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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.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. 2:24-cv-06017-JXN-CF
	)	
RENATA LIMITED, SOMERSET THERAPEUTICS, LLC, and SOMERSET PHARMA, LLC,	)	
	)	
Defendants.	)	

THIRD AMENDED 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 Renata Limited ("Renata"), Somerset Therapeutics, LLC ("Somerset Therapeutics"), and Somerset Pharma, LLC ("Somerset Pharma") (collectively, the "Defendants"). This action arises out of Defendants' submission of Abbreviated New Drug Application ("ANDA") No. 219257 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, 11,613,511, 11,926,584, 11,744,816, 12,398,087, and 12,404,227.

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 Renata is a corporation organized and existing under the laws of Bangladesh, having a place of business at Plot # 1, Milk Vita Road, Section-7, Mirpur, Dhaka-1216, Bangladesh.

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

6. Upon information and belief, Renata works on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

7. Upon information and belief, Defendant Somerset Therapeutics is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey.

8. Upon information and belief, Somerset Therapeutics 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.

9. Upon information and belief, Somerset Therapeutics directly or through its affiliates markets and sells drug products throughout the United States, including in New Jersey.

10. Upon information and belief, Somerset Therapeutics works on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

11. Upon information and belief, Defendant Somerset Pharma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 300 Franklin Square Drive, Somerset, New Jersey.

12. Upon information and belief, Somerset 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.

13. Upon information and belief, Somerset Pharma directly or through its affiliates markets and sells drug products throughout the United States, including in New Jersey.

14. Upon information and belief, Somerset Pharma works on the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products for the United States market, including New Jersey.

15. Upon information and belief, Renata prepared and submitted ANDA No. 219257 seeking approval to engage in the commercial manufacture, use, importation, offer for sale, and sale of a generic version of NEXLETOL® (the "Renata ANDA Product") prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 11,926,584, 11,744,816, 12,398,087, and 12,404,227.

16. Upon information and belief, Renata developed the Renata ANDA Product.

17. Upon information and belief, Somerset Therapeutics and Somerset Pharma (collectively, "Somerset") hold the exclusive right to market and sell the Renata ANDA Product in the United States.

18. Upon information and belief, Somerset actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the preparation, submission and maintenance of ANDA No. 219257 to the FDA.

19. Upon information and belief, Defendants are seeking regulatory approval from the FDA to market and sell the Renata ANDA Product throughout the United States, including in New Jersey.

20. Upon information and belief, Defendants intend to obtain approval for ANDA No. 219257, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import the Renata 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 Renata 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. 219257 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. 219257, Renata, will make, use, import, sell, and/or offer for sale the Renata ANDA Product in the United States, including in New Jersey, prior to the expiration of U.S. Patent Nos. 11,760,714, 11,613,511, 11,926,584, 11,744,816, 12,398,087, and 12,404,227.

23. This Court also has personal jurisdiction over Renata because, among other things, this action arises from Renata's actions directed toward New Jersey, and because, upon information and belief, Renata 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 marketing pharmaceutical products in New Jersey. Renata 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.

24. In addition, this Court has personal jurisdiction over Renata because, among other things, upon information and belief, (1) Renata filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of the Renata ANDA Product in the United States, including in New Jersey, and (2) upon approval of ANDA No. 219257, Renata will market, distribute, offer for sale, sell, and/or import the Renata ANDA Product in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of the Renata ANDA Product in New Jersey. Upon information and belief, upon approval of ANDA No. 219257, the Renata 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.

25. This Court has personal jurisdiction over Renata because, upon information and belief, Renata worked with its counsel in New Jersey, Windels Marx Lane & Mittendorf, LLP, to prepare the certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") regarding U.S. Patent Nos. 11,760,714, 11,613,511, 11,926,584, 11,744,816, 12,398,087, and 12,404,227 for ANDA No. 219257, and designated, pursuant to 21 C.F.R. §

314.95(c)(9), its New Jersey counsel, Windels Marx Lane & Mittendorf, LLP, to be its agent in the United States authorized to accept service of process in New Jersey on Renata's behalf in relation to ANDA No. 219257.

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

27. Upon information and belief, Renata's contacts with other states of the United States are no greater than its contacts with New Jersey. Therefore, to the extent Renata 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 Renata pursuant to Federal Rule of Civil Procedure 4(k)(2)(A) because Renata 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 First and Second Notice Letters (defined below) to Esperion, Renata represented that Windels Marx Lane & Mittendorf, 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."

28. This Court has personal jurisdiction over Somerset Therapeutics because Somerset Therapeutics, through its counsel, consented to personal jurisdiction in the District of New Jersey for purposes of this action prior to the filing of this Second Amended Complaint.

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

30. In view of the foregoing, Somerset Therapeutics is subject to general personal jurisdiction in New Jersey.

31. This Court has personal jurisdiction over Somerset Pharma because Somerset Pharma, through its counsel, consented to personal jurisdiction in the District of New Jersey for purposes of this action prior to the filing of this Second Amended Complaint.

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

33. In view of the foregoing, Somerset Pharma is subject to general personal jurisdiction in New Jersey.

34. 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 Renata, Somerset Therapeutics, and Somerset Pharma to litigate this action in this Court, and Renata, Somerset Therapeutics, and Somerset Pharma are subject to personal jurisdiction in New Jersey.

35. 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).

36. Venue is proper in this Court as to Renata under 28 U.S.C. §§ 1391(b) and (c), and 1400(b), because, upon information and belief, Renata is a corporation organized under the laws of Bangladesh, 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.

37. Venue is also proper in this Court as to Renata because Renata 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 the proposed generic NEXLETOL® 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.

38. Venue is proper in this Court as to Somerset Therapeutics because, among other things, Somerset Therapeutics, through its counsel, consented to venue in the District of New Jersey for purposes of this action prior to the filing of this Second Amended Complaint

39. Venue is proper in this Court as to Somerset Therapeutics 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.

40. Venue is proper in this Court as to Somerset Pharma because, among other things, Somerset Pharma, through its counsel, consented to venue in the District of New Jersey for purposes of this action prior to the filing of this Second Amended Complaint

41. Venue is proper in this Court as to Somerset Pharma 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.

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. 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 C."

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

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

51. 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."

52. Esperion is the assignee of, and holds all rights, title, and interest in the '816 Patent.

53. The '816 Patent currently expires on March 14, 2036.

54. U.S. Patent No. 12,398,087 (the "'087 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on August 26, 2025. A true and correct copy of the '087 Patent is attached hereto as "Exhibit E."

55. Esperion is the assignee of, and holds all rights, title, and interest in the '087 Patent.

56. The '087 Patent currently expires on June 19, 2040.

57. U.S. Patent No. 12,404,227 (the "'227 Patent"), entitled "Methods of Making Bempedoic Acid and Compositions of the Same," was duly and legally issued on September 2, 2025. A true and correct copy of the '227 Patent is attached hereto as "Exhibit F."

58. Esperion is the assignee of, and holds all rights, title, and interest in the '227 Patent.

59. The '227 Patent currently expires on June 19, 2040.

60. All claims of the '714, '511, '584,'816, '087, and '227 Patents are valid, enforceable, and not expired.

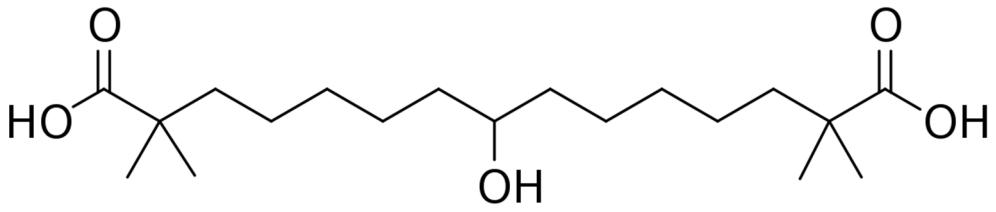
ESPERION'S NEXLETOL® PRODUCT

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

62. 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.

63. 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).

64. 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:



65. The claims of the ’714, ’511, ’584,’816, ’087, and ’227 Patents cover NEXLETOL®.

66. The ’714, ’511, ’584, ’816, ’087, and ’227 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.”[1]

THE RENATA ANDA PRODUCT

67. By letter dated March 27, 2024, and received by Esperion via Federal Express no earlier than on March 28, 2024 (the “First Notice Letter”), Renata notified Esperion that Renata had submitted ANDA No. 219257 to the FDA for a generic version of NEXLETOL®.

68. The First Notice Letter states that Renata seeks approval from the FDA to engage in the commercial manufacture, use, or sale of the Renata ANDA product before the expiration of the ’714 and ’511 Patents. Upon information and belief, Renata intends to – directly or indirectly – engage in the commercial manufacture, use, and sale of the Renata ANDA product promptly upon receiving FDA approval to do so.

69. By submitting ANDA No. 219257, Renata has represented to the FDA that the Renata ANDA Product has the same active ingredient, dosage form, and strength as NEXLETOL® and is bioequivalent to NEXLETOL®.

70. In the First Notice Letter, Renata stated that ANDA No. 219257 includes a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’714

[1] The ’087 and ’227 Patents have also been listed in connection with NEXLETOL® in the Orange Book, but Renata sent its Notice Letters prior to the issuance of the ’087 and ’227 Patents. For that reason, Renata has not indicated in its First or Second Notice Letters (defined below) that it has submitted a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’087 and ’227 Patents.

and ’511 Patents. Renata also contended that the ’714 and ’511 Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Renata ANDA Product.

71. Upon information and belief, Defendants had knowledge of the ’714 and ’511 Patents at least when ANDA No. 219257 was submitted to the FDA.

72. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product immediately and imminently upon approval of ANDA No. 219257 and prior to expiration of the ’714 and ’511 Patents.

73. Renata’s First Notice Letter only identified invalidity positions with respect to the ’714 and ’511 Patents and included limited information about the Renata ANDA Product. Renata’s Offer of Confidential Access permitted access only to limited, unspecified portions of ANDA No. 219257 on terms and conditions set by Renata.

74. On or about April 29, 2024, Esperion sent Renata a proposed revision of the Offer of Confidential Access to permit Esperion access to, among other things, the entirety of ANDA No. 219257.

75. Renata has not provided a substantive response to Esperion’s proposed revision of the Offer of Confidential Access and has not provided Esperion with any portions of its ANDA No. 219257.

76. Esperion commenced this action by filing a complaint on May 10, 2024, which was before the expiration of forty-five days from the date of Esperion’s receipt of the First Notice Letter.

77. On or about March 12, 2024, the U.S. Patent and Trademark Office issued the ’584 Patent.

78. On or about April 9, 2024, and within thirty days of issuance of the '584 Patent, Esperion submitted Form 3542 identifying the '584 Patent for listing in the Orange Book for NEXLETOL®.

79. On information and belief, at some point on or after April 9, 2024, during the pendency of ANDA No. 219257, Renata provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 Patent.

80. On or about March 22, 2024, the FDA approved a new label for NEXLETOL® including for its use 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).

81. On or about April 19, 2024, and within thirty days of the FDA approving a new indication for NEXLETOL®, Esperion submitted Form 3542 identifying the '816 Patent for listing in the Orange Book for NEXLETOL®.

82. On information and belief, at some point on or after April 19, 2024, during the pendency of ANDA No. 219257, Renata provided to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '816 Patent.

83. By letter dated June 4, 2024, and received by Esperion via Federal Express no earlier than on June 5, 2024 (the "Second Notice Letter"), Renata sent written notice to Esperion of its Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the '584 and '816 Patents. In the Second Notice Letter, Renata contended that the '584 and '816 Patents are

invalid, unenforceable or will not be infringed by the commercial manufacture, use, and/or sale of the Renata ANDA Product.

84. Upon information and belief, Defendants had knowledge of the '584 Patent since at least April 9, 2024, and certainly before June 4, 2024.

85. Upon information and belief, Defendants had knowledge of the '816 Patent since at least April 19, 2024, and certainly before June 4, 2024.

86. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product immediately and imminently upon approval of ANDA No. 219257 and prior to expiration of the '584 and '816 Patents.

87. Esperion timely filed the First Amended Complaint before the expiration of the forty-five days from the date of Esperion's receipt of the Second Notice Letter and prior to Renata's answer to the original complaint filed May 10, 2024.

88. On July 17, 2024, Counsel for Renata and Somerset represented for the first time that Renata and Somerset had entered into a Master Services Agreement in which Somerset obtained from Renata the exclusive right to market and sell the Renata ANDA Product within the United States.

89. The Second Amended Complaint was filed to join Somerset as a Defendant in this action.

90. Defendants consented to Esperion filing the Second Amended Complaint.[2]

91. On or about August 21, 2025, Esperion informed Defendants of the impending issuance of the '087 Patent on August 26, 2025, and of the '227 Patent on September 2, 2025.

[2] *See* ECF No. 31, Stipulation and Order for a Second-Amended Complaint and Setting the Deadline to Answer or Otherwise Respond to Same.

92. On or about September 9, 2025, Esperion submitted a timely Form 3542 identifying the ’087 Patent for listing in the Orange book for NEXLETOL®. The ’087 Patent was listed in the Orange Book on or about September 10, 2025, providing public notice of the ’087 Patent.

93. On or about September 9, 2025, Esperion submitted a timely Form 3542 identifying the ’227 Patent for listing in the Orange Book for NEXLETOL®. The ’227 Patent was listed in the Orange Book on or about September 10, 2025, providing public notice of the ’227 Patent.

94. Upon information and belief, Defendants had knowledge of the ’087 and ’227 Patents since at least August 21, 2025, and no later than September 10, 2025.

95. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product immediately and imminently upon approval of ANDA No. 219257 and prior to expiration of the ’087 Patent.

96. Upon information and belief, Defendants intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product immediately and imminently upon approval of ANDA No. 219257 and prior to expiration of the ’227 Patent.

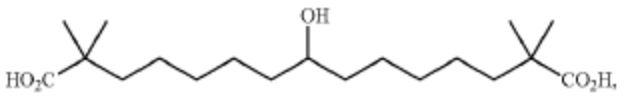
97. Upon information and belief, during the pendency of Defendants’ ANDA, Defendants intend to and will provide to the FDA a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the ’087 and ’227 Patents.

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

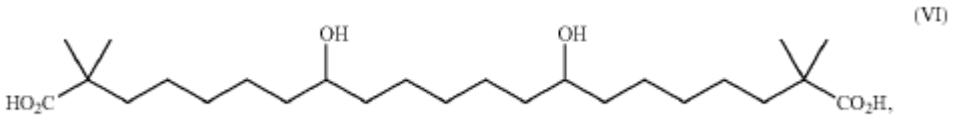
98. Esperion incorporates each of the preceding paragraphs 1-97 as if fully set forth herein.

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

(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):



(VI)

and a pharmaceutically acceptable excipient.

100. Renata's submission of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

101. Upon information and belief, Somerset's involvement in the submission and maintenance of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

102. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product prior to expiration of the '714 Patent, and Defendants' 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).

103. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants intend 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 Renata ANDA Product, unless enjoined by the Court.

104. Upon information and belief, by virtue of their listing in the Orange Book and identification in the First Notice Letter, Defendants have knowledge of the '714 Patent and knowledge that the Renata ANDA Product will infringe the '714 Patent.

105. Upon information and belief, Defendants intend 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. 219257 is approved by marketing the Renata ANDA Product and encouraging doctors and patients to infringe the '714 Patent, unless enjoined by the Court.

106. Upon information and belief, Defendants intend 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. 219257 is approved, unless enjoined by the Court, because Defendants know that the Renata ANDA Product is especially made or adapted for use in infringing the '714 Patent, and that the Renata ANDA Product is not suitable for substantial noninfringing use.

107. Defendants' infringement is imminent because, among other things, Defendants have notified Esperion of the submission of their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of the '714 Patent.

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

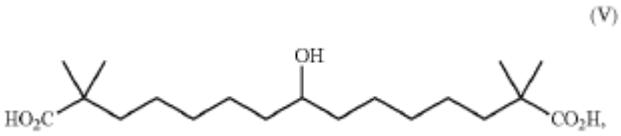
109. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Renata ANDA Product, inducement thereof or contribution thereto, will infringe the '714 Patent, either literally or under the doctrine of equivalents,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

110. Unless Defendants are 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.

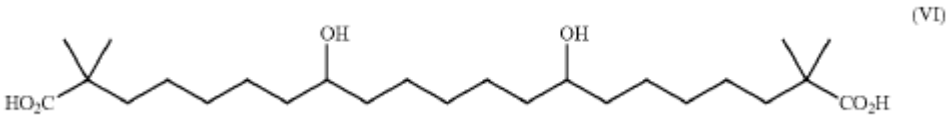
COUNT II: INFRINGEMENT OF U.S. PATENT NO. 11,613,511

111. Esperion incorporates each of the preceding paragraphs 1-110 as if fully set forth herein.

112. 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.

113. Renata's submission of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

114. Upon information and belief, Somerset's involvement in the submission and maintenance of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

115. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product prior to expiration of the '511 Patent, and Defendants' 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).

116. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants intend 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 Renata ANDA Product, unless enjoined by the Court.

117. Upon information and belief, by virtue of their listing in the Orange Book and identification in the First Notice Letter, Defendants have knowledge of the '511 Patent and knowledge that the Renata ANDA Product will infringe the '511 Patent.

118. Upon information and belief, Defendants intend 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. 219257 is approved by marketing the Renata ANDA Product and encouraging doctors and patients to infringe the '511 Patent, unless enjoined by the Court.

119. Upon information and belief, Defendants intend 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. 219257 is approved, unless enjoined by the Court, because Defendants know that the Renata

ANDA Product is especially made or adapted for use in infringing the ’511 Patent, and that the Renata ANDA Product is not suitable for substantial noninfringing use.

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

121. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Defendants’ making, using, offering to sell, selling, and/or importing the Renata 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).

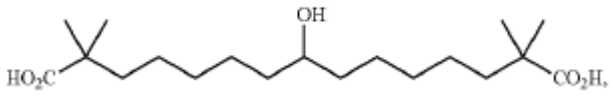
122. Unless Defendants are enjoined from directly or indirectly infringing the ’511 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

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

123. Esperion incorporates each of the preceding paragraphs 1-122 as if fully set forth herein.

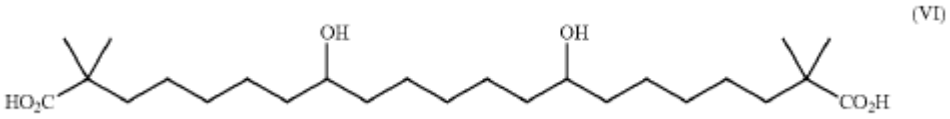
124. Claim 1 of the ’584 Patent claims a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(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):



125. Renata's submission of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

126. Upon information and belief, Somerset's involvement in the submission and maintenance of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

127. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product prior to expiration of the '584 Patent, and Defendants' 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).

128. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants will infringe at least claim 1 of the '584 Patent by making, using, offering to sell, and selling the Renata 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.

129. Upon information and belief, Defendants specifically intend to, and will, actively induce infringement of at least claim 1 of the '584 Patent under 35 U.S.C. § 271(b) when ANDA

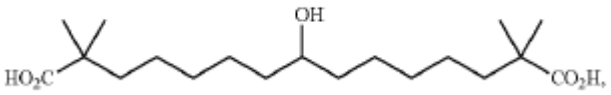
No. 19257 is approved by marketing the Renata ANDA Product and encouraging patients, medical practitioners, and/or other third parties to infringe at least claim 1 the '584 Patent, unless enjoined by the Court.

130. Upon information and belief, ANDA No. 219257 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Renata ANDA Product.

131. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants intend to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Renata ANDA Product, unless enjoined by the Court, and the Renata 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.

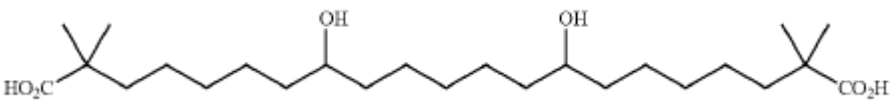
132. Upon information and belief, the proposed package insert will include a method of lowering low-density lipoprotein cholesterol (LDL-C) in a human in need thereof comprising administering to the human a therapeutically effective amount of a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(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):

(VI)



133. Upon information and belief, the use of the Renata 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.

134. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Second Notice Letter, Defendants have knowledge of the '584 Patent and knowledge that the Renata ANDA Product will infringe the '584 Patent.

135. Upon information and belief, Defendants are aware, have knowledge, and/or are willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Renata ANDA Product at least according to the proposed package insert and, therefore, will directly infringe at least claim 1 of the '584 Patent.

136. Upon information and belief, Defendants intend 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. 219257 is approved, unless enjoined by the Court, because Defendants know that the Renata ANDA Product is especially made or adapted for use in infringing the '584 Patent, and that the Renata ANDA Product is not suitable for substantial noninfringing use.

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

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

139. Unless Defendants are 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.

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

140. Esperion incorporates each of the preceding paragraphs 1-139 as if fully set forth herein.

141. 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.

142. Upon information and belief, the ANDA Product contains 180 mg of 8-hydroxy-2,2,14,14-tetramethylpentadecanedioic acid.

143. Upon information and belief, 10 mg ezetimibe is commercially available, sold in the United States, and prescribed by medical practitioners to treat patients.

144. Renata's submission of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

145. Upon information and belief, Somerset's involvement in the submission and maintenance of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata 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.

146. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product prior to expiration of the '816 Patent, and Defendants' 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).

147. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants will infringe at least claim 1 of the '816 Patent by making, using, offering to sell, and selling the Renata 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.

148. Upon information and belief, Defendants specifically intend 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. 219257 is approved by marketing the Renata 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.

149. Upon information and belief, ANDA No. 219257 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Renata ANDA Product.

150. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants intend to, and will, engage in the commercial making, using, offering to sell, selling, and/or importing the Renata ANDA Product, unless enjoined by the Court, and the Renata 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.

151. Upon information and belief, ANDA No. 219257 includes a proposed package insert with directions that instructs patients, medical practitioners, and/or other third parties to administer

and/or to prescribe the Renata ANDA Product along with 10 mg ezetimibe to lower LDL-C in a human subject who has familial hypercholesterolemia.

152. Upon information and belief, following FDA approval of ANDA No. 219257, Defendants will promote and/or market the Renata ANDA Product to patients, medical practitioners, and/or other third parties to administer and/or to prescribe the Renata ANDA Product along with 10 mg ezetimibe to lower LDL-C in a human subject who has familial hypercholesterolemia.

153. Upon information and belief, following FDA approval of ANDA No. 219257, medical practitioners and/or third parties will prescribe and/or administer, and patients with familial hypercholesterolemia will take the Renata ANDA Product along with 10 mg ezetimibe in order to lower LDL-C in the patients.

154. Upon information and belief, the use of the Renata 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.

155. Upon information and belief, by virtue of its listing in the Orange Book and identification in the Second Notice Letter, Defendants have knowledge of the ’816 Patent and knowledge that the Renata ANDA Product will infringe the ’816 Patent.

156. Upon information and belief, Defendants are aware, have knowledge, and/or are willfully blind to the fact that patients, medical practitioners, and/or other third parties will administer and/or prescribe, the Renata ANDA Product at least according to the proposed package insert and, therefore, will directly infringe at least claim 1 of the ’816 Patent.

157. Upon information and belief, Defendants intend 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. 219257 is approved, unless enjoined by the Court, because Defendants know that the Renata ANDA Product is especially made or adapted for use in infringing the '816 Patent, and that the Renata ANDA Product is not suitable for substantial noninfringing use.

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

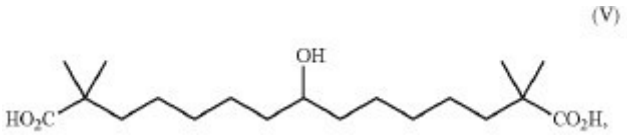
159. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Renata ANDA Product, inducement thereof or contribution thereto, will infringe the '816 Patent, either literally or under the doctrine of equivalents,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

160. Unless Defendants are 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.

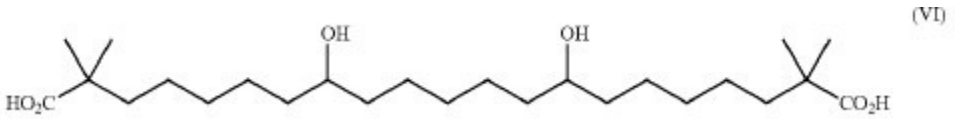
COUNT V: INFRINGEMENT OF U.S. PATENT NO. 12,398,087

161. Esperion incorporates each of the preceding paragraphs 1-160 as if fully set forth herein.

162. Claim 1 of the '087 Patent requires a pharmaceutical material comprising a compound of formula (V):



wherein the pharmaceutical material comprises the compound of formula (V) in an amount greater than 98% by weight based on the total weight of the pharmaceutical material and the pharmaceutical material comprises 0.001 % to 0.15% of a compound of formula (VI):



or a pharmaceutically acceptable salt thereof, based on the total weight of the pharmaceutical material.

163. Renata's submission of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of the '087 Patent constituted an act of infringement of the claims of the '087 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

164. Upon information and belief, Somerset's involvement in the submission and maintenance of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of the '087 Patent constituted an act of infringement of the claims of the '087 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

165. Defendants' commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product prior to expiration of the '087 Patent, and Defendants' inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '087 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

166. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants intend to, and will, infringe at least claim 1 of the '087 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 Renata ANDA Product, unless enjoined by the Court.

167. Upon information and belief, by virtue of their listing in the Orange Book, Defendants have knowledge of the '087 Patent and knowledge that the Renata ANDA Product will infringe the '087 Patent.

168. Upon information and belief, Defendants intend to, and will, actively induce infringement of at least claim 1 of the '087 Patent under 35 U.S.C. § 271(b) when ANDA No. 219257 is approved by marketing the Renata ANDA Product and encouraging doctors and patients to infringe the '087 Patent, unless enjoined by the Court.

169. Upon information and belief, Defendants intend to, and will, contribute to infringement of at least claim 1 of the '087 Patent under 35 U.S.C. § 271(c) when ANDA No. 219257 is approved, unless enjoined by the Court, because Defendants know that the Renata ANDA Product is especially made or adapted for use in infringing the '087 Patent, and that the Renata ANDA Product is not suitable for substantial noninfringing use.

170. Defendants' infringement is imminent because, among other things, Defendants have notified Esperion of the submission of their ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of the '087 Patent.

171. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '087 Patent.

172. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Renata ANDA Product, inducement thereof or contribution thereto, will infringe the '087 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

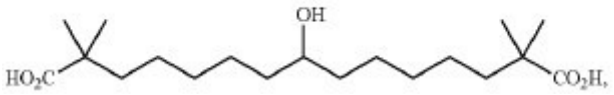
173. Unless Defendants are enjoined from directly or indirectly infringing the '087 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

COUNT VI: INFRINGEMENT OF U.S. PATENT NO. 12,404,227

174. Esperion incorporates each of the preceding paragraphs 1-173 as if fully set forth herein.

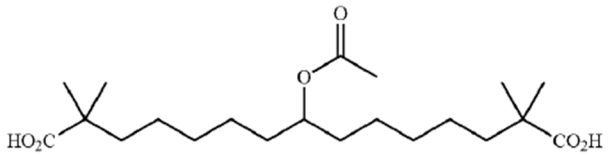
175. Claim 1 of the '227 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(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 0.15%

(VIII)



or a pharmaceutically acceptable salt thereof, based on the total weight of the pharmaceutical material.

176. Renata's submission of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of the '227 Patent constituted an act of infringement of the claims of the '227 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

177. Upon information and belief, Somerset's involvement in the submission and maintenance of ANDA No. 219257 to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of

the ’227 Patent constituted an act of infringement of the claims of the ’227 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

178. Defendants’ commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product prior to expiration of the ’227 Patent, and Defendants’ inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the ’227 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c).

179. Upon information and belief, upon FDA approval of ANDA No. 219257, Defendants intend to, and will, infringe at least claim 1 of the ’227 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 Renata ANDA Product, unless enjoined by the Court.

180. Upon information and belief, by virtue of their listing in the Orange Book, Defendants have knowledge of the ’227 Patent and knowledge that the Renata ANDA Product will infringe the ’227 Patent.

181. Upon information and belief, Defendants intend to, and will, actively induce infringement of at least claim 1 of the ’227 Patent under 35 U.S.C. § 271(b) when ANDA No. 219257 is approved by marketing the Renata ANDA Product and encouraging doctors and patients to infringe the ’227 Patent, unless enjoined by the Court.

182. Upon information and belief, Defendants intend to, and will, contribute to infringement of at least claim 1 of the ’227 Patent under 35 U.S.C. § 271(c) when ANDA No. 219257 is approved, unless enjoined by the Court, because Defendants know that the Renata ANDA Product is especially made or adapted for use in infringing the ’227 Patent, and that the Renata ANDA Product is not suitable for substantial noninfringing use.

183. Defendants’ infringement is imminent because, among other things, Defendants have notified Esperion of the submission of their ANDA seeking approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of the Renata ANDA Product before the expiration of the '227 Patent.

184. Thus, a substantial and justiciable controversy exists between the parties hereto as to the infringement of the '227 Patent.

185. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Defendants' making, using, offering to sell, selling, and/or importing the Renata ANDA Product, inducement thereof or contribution thereto, will infringe the '227 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

186. Unless Defendants are enjoined from directly or indirectly infringing the '227 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:

187. A judgment that the claims of the '714, '511, '584, '816, '087, and '227 Patents are infringed by Defendants' submission of ANDA No. 219257 under 35 U.S.C. § 271(e)(2)(A);

188. A declaratory judgment that Defendants' manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the Renata ANDA Product prior to the expiration of the '714, '511, '584, '816, '087, and '227 Patents, would infringe the '714, '511, '584, '816, '087, and '227 Patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), and/or (c);

189. A judgment that the '714, '511, '584, '816, '087, and '227 Patents are not invalid or unenforceable;

190. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 219257 shall not be earlier than the expiration of the '714, '511,

'584, '816, '087, and '227 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

191. An order permanently enjoining Defendants, and their affiliates, subsidiaries, and each of their officers, agents, servants and employees and those acting in privity or concert with Defendants, from making, using, offering to sell, selling, or importing the Renata ANDA Product until after the '714, '511, '584, '816, '087, and '227 Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

192. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Defendants engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of the Renata ANDA Product prior to the expiration of the '714, '511, '584, '816, '087, and '227 Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

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

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

Dated: September 29, 2025

/s/ *Liza M. Walsh*

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