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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. 24-_____
	)	
RENATA LIMITED,	)	
	)	
Defendant.	)	
	)	

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 Defendant Renata Limited ("Renata"). This action arises out of Renata's 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 and 11,613,511 (collectively, the "Asserted Patents").

PARTIES

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

3. Upon information and belief, Defendant 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, 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 the Asserted Patents.

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

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

10. Upon information and belief, Renata intends to obtain approval for Renata's 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

11. 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.

12. 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 the Asserted Patents.

13. 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 hailed into court here.

14. 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 Renata's ANDA, 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 Renata's ANDA, 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.

15. 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 the Asserted Patents 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 its ANDA No. 219257.

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

17. 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 Notice Letter (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."

18. 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 to litigate this action in this Court, and Renata is subject to personal jurisdiction in New Jersey.

19. 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).

20. Venue is proper in this Court 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.

21. Venue is also proper in this Court 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 Defendant's 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.

THE PATENTS-IN-SUIT

22. 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."

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

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

25. 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."

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

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

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

ESPERION'S NEXLETOL PRODUCT

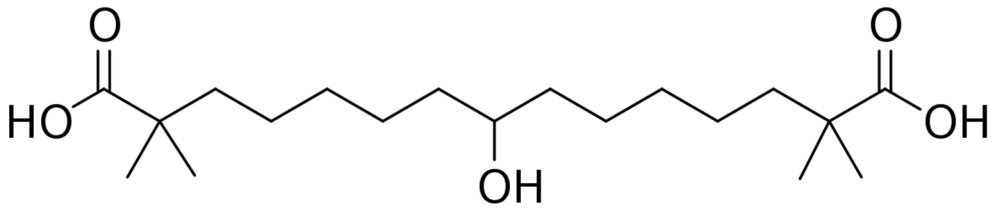
29. Esperion is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets life-saving pharmaceutical products, including NEXLETOL®.

30. 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.

31. 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).

32. 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:



33. The claims of the Asserted Patents cover NEXLETOL®.

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

RENATA'S ANDA PRODUCT

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

36. The 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 Asserted 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.

37. 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®.

38. In the Notice Letter, Renata stated that ANDA No. 219257 included a Paragraph IV Certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) with respect to the Asserted Patents. Renata also contended that the Asserted Patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the Renata ANDA Product.

39. Upon information and belief, Renata had knowledge of the Asserted Patents when it submitted ANDA No. 219257 to the FDA.

40. Upon information and belief, Renata intends 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.

41. Renata's Notice Letter only identified invalidity positions with respect to the Asserted Patents and included limited information about the Renata ANDA Product. Renata's Offer of Confidential Access permitted access only to limited, unspecified portions of Renata's ANDA on terms and conditions set by Renata.

42. On or before 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.

43. 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.

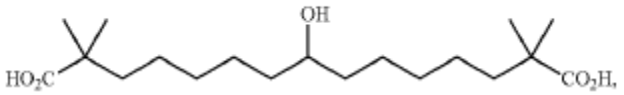
44. This action is being commenced before the expiration of forty-five days from the date of Esperion's receipt of the Notice Letter.

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

45. Esperion incorporates each of the preceding paragraphs 1 – 44 as if fully set forth herein.

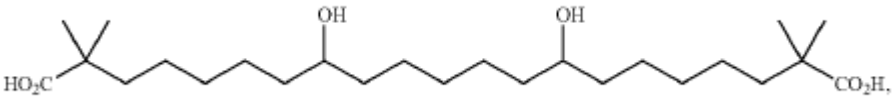
46. Claim 1 of the '714 Patent requires a pharmaceutical composition, comprising: a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(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.

47. 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.

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

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

50. Upon information and belief, by virtue of their listing in the Orange Book and identification in Renata's Notice Letter, Renata has knowledge of the Asserted Patents and knowledge that its Renata ANDA Product will infringe the Asserted Patents.

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

52. Upon information and belief, Renata 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. 219257 is approved, unless enjoined by the Court, because Renata knows 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.

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

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

55. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Renata's 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).

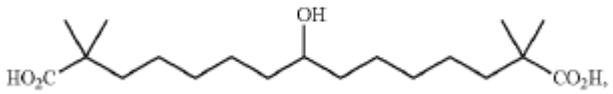
56. Unless Renata is enjoined from directly or indirectly infringing the '714 Patent, Esperion will suffer substantial and irreparable harm for which Esperion has no adequate remedy at law.

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

57. Esperion incorporates each of the preceding paragraphs 1 – 56 as if fully set forth herein.

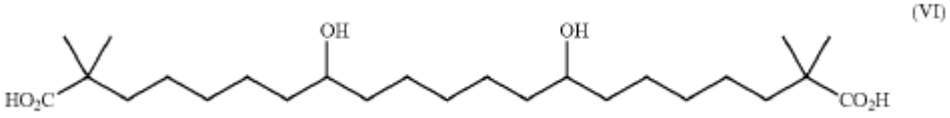
58. Claim 1 of the '511 Patent requires a pharmaceutical material comprising a crystalline form of the compound of formula (V):

(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, the pharmaceutical material comprises 0.0001 % to less than or equal to 0.15% of a compound of formula (VI):

(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.

59. 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.

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

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

62. Upon information and belief, by virtue of their listing in the Orange Book and identification in Renata's Notice Letter, Renata has knowledge of the Asserted Patents and knowledge that its Renata ANDA Product will infringe the Asserted Patents.

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

64. Upon information and belief, Renata 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. 219257 is approved, unless enjoined by the Court, because Renata knows 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.

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

66. Pursuant to 28 U.S.C. § 2201, Esperion is entitled to a declaratory judgment that Renata's 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).

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

PRAYER FOR RELIEF

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

68. A judgment that the claims of the Asserted Patents are infringed by Renata's submission of ANDA No. 219257 under 35 U.S.C. § 271(e)(2)(A);

69. A declaratory judgment that Renata's 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 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);

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

71. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Renata's ANDA No. 219257 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;

72. An order permanently enjoining Renata, and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Renata, from making, using, offering to sell, selling, or importing the Renata ANDA Product until after the

Asserted Patents' expiration, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

73. Damages or other monetary relief, including costs, fees, pre-judgement interest and post-judgment interest to Esperion if Renata engages 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 Asserted Patents, including any extensions and/or additional periods of exclusivity to which Esperion is or becomes entitled;

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

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

Dated: May 10, 2024

/s/ Liza M. Walsh

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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. 2:24-cv-05921-JXN-CLW

Dated: May 10, 2024

By: */s/Liza M. Walsh*
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Katelyn O'Reilly
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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: May 10, 2024

By: */s/ Liza M. Walsh*

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