MSN'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. MSN has knowledge and is aware of the '542 patent, as evidenced by MSN's Notice Letter.

ANSWER: Paragraph 172 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 172.

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

ANSWER: Paragraph 173 states a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed

ANDA No. 219218 for approval to market the 50 mg ubrogepant tablets described therein. MSN denies the allegations of Paragraph 173.

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

ANSWER: The allegations of Paragraph 174 are too vague and ambiguous to either admit or deny, and therefore MSN denies the allegations of Paragraph 174.

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

ANSWER: Paragraph states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 175.

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

ANSWER: Paragraph 176 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 176.

RESPONSE TO "COUNT VI: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '542 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: MSN admits that it submitted ANDA No. 219218 to the FDA seeking approval to market 50 mg ubrogepant tablets prior to the expiration of the '542 patent. MSN denies the remaining allegations of Paragraph 179.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 180.

181. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '542 patent and any additional periods of exclusivity.

ANSWER: Paragraph 181 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 181.

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

ANSWER: Paragraph 182 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 182.

183. MSN had knowledge of the '542 patent, as evidenced by MSN's Notice Letter, and, by its promotional activities and proposed package insert for MSN'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: Paragraph 183 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits it had knowledge of the '542 patent at the time it sent its Notice Letter. MSN denies the remaining allegations of Paragraph 183.

184. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '542 patent.

ANSWER: Paragraph 184 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 184.

185. The offering to sell, sale, making, and/or importation of MSN'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. MSN has knowledge and is aware of the '542 patent, as evidenced by MSN's Notice Letter.

ANSWER: Paragraph 185 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 185.

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

ANSWER: Paragraph 186 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 186.

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

ANSWER: The allegations of Paragraph 187 are too vague and ambiguous to either admit or deny, and therefore MSN denies the allegations of Paragraph 187.

188. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 188 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 188.

189. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 189 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

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

ANSWER: Paragraph 190 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 190.

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

ANSWER: Paragraph 191 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 191.

RESPONSE TO "COUNT VII: INFRINGEMENT BY MSN OF THE '709 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 193 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of paragraph 193.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '709 patent. MSN denies the remaining allegations of Paragraph 194.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 195.

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

ANSWER: Paragraph 196 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 196.

197. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

ANSWER: Paragraph 197 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 197.

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

ANSWER: Paragraph 198 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 198.

199. MSN had knowledge of the '709 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 199 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 199.

200. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

ANSWER: Paragraph 200 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 200.

201. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '709 patent.

ANSWER: Paragraph 201 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 201.

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

ANSWER: Paragraph 202 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 202.

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

ANSWER: Paragraph 203 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 203.

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

ANSWER: Paragraph 204 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 204.

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

ANSWER: The allegations of Paragraph 205 are too vague and ambiguous to either admit or deny, and therefore MSN denies the allegations of Paragraph 205.

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

ANSWER: Paragraph 206 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 206.

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

ANSWER: Paragraph 207 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 207.

RESPONSE TO "COUNT VIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '709 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: Paragraph 210 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 210.

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

ANSWER: MSN admits that it submitted ANDA No. 219218 to the FDA seeking approval to market 50 mg and 100 mg ubrogepant tablets prior to the expiration of the '709 patent. MSN denies the remaining allegations of Paragraph 211.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 212.

213. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '709 patent and any additional periods of exclusivity.

ANSWER: Paragraph 213 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 213.

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

ANSWER: Paragraph 214 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 214.

215. MSN had knowledge of the '709 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 215 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 215.

216. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '709 patent.

ANSWER: Paragraph 216 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 216.

217. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '709 patent.

ANSWER: Paragraph 217 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 217.

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

ANSWER: Paragraph 218 states a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed

ANDA No. 219218 for approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 218.

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

ANSWER: Paragraph 219 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 219.

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

ANSWER: Paragraph 220 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 220.

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

ANSWER: The allegations of Paragraph 221 are too vague and ambiguous to either admit or deny, and therefore MSN denies the allegations of Paragraph 221.

222. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 222 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 222.

223. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 223 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

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

ANSWER: Paragraph 224 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 224.

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

ANSWER: Paragraph 225 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 225.

RESPONSE TO "COUNT IX: INFRINGEMENT BY MSN OF THE '450 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 227 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 227.

228. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '450 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 100 mg ubrogepant tablets, MSN denies the remaining allegations of Paragraph 228.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 229.

230. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's generic products before

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

ANSWER: Paragraph 230 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 230.

231. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '450 patent and any additional periods of exclusivity.

ANSWER: Paragraph 231 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 231.

232. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '450 patent.

ANSWER: Paragraph 232 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 232.

233. MSN had knowledge of the '450 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 233 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 233.

234. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '450 patent.

ANSWER: Paragraph 234 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 234.

235. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '450 patent.

ANSWER: Paragraph 235 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 235.

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

ANSWER: Paragraph 236 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market the 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 236.

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

ANSWER: The allegations of Paragraph 237 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 237.

238. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '450 patent.

ANSWER: Paragraph 238 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 238.

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

ANSWER: Paragraph 239 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 239.

RESPONSE TO "COUNT X: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '450 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 241 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits that this action purports to arise under the Declaratory Judgment Act and denies any remaining allegation of Paragraph 241.

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

ANSWER: Paragraph 242 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of paragraph 242.

243. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '450 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 243.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 244.

245. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '450 patent and any additional periods of exclusivity.

ANSWER: Paragraph 245 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 245.

246. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '450 patent.

ANSWER: Paragraph 246 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 246.

247. MSN had knowledge of the '450 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 247 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 247.

248. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '450 patent.

ANSWER: Paragraph 248 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 248.

249. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '450 patent.

ANSWER: Paragraph 249 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 249.

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

ANSWER: Paragraph 250 contains a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 250.

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

ANSWER: The allegations of Paragraph 251 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 251.

252. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 252 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 252.

253. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 253 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

254. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '450 patent.

ANSWER: Paragraph 254 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 254.

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

ANSWER: Paragraph 255 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 255.

RESPONSE TO "COUNT XI: INFRINGEMENT BY MSN OF THE '004 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 257 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 257.

258. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '004 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 258.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 259.

260. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's generic products before the expiration date of the '004 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 260 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 260.

261. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '004 patent and any additional periods of exclusivity.

ANSWER: Paragraph 261 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 261.

262. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '004 patent.

ANSWER: Paragraph 262 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 262.

263. MSN had knowledge of the '004 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 263 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 263.

264. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '004 patent.

ANSWER: Paragraph 264 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 264.

265. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '004 patent.

ANSWER: Paragraph 265 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 265.

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

ANSWER: Paragraph 266 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 266.

267. MSN should have had and/or has had and continues to have knowledge that MSN's generic products are especially adapted for a use that infringes the '004 patent.

ANSWER: Paragraph 267 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 267.

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

ANSWER: Paragraph 268 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 268.

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

ANSWER: The allegations of Paragraph 269 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies Paragraph 269.

270. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '004 patent.

ANSWER: Paragraph 270 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 270.

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

ANSWER: Paragraph 271 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 271.

RESPONSE TO "COUNT XII: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '004 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: Paragraph 274 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 274.

275. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '004 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the allegations of Paragraph 275.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 276.

277. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '004 patent and any additional periods of exclusivity.

ANSWER: Paragraph 277 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 277.

278. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '004 patent.

ANSWER: Paragraph 278 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 278.

279. MSN had knowledge of the '004 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 279 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 279.

280. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '004 patent.

ANSWER: Paragraph 280 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 280.

281. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '004 patent.

ANSWER: Paragraph 281 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 281.

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

ANSWER: Paragraph 282 contains a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 282.

283. MSN should have had and/or has had and continues to have knowledge that MSN's generic products are especially adapted for a use that infringes the '004 patent.

ANSWER: Paragraph 283 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 283.

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

ANSWER: Paragraph 284 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 284.

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

ANSWER: The allegations of Paragraph 285 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 285.

286. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 286 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 286.

287. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 287 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

288. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '004 patent.

ANSWER: Paragraph 288 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 288.

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

ANSWER: Paragraph 289 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 289.

RESPONSE TO "COUNT XIII: INFRINGEMENT BY MSN OF THE '030 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 291 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 291.

292. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '030 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg ubrogepant tablets. MSN denies the allegations of Paragraph 292.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 293.

294. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's generic products before the expiration date of the '030 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 294 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 294.

295. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '030 patent and any additional periods of exclusivity.

ANSWER: Paragraph 295 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 295.

296. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '030 patent.

ANSWER: Paragraph 296 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 296.

297. MSN had knowledge of the '030 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 297 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 297.

298. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '030 patent.

ANSWER: Paragraph 298 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 298.

299. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '030 patent.

ANSWER: Paragraph 299 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 299.

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

ANSWER: Paragraph 300 contains a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 300.

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

ANSWER: The allegations of Paragraph 301 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 301.

302. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '030 patent.

ANSWER: Paragraph 302 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 302.

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

ANSWER: Paragraph 303 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 303.

RESPONSE TO "COUNT XIV: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '030 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Action.

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

ANSWER: Paragraph 306 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 306.

307. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '030 patent.

ANSWER: MSN admits it submitted ANDA No. 219218 to the FDA seeking approval to market 50 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 307.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 308.

309. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '030 patent and any additional periods of exclusivity.

ANSWER: Paragraph 309 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 309.

310. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '030 patent.

ANSWER: Paragraph 310 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 310.

311. MSN had knowledge of the '030 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 311 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 311.

312. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '030 patent.

ANSWER: Paragraph 312 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 312.

313. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '030 patent.

ANSWER: Paragraph 313 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 313.

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

ANSWER: Paragraph 314 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed

ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 314.

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

ANSWER: The allegations of Paragraph 315 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of Paragraph 315.

316. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 316 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 316.

317. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 317 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

318. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '030 patent.

ANSWER: Paragraph 318 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 318.

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

ANSWER: Paragraph 319 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 319.

RESPONSE TO "COUNT XV: INFRINGEMENT BY MSN OF THE '408 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 321 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 321.

322. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '408 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 322.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 323.

324. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's generic products before the expiration date of the '408 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 324 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 324.

325. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '408 patent and any additional periods of exclusivity.

ANSWER: Paragraph 325 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 325.

326. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '408 patent.

ANSWER: Paragraph 326 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 326.

327. MSN had knowledge of the '408 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 327 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 327.

328. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '408 patent.

ANSWER: Paragraph 328 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 328.

329. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '408 patent.

ANSWER: Paragraph 329 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 329.

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

ANSWER: Paragraph 330 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 330.

331. MSN should have had and/or has had and continues to have knowledge that MSN's generic products are especially adapted for a use that infringes the '408 patent.

ANSWER: Paragraph 331 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 331.

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

ANSWER: Paragraph 332 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 332.

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

ANSWER: The allegations of Paragraph 333 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies Paragraph 333.

334. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '408 patent.

ANSWER: Paragraph 334 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 334.

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

ANSWER: Paragraph 335 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 335.

RESPONSE TO "COUNT XVI: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '408 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: Paragraph 338 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 338.

339. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '408 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 339.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 340.

341. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '408 patent and any additional periods of exclusivity.

ANSWER: Paragraph 341 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 341.

342. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '408 patent.

ANSWER: Paragraph 342 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 342.

343. MSN had knowledge of the '408 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 343 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 343.

344. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '408 patent.

ANSWER: Paragraph 344 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 344.

345. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '408 patent.

ANSWER: Paragraph 345 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 345.

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

ANSWER: Paragraph 346 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 346.

347. MSN should have had and/or has had and continues to have knowledge that MSN's generic products are especially adapted for a use that infringes the '408 patent.

ANSWER: Paragraph 347 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 347.

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

ANSWER: Paragraph 348 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 348.

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

ANSWER: The allegations of Paragraph 349 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of 349.

350. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 350 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 350.

351. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 351 states a legal conclusion to which no response is required.

To the extent a response is required, admitted.

352. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '408 patent.

ANSWER: Paragraph 352 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 352.

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

ANSWER: Paragraph 353 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 353.

RESPONSE TO "COUNT XVII: INFRINGEMENT BY MSN OF THE '953 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 355 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 355.

356. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '953 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 356.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 357.

358. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's generic products before the expiration date of the '953 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 358 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 358.

359. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '953 patent and any additional periods of exclusivity.

ANSWER: Paragraph 359 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 359.

360. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '953 patent.

ANSWER: Paragraph 360 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 360.

361. MSN had knowledge of the '953 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 361 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 361.

362. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '953 patent.

ANSWER: Paragraph 362 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 362.

363. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '953 patent.

ANSWER: Paragraph 363 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 363.

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

ANSWER: Paragraph 364 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 364.

365. MSN should have had and/or has had and continues to have knowledge that MSN's generic products are especially adapted for a use that infringes the '953 patent.

ANSWER: Paragraph 365 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 365.

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

ANSWER: Paragraph 366 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 366.

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

ANSWER: The allegations of Paragraph 367 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of 367.

368. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '953 patent.

ANSWER: Paragraph 368 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 368.

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

ANSWER: Paragraph 369 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 369.

RESPONSE TO "COUNT XVIII: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '953 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: Paragraph 372 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 372.

373. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '953 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 373.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 374.

375. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '953 patent and any additional periods of exclusivity.

ANSWER: Paragraph 375 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 375.

376. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '953 patent.

ANSWER: Paragraph 376 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 376.

377. MSN had knowledge of the '953 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 377 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 377.

378. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '953 patent.

ANSWER: Paragraph 378 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 378.

379. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '953 patent.

ANSWER: Paragraph 379 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 379.

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

ANSWER: Paragraph 380 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 380.

381. MSN should have had and/or has had and continues to have knowledge that MSN's generic products are especially adapted for a use that infringes the '953 patent.

ANSWER: Paragraph 381 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 381.

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

ANSWER: Paragraph 382 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 382.

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

ANSWER: The allegations of Paragraph 383 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of 383.

384. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 384 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 384.

385. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 385 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

386. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '953 patent.

ANSWER: Paragraph 386 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 386.

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

ANSWER: Paragraph 387 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 387.

RESPONSE TO "COUNT XIX: INFRINGEMENT BY MSN OF THE '750 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: Paragraph 389 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 389.

390. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '750 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 390.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 391.

392. Under 35 U.S.C. § 271(e)(2)(A), the submission to the FDA of MSN's ANDA seeking approval for the commercial manufacture, use, or sale of MSN's generic products before the expiration date of the '750 patent, constitutes infringement, either literally or under the doctrine of equivalents.

ANSWER: Paragraph 392 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 392.

393. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '750 patent and any additional periods of exclusivity.

ANSWER: Paragraph 393 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 393.

394. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '750 patent.

ANSWER: Paragraph 394 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 394.

395. MSN had knowledge of the '750 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 395 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 395.

396. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '750 patent.

ANSWER: Paragraph 396 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 396.

397. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '750 patent.

ANSWER: Paragraph 397 states a legal conclusion to which no response is required.

To the extent a response is required, MSN denies the allegations of Paragraph 397.

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

ANSWER: Paragraph 398 contains a legal conclusion to which no response is required.

To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 398.

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

ANSWER: The allegations of Paragraph 399 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies Paragraph 399.

400. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '750 patent.

ANSWER: Paragraph 400 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 400.

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

ANSWER: Paragraph 401 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 401.

RESPONSE TO "COUNT XX: DECLARATORY JUDGMENT OF INFRINGEMENT BY MSN OF THE '750 PATENT"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent that a response is required, MSN incorporates by reference its response to each preceding paragraph as if fully set forth herein.

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

ANSWER: MSN admits that this action asserts to be under the Declaratory Judgment Act.

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

ANSWER: Paragraph 404 states a legal conclusion to which no response is required. To the extent a response is required, MSN admits the allegations of Paragraph 404.

405. MSN filed its ANDA in order to obtain approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '750 patent.

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets. MSN denies the remaining allegations of Paragraph 405.

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

ANSWER: MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 with the information required in 21 U.S.C. § 355(j)(2)(A). MSN denies the remaining allegations of Paragraph 406.

407. After FDA approval of MSN's ANDA, MSN 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 MSN'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 MSN's ANDA shall be no earlier than the expiration of the '750 patent and any additional periods of exclusivity.

ANSWER: Paragraph 407 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 407.

408. MSN knows or should know, and intends that healthcare providers will prescribe and patients will take MSN's generic products for which approval is sought in MSN's ANDA, and therefore will infringe at least one claim in the '750 patent.

ANSWER: Paragraph 408 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 408.

409. MSN had knowledge of the '750 patent and, by its promotional activities and proposed package insert for MSN'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: Paragraph 409 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 409.

410. MSN 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 MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes the '750 patent.

ANSWER: Paragraph 410 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 410.

411. The offering to sell, sale, making, and/or importation of MSN'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, MSN has knowledge and is aware of the '750 patent.

ANSWER: Paragraph 411 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 411.

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

ANSWER: Paragraph 412 contains a legal conclusion to which no response is required. To the extent a response is required, MSN admits that MSN Pharmaceuticals and MSN Labs filed ANDA No. 219218 for approval to market 50 mg and 100 mg ubrogepant tablets described therein. MSN denies the remaining allegations of Paragraph 412.

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

ANSWER: The allegations of Paragraph 413 are too vague and ambiguous for MSN to admit or deny, and as such MSN denies the allegations of 413.

414. On information and belief, MSN's infringing activity, including the manufacture, use, import, offer to sell, and/or sale of MSN's generic products in the United States, will begin immediately after FDA approves MSN'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: Paragraph 414 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 414.

415. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN 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: Paragraph 415 states a legal conclusion to which no response is required. To the extent a response is required, admitted.

416. Plaintiffs will be irreparably harmed if MSN is not enjoined from infringing, actively inducing, and contributing to infringement of at least one claim of the '750 patent.

ANSWER: Paragraph 416 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 416.

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

ANSWER: Paragraph 417 states a legal conclusion to which no response is required. To the extent a response is required, MSN denies the allegations of Paragraph 417.

RESPONSE TO "REQUEST FOR RELIEF"

With respect to Plaintiffs' request for relief, MSN denies that Plaintiffs are entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in paragraphs A–I.

SEPARATE DEFENSES

MSN asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. MSN does not assume any burden of proof on any asserted defenses, except those which are MSN's as required by the applicable law governing the defense. MSN reserves the right to assert other defenses and/or otherwise supplement or amend its Answer and Separate Defenses to the Complaint upon discovery of fact or evidence rendering such action appropriate.

FIRST SEPARATE DEFENSE
(Non-Infringement of the '836 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '836 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SECOND SEPARATE DEFENSE
(Invalidity of the '836 Patent)

The asserted claims of the '836 are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

THIRD SEPARATE DEFENSE
(Non-Infringement of the '515 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '515 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

FOURTH SEPARATE DEFENSE
(Invalidity of the '515 Patent)

The asserted claims of the '515 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

FIFTH SEPARATE DEFENSE
(Non-Infringement of the '542 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '542 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SIXTH SEPARATE DEFENSE
(Invalidity of the '542 Patent)

The asserted claims of the '542 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

SEVENTH SEPARATE DEFENSE
(Non-Infringement of the '709 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '709 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

EIGHTH SEPARATE DEFENSE
(Invalidity of the '709 Patent)

The asserted claims of the '709 are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

NINTH SEPARATE DEFENSE
(Non-Infringement of the '450 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '450 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

TENTH SEPARATE DEFENSE
(Invalidity of the '450 Patent)

The asserted claims of the '450 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

ELEVENTH SEPARATE DEFENSE
(Non-Infringement of the '004 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '004 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

TWELFTH SEPARATE DEFENSE
(Invalidity of the '004 Patent)

The asserted claims of the '004 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

THIRTEENTH SEPARATE DEFENSE
(Non-Infringement of the '030 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '030 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

FOURTEENTH SEPARATE DEFENSE
(Invalidity of the '030 Patent)

The asserted claims of the '030 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

FIFTEENTH SEPARATE DEFENSE
(Non-Infringement of the '408 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '408 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

SIXTEENTH SEPARATE DEFENSE
(Invalidity of the '408 Patent)

The asserted claims of the '408 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

SEVENTEENTH SEPARATE DEFENSE
(Non-Infringement of the '953 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '953 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

EIGHTEENTH SEPARATE DEFENSE
(Invalidity of the '953 Patent)

The asserted claims of the '953 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

NINETEENTH SEPARATE DEFENSE
(Non-Infringement of the '750 Patent)

MSN has not and will not infringe any valid and enforceable claim of the '750 patent either directly or indirectly, contributorily, and/or by inducement, literally or under the doctrine of equivalents.

TWENTIETH SEPARATE DEFENSE
(Invalidity of the '750 Patent)

The asserted claims of the '750 patent are invalid under one or more provisions of 35 U.S.C. §§ 101 *et seq*., including but not limited to 102, 103, and 112, statutory and obviousness-type double patenting, and the defenses recognized in 35 U.S.C. § 282(b).

TWENTY-FIRST SEPARATE DEFENSE
(Equitable Defenses)

Any claim by Plaintiffs is barred, in whole or in part, by the equitable doctrines of unclean hands, estoppel, or patent misuse.

TWENTY-SECOND SEPARATE DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to any injunctive relief because any alleged injury to Plaintiffs is not immediate nor irreparable. Plaintiffs have an adequate remedy at law, or public policy concerns weigh against any award of injunctive relief.

TWENTY-THIRD SEPARATE DEFENSE
(Failure to State a Claim)

Plaintiffs' Complaint fails to state a claim upon which relief may be granted.

TWENTY-FOURTH SEPARATE DEFENSE
(Not an Exceptional Case)

MSN's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

Reservation of Additional Defenses

MSN reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of one or more of the Patents-in-Suit.

COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendants AbbVie Inc. ("AbbVie"), Allergan Pharmaceuticals International Limited ("Allergan"), and Merck Sharp & Dohme LLC ("Merck") (collectively, "Counterclaim-Defendants"), Counterclaim-Plaintiffs MSN Pharmaceuticals Inc., MSN Laboratories Pvt. Ltd., and MSN Life Sciences Pvt. Ltd. (collectively, "MSN" or "Counterclaim-Plaintiff") state as follows:

Parties

1. MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, New Jersey 08854.

2. MSN Laboratories Private Ltd. is an Indian corporation having a principal place of business at MSN House, Plot No. C-24, Industrial Estate, Sanath Nagar, Hyderabad, Telangana, 500018 India.

3. MSN Life Sciences Pvt. Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Sy No- 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) - 502313, Telangana, India.

4. Upon information and belief, AbbVie is a company organized and existing under the laws of Delaware, having its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064.

5. Upon information and belief, Allergan Pharmaceuticals International Limited ("Allergan") is a company organized and existing under the laws of Ireland, having its principal place of business at Clonshaugh Business & Technical Park, Dublin 17, Ireland D17 E400.

6. Upon information and belief, Merck Sharp & Dohme LLC ("Merck") is a company organized and existing under the laws of the State of New Jersey, having its principal place of business at 126 Lincoln Avenue, Rahway, New Jersey 07065.

Jurisdiction and Venue

7. These counterclaims arise under the Patent Laws of the United States, 35 U.S.C. §§ 1, 271(e)(5), 1331, 1338(a), *et seq*., the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), 21 Y.S.C. § 355(j)()(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

8. This Court has original jurisdiction over the subject matter of these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202; 35 U.S.C. § 271(e)(5); and 21 U.S.C. § 355 (j)(5)(C)(i).

9. This Court has personal jurisdiction over AbbVie, Allergan, and Merck, because they availed themselves to the rights and privileges of this forum by bringing this civil action in this Judicial District, and because, upon information and belief, Counterclaim-Defendants conduct substantial business in, and have regular and systemic contact with, this Judicial District.

10. Venue for these counterclaims is proper in this Judicial District pursuant to 28 U.S.C. §§ 1391(b) and (c) and 1400(b) based on the fact that AbbVie, Allergan, and Merck have asserted the Patents-in-Suit against MSN in this Judicial District.

Factual Background

11. AbbVie holds the New Drug Application ("NDA") No. 211765 for which the United States Food and Drug Administration ("FDA") granted approval for the manufacture and sale of the active ingredient ubrogepant 50 mg and 100 mg tablets, which is prescribed and sold in the United States under the brand name UBRELVY®.

12. MSN filed Abbreviated New Drug Application ("ANDA") No. 219218 seeking approval from the FDA to market generic ubrogepant tablets, 50 mg and 100 mg, as described therein.

13. Upon information and belief, and upon their representations in the Complaint, Counterclaim-Defendants assert ownership of, and to have the right to enforce, 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").

14. The '836, '515, '542, '709, '450, '004, '030, '408, and '953 patents are listed in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), in association with the UBRELVY® drug product. As a result of such a listing, Counterclaim-Defendants maintain, and have affirmatively asserted, that a claim for patent infringement could be asserted against any generic ANDA applicant attempting to market a generic product before patent expiration, including MSN.

15. The '750 patent is not listed in the Orange Book for the UBRELVY® drug product, 50 mg, but Counterclaim-Defendants maintain, and have affirmatively asserted, a claim for patent infringement against ANDA applicants seeking approval from FDA for an ANDA referencing UBRELVY as the reference-listed drug prior to the '750 patent's expiration, including MSN.

16. MSN has certified to the FDA that its ANDA product will not infringe the '836, '515, '542, and '709 patents, or that such patents are invalid and/or unenforceable, and has further notified Counterclaim-Defendants of the legal and factual bases for that certification. This created the necessary case or controversy for MSN to file and maintain a counterclaim for declaratory judgment of patent non-infringement and/or invalidity of the '836, '515, '542, and '709 patents.

17. Counterclaim-Defendants have already created a substantial controversy through its suit of MSN for alleged infringement of the '836, '515, '542, '709, '450, '004, '030, '408, '953 and '750 patents. There is an actual, substantial, and continuing justiciable case and controversy between MSN (on one side) and AbbVie, Allergan, and Merck (on the other) regarding whether MSN will infringe at least one valid claim of the '836, '515, '542, '709, '450, '004, '030, '408,

'953 and '750 patents, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

18. MSN is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of MSN's ANDA products do not and will not infringe the '836, '515, '542, '709, '450, '004, '030, '408, '953, and '750 patents, and/or that such patents are invalid. Absent the exercise of jurisdiction by this Court and such declaratory relief, MSN will be harmed by the delay of market entry of its 50 mg and 100 mg ubrogepant tablets as described in ANDA No. 219218.

U.S. Patent No. 10,117,836

19. The '836 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 and 100 mg.

20. On November 6, 2018, the United States Patent and Trademark Office ("USPTO") issued the '836 patent, entitled "Tablet Formulations for CGRP Active Compounds."

21. Upon information and belief, Allergan and Merck hold all substantial rights to the '836 patent.

22. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 and 100 mg ubrogepant tablets described therein in the United States, prior to the expiration of the '836 patent. That ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '836 patent is invalid, unenforceable, and/or will not be infringed.

23. By letter dated February 23, 2024, MSN provided AbbVie, Allergan, and Merck with notice of the filing of ANDA No. 219218 and that said ANDA contained a Paragraph IV Certification with respect to the '836 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("MSN's First Notice Letter").

24. MSN's First Notice Letter contained an Offer of Confidential Access to its ANDA No. 219218 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

25. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of the '836 patent.

26. For at least the reasons stated in its February 23, 2024, Notice Letter, MSN seeks a declaratory judgment that the '836 patent is not valid and/or is not infringed.

U.S. Patent No. 11,717,515

27. The '515 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 mg.

28. On August 8, 2023, the United States Patent and Trademark Office ("USPTO") issued the '515 patent, entitled "Treatment of Migraine."

29. Upon information and belief, Allergan, holds all substantial rights to the '515 patent.

30. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg and 100 mg ubrogepant tablets in the United States prior to the expiration of the '515 patent. That ANDA contains a Paragraph IV Certification that the '515 patent is invalid, unenforceable, and/or will not be infringed.

31. By letter dated February 23, 2024, MSN provided AbbVie, Allergan, and Merck with notice of the filing of ANDA No. 219218 and that said ANDA contained a Paragraph IV Certification with respect to the '515 patent, as required under 21 U.S.C. § 355(j)(2)(B).

32. MSN's First Notice Letter made an Offer of Confidential Access to its ANDA No. 219218 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

33. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of the '515 patent.

34. For at least the reasons stated in its February 23, 2024, Notice Letter, MSN seeks a declaratory judgment that the '515 patent is not valid and/or is not infringed.

U.S. Patent No. 11,857,542

35. The '542 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 mg.

36. On January 2, 2024, the United States Patent and Trademark Office ("USPTO") issued the '542 patent, entitled "Treatment of Migraine."

37. Upon information and belief, Allergan holds all substantial rights to the '542 patent.

38. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg ubrogepant tablets in the United States prior to the expiration of the '542 patent. That ANDA contains a Paragraph IV Certification that the '542 patent is invalid, unenforceable, and/or will not be infringed.

39. By letter dated June 21, 2024, MSN provided AbbVie, Allergan, and Merck with notice of the filing of ANDA No. 219218 and that said ANDA contained a Paragraph IV Certification with respect to the '542 patent, as required under 21 U.S.C. § 355(j)(2)(B) ("MSN's Second Notice Letter").

40. MSN's Second Notice Letter made an Offer of Confidential Access to its ANDA No. 219218 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

41. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of the '542 patent.

42. For at least the reasons stated in its June 21, 2024, Notice Letter, MSN seeks a declaratory judgment that the '542 patent is not valid and/or is not infringed.

U.S. Patent No. 11,925,709

43. The '709 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 mg and 100 mg.

44. On March 12, 2024, the United States Patent and Trademark Office ("USPTO") issued the '709 patent, entitled "Tablet Formulation for CGRP Active Compounds."

45. Upon information and belief, Merck and Allergan hold all substantial rights to the '709 patent.

46. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg and 100 mg ubrogepant tablets in the United States prior to the expiration of the '709 patent. That ANDA contains a Paragraph IV Certification that the '709 patent is invalid, unenforceable, and/or will not be infringed.

47. By letter dated June 21, 2024, MSN provided AbbVie, Allergan, and Merck with notice of the filing of ANDA No. 219218 and that said ANDA contained a Paragraph IV Certification with respect to the '709 patent, as required under 21 U.S.C. § 355(j)(2)(B).

48. MSN's Second Notice Letter made an Offer of Confidential Access to its ANDA No. 219218 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

49. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of the '709 patent.

50. For at least the reasons stated in its June 21, 2024, Notice Letter, MSN seeks a declaratory judgment that the '709 patent is not valid and/or is not infringed.

U.S. Patent No. 12,070,450

51. The ’450 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 100 mg.

52. On August 27, 2024, the United States Patent and Trademark Office (“USPTO”) issued the ’450 patent, entitled “Treatment of Migraine.”

53. Upon information and belief, Merck and Allergan hold all substantial rights to the ’450 patent.

54. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market 100 mg ubrogepant tablets in the United States.

55. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of U.S. Patent Nos. 10,117,836 (“the ’836 patent”), 11,717,515 (“the ’515 patent”), 11,857,542 (“the ’542 patent”), and 11,925,709 (“the ’709 patent”). On January 24, 2025, Allergan and Merck filed a First Amended Complaint alleging infringement of U.S. Patent Nos. 12,070,450 (“the ’450 patent”) and 12,168,004 (“the ’004 patent”).

56. MSN seeks a declaratory judgment that the ’450 patent is not valid and/or is not infringed.

U.S. Patent No. 12,168,004

57. The ’004 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 mg and 100 mg.

58. On December 17, 2024, the United States Patent and Trademark Office (“USPTO”) issued the ’004 patent, entitled “Treatment of Migraine.”

59. Upon information and belief, Merck and Allergan hold all substantial rights to the '004 patent.

60. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg and 100 mg ubrogepant tablets in the United States.

61. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), and 11,925,709 ("the '709 patent"). On January 24, 2025, Allergan and Merck filed a First Amended Complaint alleging infringement of U.S. Patent Nos. 12,070,450 ("the '450 patent") and 12,168,004 ("the '004 patent").

62. MSN seeks a declaratory judgment that the '004 patent is not valid and/or is not infringed.

U.S. Patent No. 12,194,030

63. The '030 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 mg.

64. On January 14, 2025, the United States Patent and Trademark Office ("USPTO") issued the '030 patent, entitled "Treatment of Migraine."

65. Upon information and belief, Allergan holds all substantial rights to the '030 patent.

66. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg ubrogepant tablets in the United States.

67. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of U.S. Patent Nos. 10,117,836

("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), and 11,925,709 ("the '709 patent"). On January 24, 2025, Allergan and Merck filed a First Amended Complaint alleging infringement of U.S. Patent Nos. 12,070,450 ("the '450 patent") and 12,168,004 ("the '004 patent"). On March 3, 2025, Allergan and Merck filed a Second Amended Complaint alleging infringement of U.S. Patent Nos. 12,194,030 ("the '030 patent") and 12,220,408 ("the '408 patent").

68. MSN seeks a declaratory judgment that the '030 patent is not valid and/or is not infringed.

U.S. Patent No. 12,220,408

69. On February 11, 2025, the United States Patent and Trademark Office ("USPTO") issued the '408 patent, entitled "Treatment of Migraine."

70. Upon information and belief, and based upon Counterclaim-Defendants' allegations, Merck holds all substantial rights to the '408 patent.

71. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg and 100 mg ubrogepant tablets in the United States.

72. On April 8, 2024, AbbVie, Allergan, and Merck initiated this civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), and 11,925,709 ("the '709 patent"). On January 24, 2025, Allergan and Merck filed a First Amended Complaint alleging infringement of U.S. Patent Nos. 12,070,450 ("the '450 patent") and 12,168,004 ("the '004 patent"). On March 3, 2025, Allergan and Merck filed a Second Amended Complaint alleging infringement of U.S. Patent Nos. 12,194,030 ("the '030 patent") and 12,220,408 ("the '408 patent").

73. MSN seeks a declaratory judgment that the ’408 patent is not valid and/or is not infringed.

U.S. Patent No. 12,310,953

74. On May 27, 2025, the United States Patent and Trademark Office (“USPTO”) issued the ’953 patent, entitled “Pharmaceutical Formulations for the Treatment of Migraine.”

75. The ’953 patent is listed in the Orange Book in association with NDA No. 211765 for UBRELVY (ubrogepant) tablets, 50 mg.

76. Upon information and belief, and based upon Counterclaim-Defendants’ allegations, Merck holds all substantial rights to the ’953 patent.

77. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg and 100 mg ubrogepant tablets in the United States.

78. On April 8, 2024, AbbVie, Allergan, and Merck initiated a civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of U.S. Patent Nos. 10,117,836 (“the ’836 patent”), 11,717,515 (“the ’515 patent”), 11,857,542 (“the ’542 patent”), and 11,925,709 (“the ’709 patent”). On January 24, 2025, AbbVie, Allergan, and Merck filed a First Amended Complaint alleging infringement of U.S. Patent Nos. 12,070,450 (“the ’450 patent”) and 12,168,004 (“the ’004 patent”). On March 3, 2025, AbbVie, Allergan, and Merck filed a Second Amended Complaint alleging infringement of U.S. Patent Nos. 12,194,030 (“the ’030 patent”) and 12,220,408 (“the ’408 patent”). On June 6, 2025, AbbVie, Allergan, and Merck filed a Third Amended Complaint alleging infringement of U.S. Patent Nos. 12,310,953 (“the ’953 patent”) and 12,329,750 (“the ’750 patent”).

79. MSN seeks a declaratory judgment that the ’953 patent is not valid and/or is not infringed.

U.S. Patent No. 12,329,750

80. On June 17, 2025, the United States Patent and Trademark Office ("USPTO") issued the '750 patent, entitled "Treatment of Migraine."

81. Upon information and belief, and based upon Counterclaim-Defendants' allegations, Merck holds all substantial rights to the '750 patent.

82. MSN submitted ANDA No. 219218 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to market the 50 mg and 100 mg ubrogepant tablets in the United States.

83. On April 8, 2024, AbbVie, Allergan, and Merck initiated a civil action, 3:24-cv-04662, against MSN in this Judicial District alleging infringement of U.S. Patent Nos. 10,117,836 ("the '836 patent"), 11,717,515 ("the '515 patent"), 11,857,542 ("the '542 patent"), and 11,925,709 ("the '709 patent"). On January 24, 2025, Allergan and Merck filed a First Amended Complaint alleging infringement of U.S. Patent Nos. 12,070,450 ("the '450 patent") and 12,168,004 ("the '004 patent"). On March 3, 2025, Allergan and Merck filed a Second Amended Complaint alleging infringement of U.S. Patent Nos. 12,194,030 ("the '030 patent") and 12,220,408 ("the '408 patent"). On June 6, 2025, AbbVie, Allergan, and Merck filed a Third Amended Complaint alleging infringement of U.S. Patent Nos. 12,310,953 ("the '953 patent") and 12,329,750 ("the '750 patent").

84. MSN seeks a declaratory judgment that the '750 patent is not valid and/or is not infringed.

COUNT I (Declaratory Judgment of Invalidity of the '836 Patent)

85. MSN restates and re-alleges each of the foregoing Paragraphs 1-84 of the counterclaims as if fully set forth herein.

86. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '836 patent.

87. Upon information and belief, the claims of the '836 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq*., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

88. The Court should declare that the claims of the '836 patent are invalid and/or unenforceable.

COUNT II
(Declaratory Judgment of Non-Infringement of the '836 Patent)

89. MSN restates and re-alleges each of the foregoing Paragraphs 1-88 of the counterclaims as if fully set forth herein.

90. Counterclaim-Defendants have alleged that MSN's filing of ANDA 219218 infringes the '836 patent.

91. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '836 patent.

92. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '836 patent.

93. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '836 patent.

COUNT III
(Declaratory Judgment of Invalidity of the '515 Patent)

94. MSN restates and re-alleges each of the foregoing Paragraphs 1-93 of the counterclaims as if fully set forth herein.

95. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '515 patent.

96. Upon information and belief, the claims of the '515 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

97. The Court should declare that the claims of the '515 patent are invalid and/or unenforceable.

COUNT IV
(Declaratory Judgment of Non-Infringement of the '515 Patent)

98. MSN restates and re-alleges each of the foregoing Paragraphs 1-97 of the counterclaims as if fully set forth herein.

99. AbbVie, Allergan, and Merck have alleged that MSN's filing of ANDA 219218 infringes the '515 patent.

100. As evidenced by AbbVie, Allergan, and Merck's Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '515 patent.

101. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '515 patent.

102. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '515 patent.

COUNT V
(Declaratory Judgment of Invalidity of the '542 Patent)

103. MSN restates and re-alleges each of the foregoing Paragraphs 1-102 of the counterclaims as if fully set forth herein.

104. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '542 patent.

105. Upon information and belief, the claims of the '542 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or

251 *et seq*., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

106. The Court should declare that the claims of the ’542 patent are invalid and/or unenforceable.

COUNT VI

(Declaratory Judgment of Non-Infringement of the ’542 Patent)

107. MSN restates and re-alleges each of the foregoing Paragraphs 1-106 of the counterclaims as if fully set forth herein.

108. AbbVie, Allergan, and Merck have alleged that MSN’s filing of ANDA 219218 infringes the ’542 patent.

109. As evidenced by AbbVie, Allergan and Merck’s Complaint and MSN’s Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the ’542 patent.

110. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN’s ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’542 patent.

111. MSN is entitled to a judicial determination that MSN’s ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the ’542 patent.

COUNT VII

(Declaratory Judgment of Invalidity of the ’709 Patent)

112. MSN restates and re-alleges each of the foregoing Paragraphs 1-111 of the counterclaims as if fully set forth herein.

113. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '709 patent.

114. Upon information and belief, the claims of the '709 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq*., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

115. The Court should declare that the claims of the '709 patent are invalid and/or unenforceable.

COUNT VIII
(Declaratory Judgment of Non-Infringement of the '709 Patent)

116. MSN restates and re-alleges each of the foregoing Paragraphs 1-115 of the counterclaims as if fully set forth herein.

117. AbbVie, Allergan, and Merck have alleged that MSN's filing of ANDA 219218 infringes the '709 patent.

118. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '709 patent.

119. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '709 patent.

120. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '709 patent.

COUNT IX
(Declaratory Judgment of Invalidity of the '450 Patent)

121. MSN restates and re-alleges each of the foregoing Paragraphs 1-120 of the counterclaims as if fully set forth herein.

122. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '450 patent.

123. Upon information and belief, the claims of the '450 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq*., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

124. The Court should declare that the claims of the '450 patent are invalid and/or unenforceable.

COUNT X
(Declaratory Judgment of Non-Infringement of the '450 Patent)

125. MSN restates and re-alleges each of the foregoing Paragraphs 1-124 of the counterclaims as if fully set forth herein.

126. AbbVie, Allergan, and Merck have alleged that MSN's filing of ANDA 219218 infringes the '450 patent.

127. As evidenced by AbbVie, Allergan, and Merck's Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '450 patent.

128. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '450 patent.

129. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '450 patent.

COUNT XI
(Declaratory Judgment of Invalidity of the '004 Patent)

130. MSN restates and re-alleges each of the foregoing Paragraphs 1-129 of the counterclaims as if fully set forth herein.

131. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '004 patent.

132. Upon information and belief, the claims of the '004 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or

251 *et seq*., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

133. The Court should declare that the claims of the ’004 patent are invalid and/or unenforceable.

COUNT XII
(Declaratory Judgment of Non-Infringement of the ’004 Patent)

134. MSN restates and re-alleges each of the foregoing Paragraphs 1-133 of the counterclaims as if fully set forth herein.

135. AbbVie, Allergan, and Merck have alleged that MSN’s filing of ANDA 219218 infringes the ’004 patent.

136. As evidenced by Counterclaim-Defendants’ Complaint and MSN’s Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the ’004 patent.

137. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN’s ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’004 patent.

138. MSN is entitled to a judicial determination that MSN’s ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the ’004 patent.

COUNT XIII
(Declaratory Judgment of Invalidity of the ’030 Patent)

139. MSN restates and re-alleges each of the foregoing Paragraphs 1-138 of the counterclaims as if fully set forth herein.

140. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '030 patent.

141. Upon information and belief, the claims of the '030 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq*., and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

142. The Court should declare that the claims of the '030 patent are invalid and/or unenforceable.

COUNT XIV
(Declaratory Judgment of Non-Infringement of the '030 Patent)

143. MSN restates and re-alleges each of the foregoing Paragraphs 1-142 of the counterclaims as if fully set forth herein.

144. AbbVie, Allergan, and Merck have alleged that MSN's filing of ANDA 219218 infringes the '030 patent.

145. As evidenced by AbbVie, Allergan, and Merck's Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '030 patent.

146. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '030 patent.

147. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '030 patent.

COUNT XV
(Declaratory Judgment of Invalidity of the '408 Patent)

148. MSN restates and re-alleges each of the foregoing Paragraphs 1-147 of the counterclaims as if fully set forth herein.

149. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '408 patent.

150. Upon information and belief, the claims of the '408 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

151. The Court should declare that the claims of the '408 patent are invalid and/or unenforceable.

COUNT XVI
(Declaratory Judgment of Non-Infringement of the '408 Patent)

152. MSN restates and re-alleges each of the foregoing Paragraphs 1-151 of the counterclaims as if fully set forth herein.

153. Counterclaim-Defendants have alleged that MSN's filing of ANDA 219218 infringes the '408 patent.

154. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '408 patent.

155. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '408 patent.

156. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '408 patent.

COUNT XVII
(Declaratory Judgment of Invalidity of the '953 Patent)

157. MSN restates and re-alleges each of the foregoing Paragraphs 1-156 of the counterclaims as if fully set forth herein.

158. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '953 patent.

159. Upon information and belief, the claims of the '953 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or

251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

160. The Court should declare that the claims of the ’953 patent are invalid and/or unenforceable.

COUNT XVIII
(Declaratory Judgment of Non-Infringement of the ’953 Patent)

161. MSN restates and re-alleges each of the foregoing Paragraphs 1-160 of the counterclaims as if fully set forth herein.

162. AbbVie, Allergan, and Merck have alleged that MSN’s filing of ANDA 219218 infringes the ’953 patent.

163. As evidenced by AbbVie, Allergan, and Merck’s Complaint and MSN’s Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the ’953 patent.

164. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN’s ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the ’953 patent.

165. MSN is entitled to a judicial determination that MSN’s ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the ’953 patent.

COUNT XIX
(Declaratory Judgment of Invalidity of the ’750 Patent)

166. MSN restates and re-alleges each of the foregoing Paragraphs 1-165 of the counterclaims as if fully set forth herein.

167. As evidenced by Counterclaim-Defendants' Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the validity of the claims of the '750 patent.

168. Upon information and belief, the claims of the '750 patent are invalid for failure to comply with one or more of the requirements of at least 35 U.S.C. §§ 101, 102, 103, 112, and/or 251 *et seq.*, and/or are invalid under the doctrine of obviousness-type double patenting, and/or for any other judicially created and/or non-statutory basis for invalidity or unenforceability.

169. The Court should declare that the claims of the '750 patent are invalid and/or unenforceable.

COUNT XX
(Declaratory Judgment of Non-Infringement of the '750 Patent)

170. MSN restates and re-alleges each of the foregoing Paragraphs 1-169 of the counterclaims as if fully set forth herein.

171. AbbVie, Allergan, and Merck have alleged that MSN's filing of ANDA 219218 infringes the '750 patent.

172. As evidenced by AbbVie, Allergan, and Merck's Complaint and MSN's Answers in this action, there is an actual substantial and continuing justiciable case or controversy between MSN and Counterclaim-Defendants, having adverse-legal interests of sufficient immediacy and reality to warrant the issuance of declaratory judgment regarding the infringement of the claims of the '750 patent.

173. The manufacture, use, sale, offer for sale, and/or importation by MSN of MSN's ANDA Product will not infringe, directly or indirectly, literally or under the doctrine of equivalents, any valid claim of the '750 patent.

174. MSN is entitled to a judicial determination that MSN's ANDA Products which are the subject of ANDA No. 219218 have not infringed, do not infringe, and would not infringe, if marketed, any valid claim of the '750 patent.

PRAYER FOR RELIEF

WHEREFORE, MSN respectfully requests the following relief:

(a) Dismissing the Complaint with prejudice and entering a judgment of non-infringement and invalidity in favor of MSN;

(b) Declaring that no valid claim of the '836, '515, '542, '709, '450, '004, '030, '408, '953, or '750 patents would be infringed, either directly or indirectly, literally or under the doctrine of equivalents, by the manufacture, use, sale, offer for sale, and/or importation of MSN's ANDA Products;

(c) Declaring that all of the asserted claims of the '836, '515, '542, '709, '450, '004, '030 '408, '953, and '750 patents are invalid;

(d) Enjoining Plaintiffs, their officers, agents, servants, employees, attorneys, and any person who acts in concert or participation with Plaintiffs, from threatening to assert or otherwise attempting to enforce the '836, '515, '542, '709, '450, '004, '408, '953, and '750 patents against Defendants/Counterclaim-Plaintiffs, its customers, suppliers, or anyone in privity with Defendants/Counterclaim-Plaintiffs;

(e) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding MSN its reasonable attorneys' fees and costs incurred in this action;

(f) Awarding MSN its costs and expenses incurred in this action; and

(g) Awarding MSN such other and further relief as this Court may deem proper.

DATED: July 25, 2025

Respectfully Submitted,

/s/ Gregory D. Miller

Gregory D. Miller
Timothy P. Gonzalez
RIVKIN RADLER LLP
25 Main Street
Court Plaza North, Suite 501
Hackensack, New Jersey 07601
T: (201) 287-2460
Gregory.Miller@rivkin.com
Timothy.Gonzalez@rivkin.com

Richard J. Berman (admitted *pro hac vice*)
Janine A. Carlan (admitted *pro hac vice*)
Bradford C. Frese (admitted *pro hac vice*)
Saukshmya Trichi (admitted *pro hac vice*)
Michael J. Baldwin (admitted *pro hac vice*)
ARENTFOX SCHIFF LLP
1717 K St. NW
Washington, DC 20006
T: (202) 857-6000
richard.berman@afslaw.com
janine.carlan@afslaw.com
bradford.frese@afslaw.com
saukshmya.trichi@afslaw.com
michael.baldwin@afslaw.com

Attorneys for Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Ltd., And MSN Life Sciences Private Ltd.

CERTIFICATE OF SERVICE

I certify that a copy of the foregoing "**DEFENDANTS MSN PHARMACEUTICALS INC., MSN LABORATORIES PRIVATE LIMITED, AND MSN LIFE SCIENCES PRIVATE LIMITED'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO THIRD AMENDED COMPLAINT FOR PATENT INFRINGEMENT**" was filed on this day of July 25, 2025 via ECF and electronic means to the counsel below:

Jose L. Linares
Gregory J. Hindy
Mark M. Makhail
McCARTER & ENGLISH, LLP
4 Gateway Center
100 Mulberry St.
Newark, NJ 07102
(973) 622-4444
jlinares@mccarter.com
ghindy@mccarter.com
mmakhail@mccarter.com

William B. Raich
Jennifer H. Roscetti
Drew D. Christie
Yoonjin Lee
Elliott T. LaParne
Emma N. Ng
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave, NW
Washington, DC 20001
(202) 408-4210
william.raich@finnegan.com
jennifer.roscetti@finnegan.com
drew.christie@finnegan.com
yoonjin.lee@finnegan.com
elliott.laparne@finnegan.com
emma.ng@finnegan.com

/s/ Gregory D. Miller
Gregory D. Miller