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Attorneys for Plaintiff Esperion Therapeutics, Inc.

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

ESPERION THERAPEUTICS, INC.,	)
	)
	)
-4 4 4 400	)
Plaintiff,	)
	)
V.	)
AUROBINDO PHARMA LIMITED,	
APITORIA PHARMA PRIVATE	
LIMITED,	)
Defendente	)
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 Aurobindo Pharma Limited and Apitoria Pharma Private Limited (collectively, "Aurobindo"). This action arises out of Aurobindo's submission of Abbreviated New Drug Application ("ANDA") No. 219653 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of NEXLIZET<sup>®</sup> prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 10,912,751, 11,744,816, and 11,926,584 (collectively, the "Asserted Patents").

#### **PARTIES**

 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 Aurobindo Pharma Limited ("Aurobindo Pharma") is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad, Telangana, 500032, India.

4. Upon information and belief, Aurobindo Pharma 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, Aurobindo Pharma directly or through its affiliates develops, markets, and sells drug products throughout the United States, including in the state of New Jersey.

6. Upon information and belief, Apitoria Pharma Private Limited ("Apitoria"), formerly known as Auro Pharma India Private Limited, is a corporation organized and existing under the laws of India, having a principal place of business at Galaxy, Floors: 22-24, Plot No. 1, Survey No. 83/1, Hyderabad Knowledge City, Panmaktha, Rai Durg, Hyderabad, 500032, India.

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

9. Upon information and belief, Apitoria is the holder of FDA Drug Master File No. 38811 for Bempedoic Acid.

10. Upon information and belief, Apitoria is a wholly-owned subsidiary of Aurobindo Pharma.

11. Upon information and belief, Aurobindo Pharma directs or controls the operations, management, and activities of Apitoria.

12. Upon information and belief, Aurobindo Pharma and Apitoria are agents of each other and/or operate in concert as integrated parts of the same business group.

13. Upon information and belief, Aurobindo Pharma and Apitoria work in concert on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

14. Upon information and belief, Aurobindo Pharma and Apitoria working in concert prepared and submitted ANDA No. 219653 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLIZET<sup>®</sup> (the "Aurobindo ANDA Product") prior to the expiration of the Asserted Patents.

15. Upon information and belief, Aurobindo Pharma and Apitoria working in concert developed the Aurobindo ANDA Product.

16. Upon information and belief, Aurobindo Pharma and Apitoria working in concert seek regulatory approval from the FDA to market and sell the Aurobindo ANDA Product throughout the United States, including in New Jersey.

17. Upon information and belief, Aurobindo Pharma and Apitoria working in concert intend to obtain approval for Aurobindo Pharma and Apitoria's ANDA No. 219653, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey.

18. Upon information and belief, Aurobindo Pharma regularly works in concert with its wholly-owned U.S. subsidiaries, including Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc. to commercially manufacture, use, offer for sale, sell, and/or import pharmaceutical products in New Jersey.

19. Upon information and belief, Aurobindo Pharma USA, Inc. is a corporation with its principal place of business at 279 Princeton Hightstown Road, East Windsor, NJ 08520, 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. 0100921223, and is registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under Registration No. 5003120.

20. Upon information and belief, Aurobindo Pharma Limited, Inc. is a corporation with its principal place of business at 666 Plainsboro Rd., Plainsboro, NJ, 08536 and 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. 0100904116.

#### 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 Aurobindo Pharma because, among other things, it 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. 219653 in New Jersey, and it 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. 219653, Aurobindo Pharma will make, use, import, sell, and/or offer for sale the Aurobindo ANDA Product in the United States, including in New Jersey, prior to the expiration of the Asserted Patents.

23. This Court also has personal jurisdiction over Aurobindo Pharma because Aurobindo Pharma has consented to personal jurisdiction, engaged in, and affirmatively availed itself of the jurisdiction of this Court in *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 24-cv-06348 (JXN)(CLW) which involves the same parties, the same active pharmaceutical ingredient, and U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584.

24. This Court also has personal jurisdiction over Aurobindo Pharma because, among other things, this action arises from Aurobindo Pharma's actions directed toward New Jersey, and because, upon information and belief, Aurobindo Pharma 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; and (3) working in concert to develop and market pharmaceutical products, including in New Jersey, with its subsidiaries Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc., who are registered to do business and sell pharmaceutical products in New Jersey's laws such that it should reasonably anticipate being haled into court here.

25. In addition, this Court has personal jurisdiction over Aurobindo Pharma because, among other things, upon information and belief, (1) Aurobindo Pharma filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale of the Aurobindo ANDA Product in the United States, including in New Jersey, and (2) upon approval of the ANDA, Aurobindo Pharma will market, distribute, offer for sale, sell, and/or import

the Aurobindo ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Aurobindo ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219653, the Aurobindo 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.

26. This Court also has personal jurisdiction over Aurobindo Pharma because Aurobindo Pharma 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 *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 24-cv-06348 (JXN)(CLW); *Axsome Malta Ltd. v. Aurobindo Pharma USA, Inc.*, C.A. No. 24-cv-04002, Dkt. No. 11 (D.N.J. filed Feb. 5, 2024); *Bausch Health Ireland Limited v. Aurobindo Pharma Limited*, C.A. No. 23-cv-00170, Dkt. No. 16, (D.N.J. filed Jul. 5, 2023); and *Medicure International, Inc. v. Aurobindo Pharma Limited*, C.A. No. 21-cv-17534, Dkt. No. 6 (D.N.J. filed Oct. 15, 2021).

27. This Court also has personal jurisdiction over Aurobindo Pharma because, upon information and belief, Aurobindo Pharma worked with its counsel in New Jersey, Pergament & Cepeda, LLP, to prepare the certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding the Asserted Patents for ANDA No. 219653, and designated, pursuant to 21 C.F.R. § 314.95(c)(9), its New Jersey counsel, Pergament & Cepeda, LLP, to be its agent in the United States authorized to accept service of process in New Jersey on Aurobindo Pharma's behalf in relation to its ANDA No. 219653.

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

29. Upon information and belief, Aurobindo Pharma's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Aurobindo Pharma 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 Aurobindo Pharma pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Aurobindo Pharma 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. Relatedly, in its Notice Letter (defined below) to Esperion, Aurobindo Pharma represented that Pergament & Cepeda, LLP is the agent for service of process "[p]ursuant to 21 C.F.R. § 314.95(c)(9)," which applies "[i]f the applicant does not reside or have a place of business in the United States."

30. This Court has personal jurisdiction over Apitoria because, among other things, it 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 ANDA No. 219653 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. 219653, Apitoria, working in concert with Aurobindo Pharma, will make, use, import, sell, and/or offer for sale the Aurobindo 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 Apitoria because Apitoria has consented to personal jurisdiction, engaged in, and affirmatively availed itself of the jurisdiction of this Court in *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 24-cv-06348

(JXN)(CLW) which involves the same parties, the same active pharmaceutical ingredient, and U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584.

32. This Court also has personal jurisdiction over Apitoria because, among other things, this action arises from Apitoria's actions directed toward New Jersey, and because, upon information and belief, Apitoria 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; and (3) working in concert with its affiliates Aurobindo Pharma USA, Inc. and Aurobindo Pharma Limited, Inc. to develop and market pharmaceutical products, including in New Jersey. Apitoria 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.

33. In addition, this Court has personal jurisdiction over Apitoria because, among other things, upon information and belief, (1) Apitoria working in concert with Aurobindo Pharma filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, and/or offer for sale of the Aurobindo ANDA Product in the United States, including in New Jersey, and (2) upon approval of the ANDA, Apitoria working in concert with Aurobindo Pharma will market, distribute, offer for sale, sell, and/or import the Aurobindo ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Aurobindo ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219653, the Aurobindo 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.

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

35. Upon information and belief, Apitoria's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Apitoria 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 Apitoria pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Apitoria 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.

36. 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 Aurobindo Pharma and Apitoria to litigate this action in this Court, and Aurobindo Pharma and Apitoria are subject to personal jurisdiction in New Jersey.

37. 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).

38. Venue is proper in this Court as to Aurobindo Pharma because Aurobindo Pharma has consented to venue, engaged in, and affirmatively availed itself of the jurisdiction of this Court in *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 24-cv-06348 (JXN)(CLW) which involves the same parties, the same active pharmaceutical ingredient, and U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584.

39. Venue is proper in this Court as to Aurobindo Pharma under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, upon information and belief, Aurobindo Pharma 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.

40. Venue is also proper in this Court as to Aurobindo Pharma because Aurobindo Pharma has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Aurobindo's proposed generic NEXLIZET<sup>®</sup> product in New Jersey; and (2) has 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.

41. Venue is proper in this Court as to Apitoria under 28 U.S.C. §§ 1391(b) and (c) and 1400(b), because, upon information and belief, Apitoria 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.

42. Venue is proper in this Court as to Apitoria because Apitoria has consented to venue, engaged in, and affirmatively availed itself of the jurisdiction of this Court in *Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd.*, C.A. No. 24-cv-06348 (JXN)(CLW), which involves the same parties, the same active pharmaceutical ingredient, and U.S. Patent Nos. 11,760,714, 11,613,511, and 11,926,584.

43. Venue is also proper in this Court as to Apitoria because Apitoria has a regular and established place of business in New Jersey at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell Aurobindo's proposed generic NEXLIZET<sup>®</sup> product in New Jersey; and (2) has 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

44. 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."

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

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

47. 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."

- 48. Esperion is the assignee of, and holds all rights, title, and interest in the '511 Patent.
- 49. The '511 Patent currently expires on June 19, 2040.

50. U.S. Patent No. 10,912,751 (the "751 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on February 9, 2021. A true and correct copy of the '751 Patent is attached hereto as "Exhibit C."

51. Esperion is the assignee of, and holds all rights, title, and interest in the '751 Patent.

52. The '751 Patent currently expires on March 14, 2036.

53. U.S. Patent No. 11,744,816 (the "'816 Patent"), entitled "Fixed Dose Combinations and Formulations Comprising ETC1002 and Ezetimibe and Methods of Treating or Reducing the Risk of Cardiovascular Disease," was duly and legally issued on September 5, 2023. A true and correct copy of the '816 Patent is attached hereto as "Exhibit D."

54. Esperion is the assignee of, and holds all rights, title, and interest in the '816 Patent.
55. The '816 Patent currently expires on March 14, 2036.

56. U.S. Patent No. 11,926,584 (the "'584 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on March 12, 2024. A true and correct copy of the '584 Patent is attached hereto as "Exhibit E."

57. Esperion is the assignee of, and holds all rights, title, and interest in the '584 Patent.

58. The '584 Patent currently expires on June 19, 2040.

59. All claims of the '714, '511, '751, '816 and '584 Patents are valid, enforceable, and not expired.

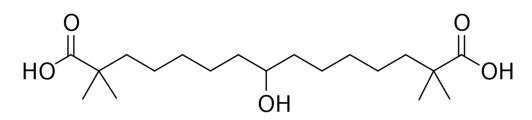
# **ESPERION'S NEXLIZET® PRODUCT**

60. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL<sup>®</sup> and NEXLIZET<sup>®</sup>

61. Esperion is the holder of NDA No. 211617, which was approved by the FDA on February 26, 2020, for the marketing and sale of a combined bempedoic acid and ezetimibe product in the United States under the trade name "NEXLIZET<sup>®</sup>." Esperion sells NEXLIZET<sup>®</sup> in the United States pursuant to NDA No. 211617.

62. NEXLIZET<sup>®</sup> is a combination of bempedoic acid, an adenosine triphosphate citrate lyase (ACL) inhibitor, and ezetimibe, a dietary cholesterol absorption inhibitor, indicated as an adjunct to diet, alone or in combination with other low-density lipoprotein cholesterol (LDL-C) lowering therapies, to reduce LDL-C in adults with primary hyperlipidemia, including heterozygous familial hypercholesterolemia (HeFH). The bempedoic acid component of NEXLIZET<sup>®</sup> is indicated to 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 (1) established cardiovascular disease (CVD), or (2) a high risk for a CVD event but without established CVD.

63. Bempedoic acid, one of the active pharmaceutical ingredients in NEXLIZET<sup>®</sup>, has the chemical name 8-hydroxy-2,2,14,14-tetramethyl-pentadecanedioic acid and has the following chemical structure:



64. Ezetimibe, the other active pharmaceutical ingredient in NEXLIZET<sup>®</sup>, has the chemical name 1-(4-fluorophenyl)-3(R)-[3-(4-fluorophenyl)-3(S)-hydroxypropyl]-4(S)-(4-hydroxyphenyl)-2-azetidinone.

65. The claims of the Asserted Patents cover NEXLIZET<sup>®</sup>.

66. The Asserted Patents have been listed in connection with NEXLIZET<sup>®</sup> in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

## **AUROBINDO'S ANDA PRODUCT**

67. By letter dated August 12, 2024, and received by Esperion via Federal Express no earlier than on August 13, 2024 (the "Notice Letter"), Aurobindo notified Esperion that Aurobindo had submitted ANDA No. 219653 to the FDA for a generic version of NEXLIZET<sup>®</sup>.

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

69. By submitting ANDA No. 219653, Aurobindo has represented to the FDA that the Aurobindo ANDA Product has the same active ingredient, dosage form, and strength as NEXLIZET<sup>®</sup> and is bioequivalent to NEXLIZET<sup>®</sup>.

70. In Aurobindo's Notice Letter, Aurobindo stated that ANDA No. 219653 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents. Aurobindo also contended that the Asserted Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, and/or sale of the Aurobindo ANDA Product.

71. Upon information and belief, Aurobindo had knowledge of the Asserted Patents at least when it submitted ANDA No. 219653 to the FDA.

72. Upon information and belief, Aurobindo intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product immediately and imminently upon approval of ANDA No. 219653 and prior to the expiration of the Asserted Patents.

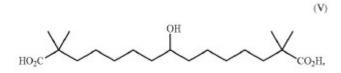
73. On or about August 28, 2024, Esperion and Aurobindo executed an Offer for Confidential Access. On August 30, 2024, Aurobindo produced a partial version of ANDA No. 219653, but it has not provided samples of its Aurobindo ANDA Product or any components thereof to Esperion.

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

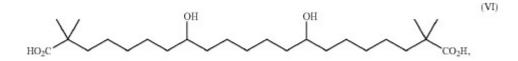
## COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,760,714

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

76. 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.

77. Aurobindo's submission of ANDA No. 219653 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo 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.

78. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '714 Patent, and Aurobindo'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).

79. Upon information and belief, upon FDA approval of ANDA No. 219653, Aurobindo 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 Aurobindo ANDA Product, unless enjoined by the Court.

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

81. Upon information and belief, Aurobindo 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. 219653 is approved by marketing the Aurobindo ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

82. Upon information and belief, Aurobindo 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. 219653 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

83. Aurobindo's infringement is imminent because, among other things, Aurobindo 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 Aurobindo ANDA Product before the expiration of the '714 Patent.

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

85. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA

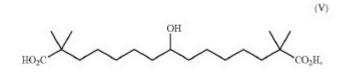
Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

86. Unless Aurobindo 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.

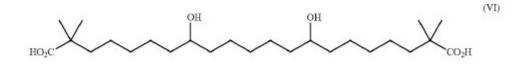
## COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

87. Esperion incorporates each of the preceding paragraphs 1-86 as if fully set forth herein.

88. 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 (2 $\theta$ ): 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.

89. Aurobindo's submission of ANDA No. 219653 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo 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.

90. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '511 Patent, and Aurobindo'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).

91. Upon information and belief, upon FDA approval of ANDA No. 219653, Aurobindo 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 Aurobindo ANDA Product, unless enjoined by the Court.

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

93. Upon information and belief, Aurobindo 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. 219653 is approved by marketing the Aurobindo ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

94. Upon information and belief, Aurobindo 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. 219653 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '511 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

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

96. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo 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).

97. Unless Aurobindo 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.

#### COUNT III: INFRINGEMENT OF U.S. PATENT NO. 10,912,751

98. Esperion incorporates each of the preceding paragraphs 1-97 as if fully set forth herein.

99. Claim 1 of the '751 Patent claims a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

100. Aurobindo's submission of ANDA No. 219653 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo NEXLIZET<sup>®</sup> ANDA Product before the expiration of the '751 Patent constituted an act of infringement of the claims of the '751 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

101. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo NEXLIZET<sup>®</sup> ANDA Product prior to expiration of the '751 Patent, and

Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '751 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

102. Upon information and belief, upon FDA approval of Aurobindo's ANDA No. 219653, Aurobindo will infringe at least claim 1 of the '751 Patent by making, using, offering to sell, and selling the Aurobindo NEXLIZET<sup>®</sup> ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '751 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

103. Upon information and belief, Aurobindo specifically intends to, and will, actively induce infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(b) when ANDA No. 219653 is approved by marketing the Aurobindo NEXLIZET<sup>®</sup> ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '751 Patent, unless enjoined by the Court.

104. Upon information and belief, Aurobindo's ANDA No. 219653 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Aurobindo NEXLIZET<sup>®</sup> ANDA Product.

105. Upon information and belief, upon FDA approval of ANDA No. 219653, Aurobindo intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Aurobindo NEXLIZET<sup>®</sup> ANDA Product, unless enjoined by the Court, and the Aurobindo NEXLIZET<sup>®</sup> ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

106. On information and belief, the proposed package insert will include a method of treating familial hypercholesterolemia in a subject in need thereof, the method comprising administering a fixed-dosed combination of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and Ezetimibe to the subject, wherein the fixed-dose combination comprises a fixed 180 milligram (mg) dose of 8-hydroxy-2,2, 14, 14-tetramethylpentadecanedioic acid and a fixed 10 milligram (mg) dose of Ezetimibe.

107. Upon information and belief, the use of the Aurobindo NEXLIZET<sup>®</sup> ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '751 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

108. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's Notice Letter, Aurobindo has knowledge of the '751 Patent and knowledge that its Aurobindo NEXLIZET<sup>®</sup> ANDA Product will infringe the '751 Patent.

109. On information and belief, Aurobindo is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Aurobindo NEXLIZET<sup>®</sup> ANDA Product at least according to Aurobindo's proposed package insert and, therefore, will directly infringe at least claim 1 of the '751 Patent.

110. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '751 Patent under 35 U.S.C. § 271(c) when ANDA No. 219653 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo NEXLIZET<sup>®</sup> ANDA Product is especially made or adapted for use in infringing the '751 Patent, and that the Aurobindo NEXLIZET<sup>®</sup> ANDA Product is not suitable for substantial noninfringing use.

111. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '751 Patent.

112. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo NEXLIZET<sup>®</sup> ANDA Product, inducement thereof or contribution thereto, will infringe the '751 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

113. Unless Aurobindo is enjoined from directly or indirectly infringing the '751 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

#### COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 11,744,816

114. Esperion incorporates each of the preceding paragraphs 1-113 as if fully set forth herein.

115. Claim 1 of the '816 Patent claims a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

116. Aurobindo's submission of ANDA No. 219653 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo NEXLIZET<sup>®</sup> ANDA Product before the expiration of the '816 Patent constituted an act of infringement of the claims of the '816 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

117. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo NEXLIZET<sup>®</sup> ANDA Product prior to expiration of the '816 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least

claim 1 of the '816 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(b), and/or (c).

118. Upon information and belief, upon FDA approval of Aurobindo's ANDA No. 219653, Aurobindo will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the Aurobindo NEXLIZET<sup>®</sup> ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '816 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

119. Upon information and belief, Aurobindo specifically intends to, and will, actively induce infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(b) when ANDA No. 219653 is approved by marketing the Aurobindo NEXLIZET<sup>®</sup> ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '816 Patent, unless enjoined by the Court.

120. Upon information and belief, Aurobindo's ANDA No. 219653 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Aurobindo NEXLIZET<sup>®</sup> ANDA Product.

121. Upon information and belief, upon FDA approval of ANDA No. 219653, Aurobindo intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Aurobindo NEXLIZET<sup>®</sup> ANDA Product, unless enjoined by the Court, and the Aurobindo NEXLIZET<sup>®</sup> ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

122. On information and belief, the proposed package insert will include a method of lowering LDL-C in a subject in need thereof, the method comprising administering 180 mg 8-

hydroxy-2,2,14,14-tetramethylpentadecanedioic acid and 10 mg Ezetimibe to the subject, wherein the subject has familial hypercholesterolemia.

123. Upon information and belief, the use of the Aurobindo NEXLIZET<sup>®</sup> ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '816 Patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

124. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's NEXLIZET<sup>®</sup> Notice Letter, Aurobindo has knowledge of the '816 Patent and knowledge that its Aurobindo NEXLIZET<sup>®</sup> ANDA Product will infringe the '816 Patent.

125. On information and belief, Aurobindo is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Aurobindo NEXLIZET<sup>®</sup> ANDA Product at least according to Aurobindo's proposed package insert and, therefore, will directly infringe at least claim 1 of the '816 Patent.

126. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '816 Patent under 35 U.S.C. § 271(c) when ANDA No. 219653 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo NEXLIZET<sup>®</sup> ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Aurobindo NEXLIZET<sup>®</sup> ANDA Product is not suitable for substantial noninfringing use.

127. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '816 Patent.

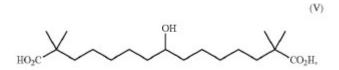
128. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo NEXLIZET<sup>®</sup> ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

129. Unless Aurobindo is enjoined from directly or indirectly infringing the '816 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

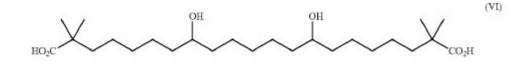
# COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,926,584

130. Esperion incorporates each of the preceding paragraphs 1-129 as if fully set forth herein.

131. Claim 1 of the '584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of 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, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



132. Aurobindo's submission of ANDA No. 219653 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product before the expiration of the '584 Patent constituted an act of infringement of the claims of the '584 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

133. Aurobindo's commercial manufacture, use, offer for sale, sale, and/or importation of the Aurobindo ANDA Product prior to expiration of the '584 Patent, and Aurobindo's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '584 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b), and/or (c).

134. Upon information and belief, upon FDA approval of Aurobindo's ANDA No. 219653, Aurobindo will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Aurobindo ANDA Product in the United States and/or importing said product into the United States, and/or by actively inducing or contributing to infringement of the '584 Patent by others, under at least 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

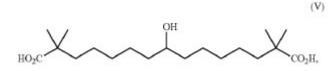
135. Upon information and belief, Aurobindo specifically intends to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA No. 219653 is approved by marketing the Aurobindo ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

136. Upon information and belief, Aurobindo' ANDA No. 219653 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Aurobindo ANDA Product.

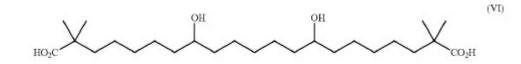
137. Upon information and belief, upon FDA approval of ANDA No. 219653, Aurobindo intends to, and will, engage in the commercial making, using, offering to sell, selling, and/or

importing the Aurobindo ANDA Product, unless enjoined by the Court, and the Aurobindo ANDA Product will be administered by patients, medical practitioners, and/or other third parties in the United States according to the directions and instructions in the proposed package insert.

138. On information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of 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, and the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):



139. Upon information and belief, the use of the Aurobindo ANDA Product by patients, medical practitioners, and/or other third parties according to the proposed package insert will constitute an act of direct infringement by those patients, medical practitioners, and/or other third parties of at least claim 1 of the '584 patent, under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

140. Upon information and belief, by virtue of its listing in the Orange Book and identification in Aurobindo's Notice Letter, Aurobindo has knowledge of the '584 Patent and knowledge that its Aurobindo ANDA Product will infringe the '584 Patent.

141. On information and belief, Aurobindo is aware, has knowledge, and/or is willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Aurobindo ANDA Product at least according to Aurobindo's proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

142. Upon information and belief, Aurobindo intends to, and will, contribute to infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(c) when ANDA No. 219653 is approved, unless enjoined by the Court, because Aurobindo knows that the Aurobindo ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Aurobindo ANDA Product is not suitable for substantial noninfringing use.

143. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '584 Patent.

144. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Aurobindo's making, using, offering to sell, selling, and/or importing the Aurobindo ANDA Product, inducement thereof or contribution thereto, will infringe the '584 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(b) and/or (c).

145. Unless Aurobindo is enjoined from directly or indirectly infringing the '584 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:

146. A judgment that the claims of the Asserted Patents are infringed by Aurobindo's submission of ANDA No. 219653 under 35 U.S.C. § 271(e)(2)(A);

147. A declaratory judgment that Aurobindo's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Aurobindo 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);

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

149. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Aurobindo's ANDA No. 219653 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;

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

151. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Aurobindo engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Aurobindo 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;

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

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

Dated: September 25, 2024

/s/ Liza M. Walsh

Liza M. Walsh Katelyn O'Reilly Jessica K. Formichella WALSH PIZZI O'REILLY FALANGA LLP Three Gateway Center 100 Mulberry Street, 15th Floor Newark, NJ 07102 (973) 757-1100

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Attorneys for Plaintiff Esperion Therapeutics, Inc.

# **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. 2:24cv-05921-JXN-CLW
- Esperion Therapeutics, Inc. v. Renata Ltd., 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. MSN Pharmaceuticals Inc., et al.*, Civil Action No. 2:24-cv-06386-JXN-CLW
- Esperion Therapeutics, Inc. v. Sandoz Inc., Civil Action No. 2:24-cv-06387-JXN-CLW
- Esperion Therapeutics, Inc. v. Hetero USA Inc., Civil Action No. 2:24-cv-06389-JXN-CLW
- *Esperion Therapeutics, Inc. v. Dr. Reddy's Laboratories, Inc., et al.*, Civil Action No. 2:24-cv-06391-JXN-CLW
- Esperion Therapeutics, Inc. v. Aurobindo Pharma Ltd., Civil Action No. 2:24- cv-06348-JXN-CLW

Dated: September 25, 2024

OF COUNSEL (pro hac vice forthcoming):

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Elizabeth J. Holland Dov Hirsch Ryan Curiel ALLEN OVERY SHEARMAN STERLING US LLP 1221 Avenue of the Americas New York, NY 10020 By: /s/ Liza M. Walsh

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Attorneys for Plaintiff Esperion Therapeutics, Inc.

# 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.

Dated: September 25, 2024

OF COUNSEL (pro hac vice forthcoming):

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