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

ESPERION THERAPEUTICS, INC.,)	
)	
)	
)	
Plaintiff,)	
)	
v.)	C.A. No. 24-_____
)	
MSN PHARMACEUTICALS INC.,)	
MSN LABORATORIES PRIVATE)	
LIMITED,)	
APICHEM LABORATORIES PRIVATE)	
LIMITED,)	
)	
Defendants.)	
)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement by Esperion Therapeutics, Inc. (“Esperion”) under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, against Defendants MSN Pharmaceuticals Inc., MSN Laboratories Private Limited, and APICHEM Laboratories Private Limited (collectively, “MSN”). This action arises out of MSN’s submission of Abbreviated New Drug Application (“ANDA”) No. 219437 to the U.S. Food and Drug Administration (“FDA”) seeking approval to manufacture

and sell a generic version of NEXLETOL[®] prior to the expiration of U.S. Patent Nos. 11,760,714 and 11,613,511 (collectively, the “Asserted Patents”).

PARTIES

2. Plaintiff Esperion is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 3891 Ranchero Drive, Suite 150 Ann Arbor, MI 48108.

3. Upon information and belief, Defendant MSN Pharmaceuticals Inc. (“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.

4. Upon information and belief, MSN Pharmaceuticals is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

5. Upon information and belief, MSN Pharmaceuticals directly or through its affiliates, markets and sells drug products throughout the United States, including in the state of New Jersey.

6. Upon information and belief, MSN Laboratories Private Limited (“MSN Laboratories”) 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, 500018, Telangana, India.

7. Upon information and belief, MSN Laboratories is a pharmaceutical company that engages in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

8. Upon information and belief, MSN Laboratories directly or through its subsidiaries, including MSN Pharmaceuticals, markets and sells drug products throughout the United States, including in the state of New Jersey.

9. Upon information and belief, APICHEM Laboratories Private Limited (“APICHEM”) is a corporation organized and existing under the laws of India, having a principal place of business at H. No. 8-2-293/82/A/141, Road No. 10, Jubilee Hills, Hyderabad, Telangana, India.

10. Upon information and belief, APICHEM is a pharmaceutical company that engages directly or through its affiliates in the manufacture, marketing, or sale of pharmaceutical products, including generic drug products manufactured and sold pursuant to approved ANDAs.

11. Upon information and belief, APICHEM directly or through its affiliates, including MSN Pharmaceuticals and MSN Laboratories, markets and sells drug products throughout the United States, including in the state of New Jersey.

12. Upon information and belief, APICHEM is the holder of FDA Drug Master File No. 036773 for Bempedoic Acid.

13. Upon information and belief, MSN Pharmaceuticals and APICHEM are wholly owned subsidiaries of MSN Laboratories.

14. Upon information and belief, MSN Laboratories directs or controls the operations, management, and activities of MSN Pharmaceuticals and APICHEM, including in the United States.

15. Upon information and belief, MSN Pharmaceuticals, MSN Laboratories, and APICHEM are agents of each other and/or operate in concert as integrated parts of the same business group.

16. Upon information and belief, MSN Pharmaceuticals, MSN Laboratories, and APICHEM work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

17. Upon information and belief, MSN Pharmaceuticals, MSN Laboratories, and APICHEM working in concert prepared and submitted ANDA No. 219437 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL[®] (the “MSN ANDA Product”) prior to the expiration of the Asserted Patents.

18. Upon information and belief, MSN Pharmaceuticals, MSN Laboratories, and APICHEM working in concert developed the MSN ANDA Product.

19. Upon information and belief, MSN Pharmaceuticals, MSN Laboratories, and APICHEM working in concert seek regulatory approval from the FDA to market and sell the MSN ANDA Product throughout the United States, including in New Jersey.

20. Upon information and belief, MSN Pharmaceuticals, MSN Laboratories, and APICHEM working in concert intend to obtain approval for MSN’s ANDA No. 219437, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the MSN ANDA Product in the United States, including in New Jersey.

JURISDICTION AND VENUE

21. This action arises under the patent laws of the United States of America, 35 U.S.C. § 100 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

22. This Court has personal jurisdiction over MSN Pharmaceuticals because, upon information and belief, MSN Pharmaceuticals is a corporation with its principal place of business in New Jersey and is qualified to do business in New Jersey.

23. In view of the foregoing, MSN Pharmaceuticals is subject to general personal jurisdiction in New Jersey.

24. This Court has personal jurisdiction over MSN Laboratories because MSN Laboratories, in concert with its subsidiaries MSN Pharmaceuticals and APICHEM, among other

things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219437 in New Jersey, and intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219437, MSN Laboratories, in concert with its subsidiaries MSN Pharmaceuticals and APICHEM, will make, use, import, sell, and/or offer for sale the MSN ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

25. This Court also has personal jurisdiction over MSN Laboratories because, among other things, this action arises from MSN Laboratories', and its subsidiaries MSN Pharmaceuticals' and APICHEM's, concerted actions directed toward New Jersey, and because, upon information and belief, MSN Laboratories, with its subsidiaries MSN Pharmaceuticals and APICHEM, has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; (3) creating a presence in New Jersey through the registration of MSN Pharmaceuticals with both the New Jersey Division of Revenue and Enterprise Services, as a business operating in New Jersey under Business Entity ID No. 0400627791, and the New Jersey Department of Health, as a drug manufacturer and wholesaler, and maintaining a Drug and Medical Device Certificate of Registration under Registration No. 5006107; and (4) requesting that a copy of any Complaint filed concerning MSN Laboratories' Notice Letter be sent to Kondal Reddy Bairy, Ph.D. at MSN Pharmaceuticals Inc., 20 Duke Road, Piscataway, NJ 08854. MSN Laboratories has, therefore, purposely availed itself

of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

26. In addition, this Court has personal jurisdiction over MSN Laboratories because, among other things, upon information and belief, (1) MSN Laboratories, in concert with its subsidiaries MSN Pharmaceuticals and APICHEM, filed ANDA No. 219437 for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the MSN ANDA Product in the United States, including in New Jersey, and (2) upon approval of ANDA No. 219437, will market, distribute, offer for sale, sell, and/or import the MSN ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the MSN ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219437, the MSN ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

27. This Court also has personal jurisdiction over MSN Laboratories because it regularly engages in patent litigation in this forum, and affirmatively avails itself of the jurisdiction of this Court by filing counterclaims in this District and by being sued in this District without challenging personal jurisdiction, including in at least *Jazz Pharmaceuticals Research UK Limited f/k/a GW Research Limited v. Apotex Inc.*, C.A. No. 23-cv-23141, Dkt. No. 44 (D.N.J. filed Apr. 3, 2024); *Bausch Health Ireland Ltd. v. MSN Labs. Private Ltd.*, C.A. No 23-cv-03333, Dkt. No. 7 (D.N.J. filed Jul. 6, 2023); and *Merck Sharp & Dohme BV v. MSN Labs. Private Ltd.*, C.A. No. 20-cv-03314, Dkt. 21 (D.N.J. filed Jul. 8, 2020).

28. Based on the foregoing systematic and continuous contacts with New Jersey, MSN Laboratories is subject to personal jurisdiction in New Jersey.

29. Upon information and belief, MSN Laboratories' contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent MSN Laboratories denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over MSN Laboratories pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because MSN Laboratories is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

30. This Court has personal jurisdiction over APICHEM because APICHEM, in concert with its affiliates MSN Pharmaceuticals and MSN Laboratories, among other things, has committed, aided, abetted, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) by preparing and filing portions of its ANDA No. 219437 in New Jersey, and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. § 271(a), (b), and/or (c) in New Jersey. These acts have led and will continue to lead to foreseeable harm and injury to Esperion. For example, upon information and belief, following approval of ANDA No. 219437, APICHEM, in concert with its affiliates MSN Pharmaceuticals and MSN Laboratories, will make, use, import, sell, and/or offer for sale the MSN ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

31. This Court also has personal jurisdiction over APICHEM because, among other things, this action arises from APICHEM's, and its affiliates MSN Pharmaceuticals' and MSN Laboratories', concerted actions directed toward New Jersey, and because, upon information and belief, APICHEM, and its affiliates MSN Pharmaceuticals and MSN Laboratories, have purposefully availed themselves of the rights and benefits of New Jersey law by engaging in

systematic and continuous contacts with New Jersey, including by, among other things, (1) intentionally marketing and providing its generic pharmaceutical products to residents of New Jersey; (2) enjoying substantial income from New Jersey; and (3) creating a presence in New Jersey through the registration of MSN Pharmaceuticals with both the New Jersey Division of Revenue and Enterprise Services, as a business operating in New Jersey under Business Entity ID No. 0400627791, and the New Jersey Department of Health, as a drug manufacturer and wholesaler, and maintaining a Drug and Medical Device Certificate of Registration under Registration No. 5006107. APICHEM has, therefore, purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here.

32. In addition, this Court has personal jurisdiction over APICHEM because, among other things, upon information and belief, (1) APICHEM in concert with its affiliates MSN Pharmaceuticals and MSN Laboratories filed ANDA No. 219437 for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the MSN ANDA Product in the United States, including in New Jersey, and (2) upon approval of ANDA No. 219437, they will market, distribute, offer for sale, sell, and/or import the MSN ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the MSN ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219437, the MSN ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in New Jersey; prescribed by physicians practicing in New Jersey; dispensed by pharmacies located within New Jersey; and/or used by patients in New Jersey, all of which would have substantial effects on New Jersey and lead to foreseeable harm and injury to Esperion.

33. Based on the foregoing systematic and continuous contacts with New Jersey, APICHEM is subject to specific personal jurisdiction in New Jersey.

34. Upon information and belief, APICHEM's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent APICHEM denies that this Court has personal jurisdiction over it because of its systematic and continuous contacts with New Jersey, this Court also has personal jurisdiction over APICHEM pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because APICHEM is not subject to the general jurisdiction of the courts of any state, and based on its contacts with the United States as a whole.

35. For at least the above reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, it would not be unfair or unreasonable for MSN Pharmaceuticals, MSN Laboratories, and APICHEM to litigate this action in this Court, and MSN Pharmaceuticals, MSN Laboratories, and APICHEM are subject to personal jurisdiction in New Jersey.

36. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

37. Venue is proper in this Court as to MSN Pharmaceuticals under 28 U.S.C. § 1400(b) because it is a corporation with its regular and established principal place of business in New Jersey, is subject to personal jurisdiction in this Court, as set forth above, has committed acts of infringement, and, upon information and belief, will commit further acts of infringement in New Jersey.

38. Venue is proper in this Court as to MSN Laboratories under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, MSN Laboratories is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

39. Venue is also proper in this Court for MSN Laboratories because, among other things, MSN Laboratories has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) acted in concert with its subsidiaries MSN Pharmaceuticals and APICHEM to seek approval from the FDA to market and sell the MSN ANDA Product in New Jersey; and (2) in concert with its subsidiaries MSN Pharmaceuticals and APICHEM engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

40. Venue is proper in this Court as to APICHEM under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, APICHEM is a corporation organized under the laws of India, is not a resident of the United States, and thus may be sued in any jurisdiction. 28 U.S.C. §§ 1391(c)(3); *HTC*, 889 F.3d at 1354.

41. Venue is also proper in this Court for APICHEM because, among other things, APICHEM has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) acted in concert with its affiliates MSN Pharmaceuticals and MSN Laboratories to seek approval from the FDA to market and sell the MSN ANDA Product in New Jersey; and (2) in concert with its affiliates MSN Pharmaceuticals and MSN Laboratories engaged in regular and established business contacts with New Jersey by, among other things, marketing, making, shipping, using, offering to sell or selling pharmaceutical products in New Jersey, and deriving substantial revenue from such activities.

THE PATENTS-IN-SUIT

42. U.S. Patent No. 11,760,714 (the “’714 Patent”), entitled “Methods of Making Bempedoic Acid and Compositions of the Same,” was duly and legally issued on September 19, 2023. A true and correct copy of the ’714 Patent is attached hereto as “Exhibit A.”

43. Esperion is the assignee of, and holds all rights, title and interest in the '714 Patent.

44. The '714 Patent currently expires on June 19, 2040.

45. U.S. Patent No. 11,613,511 (the "'511 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 28, 2023. A true and correct copy of the '511 Patent is attached hereto as "Exhibit B."

46. Esperion is the assignee of, and holds all rights, title and interest in the '511 Patent.

47. The '511 Patent currently expires on June 19, 2040.

48. All claims of the '714 and '511 Patents are valid, enforceable, and not expired.

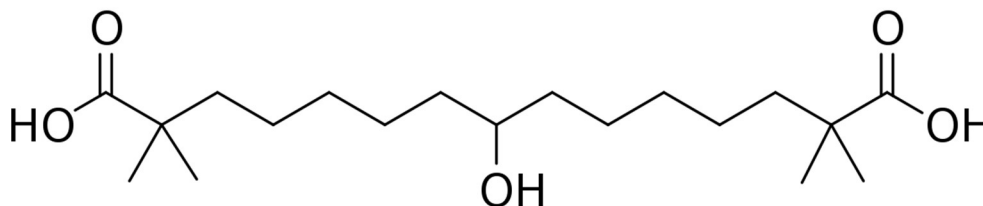
ESPERION'S NEXLETOL® PRODUCT

49. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

50. Esperion is the holder of New Drug Application ("NDA") No. 211616, which was approved by the FDA on February 21, 2020, for the marketing and sale of bempedoic acid in the United States under the trade name "NEXLETOL®." Esperion sells NEXLETOL® in the United States pursuant to NDA No. 211616.

51. NEXLETOL® (bempedoic acid) is an adenosine triphosphate-citrate lyase (ACL) inhibitor indicated to 1) reduce the risk of myocardial infarction and coronary revascularization in adults who are unable to take recommended statin therapy (including those not taking a statin) with established cardiovascular disease (CVD), or a high risk for a CVD event but without established CVD and 2) as an adjunct to diet, in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, or alone when concomitant LDL-C lowering therapy is not possible, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH).

52. Bempedoic acid, the active pharmaceutical ingredient in NEXLETOL[®], has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



53. The claims of the Asserted Patents cover NEXLETOL[®].

54. The Asserted Patents have been listed in connection with NEXLETOL[®] in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

MSN'S ANDA PRODUCT

55. By letter dated April 9, 2024, and received by Esperion via Federal Express no earlier than on April 10, 2024 (the "Notice Letter"), MSN notified Esperion that MSN had submitted ANDA No. 219437 to the FDA for a generic version of NEXLETOL[®].

56. The Notice Letter states that MSN seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the MSN ANDA product before the expiration of the Asserted Patents. Upon information and belief, MSN intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the MSN ANDA product promptly upon receiving FDA approval to do so.

57. By submitting ANDA No. 219437, MSN has represented to the FDA that the MSN ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL[®] and is bioequivalent to NEXLETOL[®].

58. In the Notice Letter, MSN stated that ANDA No. 219437 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents. MSN also contended that the Asserted Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the MSN ANDA Product.

59. Upon information and belief, MSN had knowledge of the Asserted Patents when it submitted ANDA No. 219437 to the FDA.

60. Upon information and belief, 219437 intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product immediately and imminently upon approval of ANDA No. 219437.

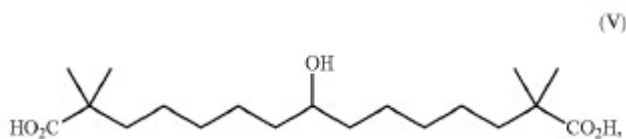
61. On or before May 14, 2024, pursuant to an Offer of Confidential Access, MSN produced portions of its ANDA No. 219437 to Esperion. MSN refused to produce the entirety of ANDA No. 219437 to Esperion and refused to provide samples of its ANDA Product or components.

62. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the Notice Letter.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

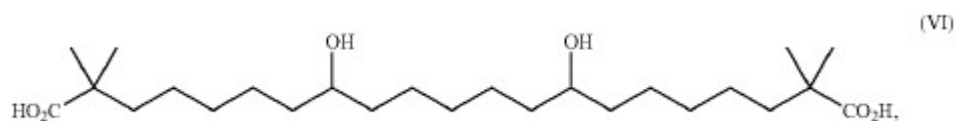
63. Esperion incorporates each of the preceding paragraphs 1-62 as if fully set forth herein.

64. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than

98% by weight based on the total weight of the pharmaceutical material, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and a pharmaceutically acceptable excipient.

65. MSN's submission of ANDA No. 219437 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the '714 Patent constituted an act of infringement of the claims of the '714 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

66. MSN's commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product prior to expiration of the '714 Patent, and MSN's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '714 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

67. Upon information and belief, upon FDA approval of ANDA No. 219437, MSN intends to, and will, infringe at least claim 1 of the '714 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the MSN ANDA Product, unless enjoined by the Court.

68. Upon information and belief, by virtue of its listing in the Orange Book and identification in MSN's Notice Letter, MSN has knowledge of the '714 Patent and knowledge that its MSN ANDA Product will infringe the '714 Patent.

69. Upon information and belief, MSN intends to, and will, actively induce infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(b) when ANDA No. 219437 is approved

by marketing the MSN ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

70. Upon information and belief, MSN intends to, and will, contribute to infringement of at least claim 1 of the '714 Patent under 35 U.S.C. § 271(c) when ANDA No. 219437 is approved, unless enjoined by the Court, because MSN knows that the MSN ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the MSN ANDA Product is not suitable for substantial noninfringing use.

71. MSN's infringement is imminent because, among other things, MSN has notified Esperion of the submission of its ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the '714 Patent.

72. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '714 Patent.

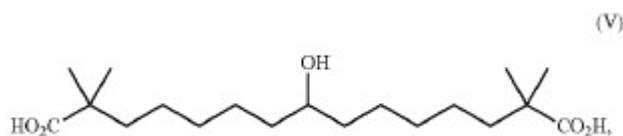
73. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that MSN's making, using, offering to sell, selling, and/or importing the MSN ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

74. Unless MSN is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

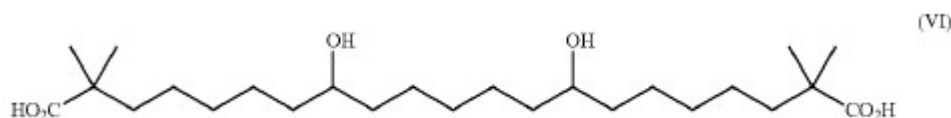
COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

75. Esperion incorporates each of the preceding paragraphs 1-74 as if fully set forth herein.

76. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):



or a pharmaceutically acceptable salt thereof; wherein the pharmaceutical material comprises the compound of formula (V), or a pharmaceutically acceptable salt thereof, in an amount greater than 99.0% by weight based on the total weight of the pharmaceutical material, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



and the crystalline form of the compound of formula (V) exhibits an X-ray powder diffraction pattern comprising peaks at the following diffraction angles (2θ): 10.3 ± 0.2 , 10.4 ± 0.2 , 17.9 ± 0.2 , 18.8 ± 0.2 , 19.5 ± 0.2 , and 20.7 ± 0.2 .

77. MSN's submission of ANDA No. 219437 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product before the expiration of the '511 Patent constituted an act of infringement of the claims of the '511 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

78. MSN's commercial manufacture, use, offer for sale, sale, and/or importation of the MSN ANDA Product prior to expiration of the '511 Patent, and MSN's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '511 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

79. Upon information and belief, upon FDA approval of ANDA No. 219437, MSN intends to, and will, infringe at least claim 1 of the '511 Patent under 35 U.S.C. § 271(a), either

literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the MSN ANDA Product, unless enjoined by the Court.

80. Upon information and belief, by virtue of its listing in the Orange Book and identification in MSN's Notice Letter, MSN has knowledge of the '511 Patent and knowledge that its MSN ANDA Product will infringe the '511 Patent.

81. Upon information and belief, MSN intends to, and will, actively induce infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(b) when ANDA No. 219437 is approved by marketing the MSN ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

82. Upon information and belief, MSN intends to, and will, contribute to infringement of at least claim 1 of the '511 Patent under 35 U.S.C. § 271(c) when ANDA No. 219437 is approved, unless enjoined by the Court, because MSN knows that the MSN ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the MSN ANDA Product is not suitable for substantial noninfringing use.

83. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '511 Patent.

84. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that MSN's making, using, offering to sell, selling, and/or importing the MSN ANDA Product, inducement thereof or contribution thereto, will infringe the '511 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

85. Unless MSN is enjoined from directly or indirectly infringing the '511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Esperion asks that this Court grant the following relief:

86. A judgment that the claims of the Asserted Patents are infringed by MSN's submission of ANDA No. 219437 under 35 U.S.C. § 271(e)(2)(A);

87. A declaratory judgment that MSN's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the MSN ANDA Product prior to the expiration of the Asserted Patents, would infringe the Asserted Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

88. A judgment that the Asserted Patents are not invalid or unenforceable;

89. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of MSN's ANDA No. 219437 shall not be earlier than the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

90. An order permanently enjoining MSN, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with MSN, from making, using, offering to sell, selling, or importing the MSN ANDA Product until after the Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

91. Damages or other monetary relief, including costs, fees, pre-judgment interest and post-judgment interest to Esperion if MSN engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the MSN ANDA Product prior to the expiration of the Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

92. A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285; and

93. Such further and other relief as this Court deems proper and just.

Dated: May 23, 2024

/s/ Liza M. Walsh

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LOCAL RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following action:

- *Esperion Therapeutics, Inc. v. Micro Labs USA, Inc., et al.*, Civil Action No. 2:24-cv-05921-JXN-CLW
- *Esperion Therapeutics, Inc. v. Renata Limited., et al.*, Civil Action No. 2:24-cv-06017-JXN-CLW
- *Esperion Therapeutics, Inc. v. Accord Healthcare Inc., et al.*, Civil Action No. 2:24-cv-06224-JXN-CLW
- *Esperion Therapeutics, Inc. v. Alkem Labs., et al.*, Civil Action No. 2:24-cv-06263-JXN-CLW
- *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, Civil Action No. 2:24-cv-06348

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

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