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*Attorneys for Plaintiffs AbbVie Inc., Allergan Pharmaceuticals International Limited  
and Merck Sharp & Dohme LLC*

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. \_\_\_\_\_

**COMPLAINT FOR PATENT INFRINGEMENT**

Plaintiffs AbbVie Inc. (“AbbVie”), Allergan Pharmaceuticals International Limited (“Allergan”), and Merck Sharp & Dohme LLC (“Merck”) (collectively, “Plaintiffs”), by its attorneys, bring this action against Defendants MSN Pharmaceuticals Inc. (“MSN

Pharmaceuticals”), MSN Laboratories Private Limited (“MSN Labs”), and MSN Life Sciences Private Limited (“MSN Life”) (collectively “MSN”), and allege as follows:

**NATURE OF THE ACTION**

1. This is a civil action for patent infringement of U.S. Patent Nos. 10,117,836 (“the ’836 patent”), 11,717,515 (“the ’515 patent”), 11,857,542 (“the ’542 patent”), and 11,925,709 (“the ’709 patent”) (collectively, “the Patents-in-Suit”) arising under the United States Patent Laws, Title 35, United States Code, § 1, *et seq.*, and in particular under 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This action relates to 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<sup>®</sup> (ubrogepant) oral tablets in 50 mg and 100 mg dosage forms (“UBRELVY<sup>®</sup> 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<sup>®</sup> Tablets. MSN has submitted ANDA No. 219218 (“MSN’s ANDA”), which seeks approval to market its generic version of UBRELVY<sup>®</sup> Tablets, ubrogepant oral tablets, 50 mg, 100 mg (“MSN’s generic products”), prior to the expiration of the Patents-in-Suit.

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.

### **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<sup>®</sup> Tablets.

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

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

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

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

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

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

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.

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.

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.

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.

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.

#### **JURISDICTION AND VENUE**

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

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

17. This Court has personal jurisdiction over Defendant 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.

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.

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.

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.

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

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.

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] 1<sup>st</sup> 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).

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).

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.

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.

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.

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.

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.

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.

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).

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.

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.

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.



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.

### **FACTUAL BACKGROUND**

#### **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.

37. The FDA 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; and the ’542 patent.

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.

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.

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.

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

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

#### **The Patents-in-Suit**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

**MSN's ANDA No. 219218**

62. 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<sup>®</sup> Tablets.

63. AbbVie received a letter sent by MSN ("MSN's Notice Letter"), 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."

64. MSN's Notice Letter 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.

65. Plaintiffs have not yet received a Notice of Paragraph IV Certification regarding MSN's ANDA No. 219218 for the '709 patent ("709 Patent Notice Letter") under Section 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95.

66. On information and belief, MSN's Notice Letter and the information contained therein, coupled with regulatory requirements, demonstrate MSN's infringement of the '709 patent.

67. MSN's Notice Letter does 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<sup>®</sup> (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.

68. 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 and '515 patents. MSN intends to market MSN's generic products before the expiration of the '542 and '709 patents.

69. 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.

70. 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.

71. MSN's Notice Letter purported to offer confidential access to MSN's ANDA No. 219218 on terms and conditions set forth in MSN's Notice Letter ("MSN's Offer of Confidential Access"). Outside counsel for AbbVie, Allergan, and Merck negotiated in good faith with counsel for MSN in an attempt to reach agreement on reasonable terms of confidential access to MSN's ANDA No. 219218. The parties engaged in multiple rounds of negotiation. As of April 8, 2024, the parties were unable to reach agreement. To date, AbbVie, Allergan, and Merck have not received access to MSN's ANDA No. 219218.

72. 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.

73. 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.

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

**COUNT I**  
**INFRINGEMENT BY MSN OF THE '836 PATENT**

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

76. 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.

77. 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.

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

79. 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.

80. 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.

81. 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.

82. 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.

83. 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.

84. 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.

85. 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.

86. 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.

87. 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.

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

89. 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.

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

**COUNT II**  
**DECLARATORY JUDGMENT OF**  
**INFRINGEMENT BY MSN OF THE '836 PATENT**

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

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

93. 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.

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

95. 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.

96. 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.

97. 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.

98. 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.

99. 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.

100. 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.

101. 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.

102. 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.

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

104. 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).

105. 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.

106. 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.

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

**COUNT III**  
**INFRINGEMENT BY MSN OF THE '515 PATENT**

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

109. 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.

110. 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.

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

112. 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.

113. 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.

114. 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.

115. 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.

116. 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.

117. 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.

118. 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.

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

120. 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.

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

**COUNT IV**  
**DECLARATORY JUDGMENT OF**  
**INFRINGEMENT BY MSN OF THE '515 PATENT**

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

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

124. 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.

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

126. 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.

127. 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.

128. 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.

129. 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.

130. 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.

131. 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.

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

133. 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).

134. 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.

135. 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.

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

**COUNT V**  
**INFRINGEMENT BY MSN OF THE '542 PATENT**

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

138. 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.

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

140. 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.

141. 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.

142. 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.

143. 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.

144. 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.

145. 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.

146. 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.

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

148. 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.

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

**COUNT VI**  
**DECLARATORY JUDGMENT OF**  
**INFRINGEMENT BY MSN OF THE '542 PATENT**

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

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



152. 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.

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

154. 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.

155. 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.

156. 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.

157. 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.

158. 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.

159. 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.

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

161. 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).

162. 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.

163. 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.

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

**COUNT VII**  
**INFRINGEMENT BY MSN OF THE '709 PATENT**

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

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

167. 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.

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

169. 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.

170. 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.

171. 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.

172. 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.

173. 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.

174. 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.

175. 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.

176. 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.

177. 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.

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

179. 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.

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

**COUNT VIII**  
**DECLARATORY JUDGMENT OF**  
**INFRINGEMENT BY MSN OF THE '709 PATENT**

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

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

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

184. 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.

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

186. 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.

187. 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.

188. 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.

189. 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.

190. 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.

191. 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.

192. 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.

193. 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.

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

195. 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).

196. 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.

197. 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.

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

#### **REQUEST FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request the following relief:

A. The entry of judgment under 35 U.S.C. § 271(e)(2)(A) that MSN has infringed at least one claim of the Patents-in-Suit through MSN's submission of ANDA No. 219218 to the FDA 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 Patents-in-Suit;

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

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

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

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

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

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

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

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

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



Dated: April 8, 2024

/s/ Jose L. Linares

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