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

**ALLERGAN SALES, LLC, FOREST
LABORATORIES HOLDINGS LIMITED,
ALLERGAN USA, INC., and PIERRE FABRE
MEDICAMENT S.A.S.,**

Plaintiffs,

v.

**TORRENT PHARMACEUTICALS LIMITED
and TORRENT PHARMA INC.,**

Defendants.

C.A. No.:

Electronically Filed

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan Sales, LLC, Forest Laboratories Holdings Limited, Allergan USA, Inc. (collectively, "Allergan") and Pierre Fabre Medicament S.A.S. (collectively, with Allergan, "Plaintiffs") file this Complaint for patent infringement against Defendants Torrent Pharmaceuticals Limited and Torrent Pharma Inc. (collectively, "Torrent") under 35 U.S.C. §§ 271(e)(2), (a), (b), and (c). This patent action concerns the pharmaceutical drug product Fetzima® and Torrent's infringement of United States Patent Nos. 8,481,598 ("the '598 patent"),

8,865,937 (“the ’937 patent”), and RE43,879 (“the ’879 patent”). Plaintiffs hereby allege as follows:

JURISDICTION AND PARTIES

1. Plaintiff Allergan Sales, LLC (“Allergan Sales”) is a Delaware limited liability company having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.
2. Plaintiff Forest Laboratories Holdings Limited (“Forest Holdings”) is a corporation organized under the laws of the Republic of Ireland having offices at Victoria Place, 5th Floor, 31 Victoria Street, Hamilton, HM 10, Bermuda.
3. Plaintiff Allergan USA, Inc. (“Allergan USA”) is a Delaware corporation having a place of business at 5 Giralda Farms, Madison, New Jersey 07940.
4. Plaintiff Pierre Fabre Medicament S.A.S. (“Pierre Fabre”) is a corporation organized under the laws of France having offices at 45, Place Abel Gance 92100 Boulogne - France.
5. On information and belief, Defendant Torrent Pharmaceuticals Limited (“Torrent Limited”) is an Indian corporation, having a principal place of business at Torrent Research Centre Ahmedabad, Gujarat 382 428, India.
6. On information and belief, Defendant Torrent Pharma Inc. (“Torrent Inc.”) is a Delaware limited liability company, having its principal place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey 07920.
7. On information and belief, Torrent Limited is a generic pharmaceutical company in the business of marketing and developing generic drug products. On information and belief, Torrent Limited directly and through its affiliates markets and sells drug products in the State of New Jersey and throughout the United States.

8. On information and belief, Torrent Inc. is a generic pharmaceutical company in the business of marketing and developing generic drug products. On information and belief, Torrent Inc. directly and through its affiliates markets and sells drug products in the State of New Jersey and throughout the United States.

9. On information and belief, Torrent Limited and Torrent Inc. are acting cooperatively with respect to Abbreviated New Drug Application (“ANDA”) No. 210813.

10. Torrent “has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at,” upon information and belief, the District of New Jersey and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016), *cert. denied*, 137 S. Ct. 625 (U.S. 2017). Torrent’s “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.” *Id.* at 760. On information and belief, Torrent “intends to direct sales of its drugs into [New Jersey], among other places, once it has the requested FDA approval to market them.” *Id.* at 758. Upon information and belief, Torrent will market its proposed ANDA products throughout the United States, including New Jersey, upon approval of its ANDA.

11. Torrent has affirmatively availed itself of this Court’s jurisdiction by filing counterclaims in this district, and was previously sued in this district and did not challenge personal jurisdiction. *See, e.g., Takeda GmbH et al. v. Torrent Pharma et al.*, 3:15-cv-03375 (D.N.J. Sept. 1, 2015).

12. For the reasons stated above, this Court has personal jurisdiction over Torrent.

13. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because, on information and belief, Torrent Limited is incorporated in India and may be sued in

any judicial district in the United States, in which the Defendant is subject to the court's personal jurisdiction.

14. Venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because, on information and belief, Torrent Inc. has a principal business in New Jersey and has and will continue to engage in infringing activities in New Jersey.

15. This patent infringement action arises under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2). This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

COUNT I FOR PATENT INFRINGEMENT
(Infringement of the '598 Patent Under 35 U.S.C. § 271(e)(2))

16. Plaintiffs reallege and incorporate by reference paragraphs 1-15.

17. The '598 patent, titled "Stable Dosage Forms of Levomilnacipran," was duly and legally issued to inventors Rahul Surana, Murali Divi, and Anil Chhetry by the United States Patent and Trademark Office ("PTO") on July 9, 2013. The '598 patent is assigned to Forest Holdings and expires on March 2, 2031. This expiration date includes a 114-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '598 patent is attached as Exhibit A. A true and correct copy of the Certificate Adjusting Patent Term is attached as Exhibit B.

18. New Drug Application ("NDA") No. 204168 is directed to the use of Fetzima[®] for the treatment of major depressive disorder ("MDD"). The FDA approved NDA No. 204168 on July 25, 2013. The '598 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 204168.

19. Plaintiff Forest Holdings is the assignee of the '598 patent. Allergan Sales is the NDA holder for extended release capsules containing 20 mg, 40 mg, 80 mg, and 120 mg of the

active ingredient levomilnacipran in the United States, which are sold under the brand name Fetzima[®]. Allergan USA is a distributor of Fetzima[®] in the United States.

20. On information and belief, Torrent filed, or caused to be filed, ANDA No. 210813 with the FDA under 21 U.S.C. § 355(j), seeking approval for the commercial manufacture, use, and sale of levomilnacipran hydrochloride extended release capsules in 20 mg, 40 mg, 80 mg, and 120 mg dosage strengths (“Torrent’s generic levomilnacipran products”) in the United States before the ’598 patent expires.

21. On information and belief, ANDA No. 210813 contains a Paragraph IV certification alleging that all claims of the ’598 are invalid and/or not infringed.

22. Torrent sent, or caused to be sent, to Plaintiffs a letter dated November 5, 2019 (“Torrent’s Notice Letter”) notifying Plaintiffs that Torrent submitted ANDA No. 210813, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Torrent’s Notice Letter alleges that all claims of the ’598 patent are invalid. Torrent’s Notice Letter does not allege non-infringement of any claim of the ’598 patent. However, Torrent’s Notice Letter incorporates by reference its previous Notice Letter dated September 18, 2017 and all defenses raised in litigation C.A. No., 2:17-CV-10230-ES-SCM.

23. Plaintiffs received Torrent’s Notice Letter no earlier than November 6, 2019. Plaintiffs filed this complaint within 45 days of receipt of Torrent’s Notice Letter and, as a result, the 30-month stay under 21 C.F.R. § 314.107(b)(3) with respect to ANDA No. 210813 is no earlier than May 6, 2022.

24. On information and belief, Torrent seeks approval of at least one indication for Torrent’s generic levomilnacipran products that are claimed in the ’598 patent.

25. Under 35 U.S.C. § 271(e)(2)(A), Torrent infringed one or more claims of the '598 patent in violation of Plaintiffs' patent rights, by submitting an ANDA to the FDA that seeks approval to commercially market—before the '598 patent expires—Torrent's generic levomilnacipran products, the use of which would directly infringe one or more claims of the '598 patent, literally and/or through the doctrine of equivalents, and the manufacture, use, offer for sale, or sale within the United States, or importation into the United States would contribute to or induce the direct infringement of one or more claims of the '598 patent, by users of Torrent's generic levomilnacipran products.

26. On information and belief, Torrent has knowledge of the '598 patent and filed ANDA No. 210813 seeking authorization to commercially manufacture, use, offer for sale, and sell Torrent's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210813, physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '598 patent.

27. On information and belief, Torrent knows and intends that physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions and/or label, and will therefore induce infringement of one or more claims of the '598 patent with the requisite intent.

28. On information and belief, if the FDA approves ANDA No. 210813, Torrent will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more of the method claims of the '598 patent, wherein Torrent's generic levomilnacipran products are a material part of the method claimed, wherein Torrent knows that physicians will

prescribe and patients will use Torrent's generic levomilnacipran products in practicing one or more of the methods claimed in the '598 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Torrent will thus contribute to the infringement of the '598 patent.

29. Plaintiffs will be substantially and irreparably harmed by Torrent's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT

(Infringement of the '937 Patent Under 35 U.S.C. § 271(e)(2))

30. Plaintiffs reallege and incorporate by reference paragraphs 1-29.

31. The '937 patent, titled "Crystalline Forms of (1S, 2R)-2-(Amino methyl)-N, N-Diethyl-1-Phenyl Cyclopropane Carboxamide," was duly and legally issued to inventors Mahendra G. Dedhiya and Rahul Surana by the PTO on October 21, 2014. The '937 patent is assigned to Forest Holdings and expires on May 23, 2032. This expiration date includes a 562-day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '937 patent is attached as Exhibit C. A true and correct copy of the Certificate Adjusting Patent Term is attached as Exhibit D.

32. NDA No. 204168 is directed to the use of Fetzima[®] for the treatment of MDD. The FDA approved NDA No. 204168 on July 25, 2013. The '937 patent is listed in the Orange Book for NDA No. 204168.

33. Plaintiff Forest Holdings is the assignee of the '937 patent. Allergan Sales is the NDA holder for extended release capsules containing 20 mg, 40 mg, 80 mg, and 120 mg of the active ingredient levomilnacipran in the United States, which are sold under the brand name Fetzima[®]. Allergan USA is a distributor of Fetzima[®] in the United States.

34. On information and belief, Torrent filed, or caused to be filed, ANDA No. 210813 with the FDA under 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and sell Torrent's generic levomilnacipran products in the United States before the '937 patent expires.

35. On information and belief, ANDA No. 210813 contains a Paragraph IV certification alleging that all claims of the '937 patent are invalid and/or not infringed.

36. Torrent sent, or caused to be sent, to Plaintiffs, Torrent's Notice Letter notifying Plaintiffs that Torrent submitted ANDA No. 210813, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Torrent's Notice Letter does not allege non-infringement of any claim of the '937 patent. However, Torrent's Notice Letter incorporates by reference its previous Notice Letter dated September 18, 2017 and all defenses raised in litigation C.A. No., 2:17-CV-10230-ES-SCM.

37. Plaintiffs received Torrent's Notice Letter no earlier than November 6, 2019. Plaintiffs filed this complaint within 45 days of receipt of Torrent's Notice Letter and, as a result, the 30-month stay under 21 C.F.R. § 314.107(b)(3) with respect to ANDA No. 210813 is no earlier than May 6, 2022.

38. On information and belief, Torrent seeks approval for at least one indication of Torrent's generic levomilnacipran products that are claimed in the '937 patent.

39. Under 35 U.S.C. § 271(e)(2)(A), Torrent infringed one or more claims of the '937 patent in violation of Plaintiffs' patent rights, by submitting an ANDA to the FDA that seeks approval to commercially market—before the '937 patent expires—Torrent's generic levomilnacipran products. The manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Torrent's generic levomilnacipran products would

directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '937 patent.

40. Plaintiffs will be substantially and irreparably harmed by Torrent's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT III FOR PATENT INFRINGEMENT

(Infringement of the '879 Patent Under 35 U.S.C. § 271(e)(2))

41. Plaintiffs reallege and incorporate by reference paragraphs 1-40.

42. The '879 patent, titled "Use of the Dextrogyral Enantiomer of Milnacipran for the Preparation of a Drug," was duly and legally reissued to inventors Jean Deregnaucourt and Richard Grosse by the PTO on December 25, 2012. The '879 patent is assigned to Pierre Fabre and expires on June 3, 2023. A true and correct copy of the '879 patent is attached as Exhibit E. An application for Patent Term Extension pursuant to 35 U.S.C. § 156 is currently pending.

43. NDA No. 204168 is directed to the use of Fetzima[®] for the treatment of MDD. The FDA approved NDA No. 204168 on July 25, 2013. The '879 patent is listed in the Orange Book for NDA No. 204168.

44. Plaintiff Pierre Fabre is the assignee of the '879 patent and Forest Holdings is the exclusive licensee of the '879 patent. Allergan Sales is the NDA holder for extended-release capsules containing 20 mg, 40 mg, 80 mg, and 120 mg of the active ingredient levomilnacipran in the United States, which are sold under the brand name Fetzima[®]. Allergan USA is a distributor of Fetzima[®] in the United States.

45. On information and belief, Torrent filed, or caused to be filed, ANDA No. 210813 with the FDA under 21 U.S.C. § 355(j), seeking approval to commercially manufacture, use, and

sell Torrent's generic levomilnacipran products in the United States before the '879 patent expires.

46. On information and belief, ANDA No. 210813 contains a Paragraph IV certification alleging that all claims of the '879 patent are invalid and/or not infringed.

47. Torrent sent, or caused to be sent, to Plaintiffs, Torrent's Notice Letter notifying Plaintiffs that Torrent submitted ANDA No. 210813, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). Torrent's Notice Letter does not allege non-infringement of any claim of the '879 patent. However, Torrent's Notice Letter incorporates by reference its previous Notice Letter dated September 18, 2017 and all defenses raised in litigation C.A. No., 2:17-CV-10230-ES-SCM.

48. Plaintiffs received Torrent's Notice Letter no earlier than November 6, 2019. Plaintiffs filed this complaint within 45 days of receipt of Torrent's Notice Letter and, as a result, the 30-month stay under 21 C.F.R. § 314.107(b)(3) with respect to ANDA No. 210813 is no earlier than May 6, 2022.

49. On information and belief, Torrent seeks approval for at least one indication of Torrent's generic levomilnacipran products that are claimed in the '879 patent.

50. Under 35 U.S.C. § 271(e)(2)(A), Torrent infringed one or more claims of the '879 patent in violation of Plaintiffs' patent rights, by submitting an ANDA to the FDA seeking approval to commercially market—before the '879 patent expires—Torrent's generic levomilnacipran products, the use of which would directly infringe one or more claims of the '879 patent, literally and/or through the doctrine of equivalents, and the manufacture, use, offer for sale, or sale within the United States, or importation into the United States would contribute

to or induce the direct infringement of one or more claims of the '879 patent, by users of Torrent's generic levomilnacipran products.

51. On information and belief, Torrent has knowledge of the '879 patent and filed ANDA No. 210813 seeking authorization to commercially manufacture, use, offer for sale, and sell Torrent's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210813, physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '879 patent.

52. On information and belief, Torrent knows and intends that physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions and/or label, and will therefore induce infringement of one or more claims of the '879 patent with the requisite intent.

53. On information and belief, if the FDA approves ANDA No. 210813, Torrent will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more of the method claims of the '879 patent, wherein Torrent's generic levomilnacipran products are a material part of the method claimed, wherein Torrent knows that physicians will prescribe and patients will use Torrent's generic levomilnacipran products in practicing one or more of the methods claimed in the '879 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Torrent will thus contribute to the infringement of the '879 patent.

54. Plaintiffs will be substantially and irreparably harmed by Torrent's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

COUNT IV FOR DECLARATORY JUDGMENT

(Declaratory Judgment of Patent Infringement of the '598 Patent Under
35 U.S.C. § 271 (b), and/or (c))

55. Plaintiffs reallege and incorporate by reference paragraphs 1-54.

56. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

57. On information and belief, Torrent, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Torrent's generic levomilnacipran products so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '598 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

58. On information and belief, Torrent has knowledge of the '598 patent and has filed ANDA No. 210813 seeking authorization to commercially manufacture, use, offer for sale, and sell Torrent's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210813, physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '598 patent in violation of Plaintiffs' patent rights.

59. On information and belief, Torrent knows and intends that physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to

Torrent's provided instructions in the '598 patent and/or label with the requisite intent under 35 U.S.C. § 271(b).

60. On information and belief, if the FDA approves ANDA No. 210813, Torrent will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more claims of the '598 patent, wherein Torrent's generic levomilnacipran products are a material part of the invention claimed in the '598 patent, wherein Torrent knows that physicians will prescribe and patients will use Torrent's generic levomilnacipran products for practicing one or more claims in the '598 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Torrent will thus contribute to the infringement of the '598 patent under 35 U.S.C. § 271(c).

61. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Torrent as to liability for infringement of the '598 patent claims. Torrent's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Torrent's threatened imminent actions.

COUNT V FOR DECLARATORY JUDGMENT

(Declaratory Judgment of Patent Infringement of the '937 Patent Under
35 U.S.C. § 271 (a))

62. Plaintiffs reallege and incorporate by reference paragraphs 1-61.

63. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

64. On information and belief, Torrent, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Torrent's generic

levomilnacipran products so labeled, if approved by the FDA, will infringe one or more claims of the '937 patent under 35 U.S.C. § 271(a) in violation of Plaintiffs' patent rights.

65. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Torrent as to liability for infringement of the '937 patent claims. Torrent's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Torrent's threatened imminent actions.

COUNT VI FOR DECLARATORY JUDGMENT

(Declaratory Judgment of Patent Infringement of the '879 Patent Under
35 U.S.C. § 271 (b), and/or (c))

66. Plaintiffs reallege and incorporate by reference paragraphs 1-65.

67. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(b)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. On information and belief, Torrent, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Torrent's generic levomilnacipran products so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '879 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

69. On information and belief, Torrent has knowledge of the '879 patent and filed ANDA No. 210813 seeking authorization to commercially manufacture, use, offer for sale, and sell Torrent's generic levomilnacipran products in the United States. On information and belief, if the FDA approves ANDA No. 210813, physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions

and/or label and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '879 patent, in violation of Plaintiffs' patent rights.

70. On information and belief, Torrent knows and intends that physicians, health care providers, and/or patients will use Torrent's generic levomilnacipran products according to Torrent's provided instructions in the '879 patent and/or label with the requisite intent under 35 U.S.C. § 271(b).

71. On information and belief, if the FDA approves ANDA No. 210813, Torrent will sell or offer to sell its generic levomilnacipran products specifically labeled for use in practicing one or more claims of the '879 patent, wherein Torrent's generic levomilnacipran products are a material part of the invention claimed in the '879 patent, wherein Torrent knows that physicians will prescribe and patients will use Torrent's generic levomilnacipran products for practicing one or more claims in the '879 patent, and wherein levomilnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. On information and belief, Torrent will thus contribute to the infringement of the '879 patent under 35 U.S.C. § 271(c).

72. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Torrent as to liability for infringement of the '879 patent claims. Torrent's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Torrent's threatened imminent actions.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in its favor as follows:

- a) declare that, under 35 U.S.C. § 271(e)(2)(A), Torrent infringed United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 by submitting ANDA No. 210813 to the FDA for approval to commercially manufacture, use, offer for sale, sell, or import into the United States Torrent's generic levomilnacipran products before the said patents expire;

- b) declare that Torrent's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Torrent's generic levomilnacipran products before United States Patent Nos. 8,481,598 and RE43,879 expire, would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271(b) and/or (c);
- c) declare that Torrent's commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Torrent's generic levomilnacipran products before United States Patent No. 8,865,937 expires, would constitute infringement of one or more claims of said patent under 35 U.S.C. § 271(a);
- d) declare that United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 are valid;
- e) order that the effective date of any FDA approval for Torrent's generic levomilnacipran products shall be no earlier than the expiration date of United States Patent Nos. 8,481,598, 8,865,937, and RE43,879, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);
- f) enjoin Torrent, and all persons acting in concert with Torrent, from seeking, obtaining, or maintaining final approval for ANDA No. 210813 until United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 expire, including any exclusivities or extensions to which Plaintiffs are or become entitled;
- g) enjoin Torrent, and all persons acting in concert with Torrent, from commercially manufacturing, using, offering for sale, or selling Torrent's generic levomilnacipran products within the United States, or importing Torrent's generic levomilnacipran products into the United States, until United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 expire, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);
- h) enjoin Torrent, and all persons acting in concert with Torrent, from commercially manufacturing, using, offering for sale, or selling Torrent's generic levomilnacipran products within the United States, or importing Torrent's generic levomilnacipran products into the United States, until United States Patent Nos. 8,481,598, 8,865,937, and RE43,879 expire, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 283;
- i) declare this to be an exceptional case and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4); and

- j) grant Plaintiffs such further and additional relief that this Court deems just and proper.

Respectfully submitted,

Dated: December 20, 2019

By: s/Liza M. Walsh

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Eleonore Ofosu-Antwi
Hector D. Ruiz
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Attorneys for Plaintiffs

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 401

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the matters captioned *Forest Laboratories, LLC, et al. v. Aurobindo Pharma USA, Inc., et al.*, Civ. A. No. 17-11679(ES)(SCM); *Forest Laboratories, LLC, et al. v. MSN Laboratories Private Limited et al.*, Civ. A. No. 17-10140(ES)(SCM); *Forest Laboratories, LLC, et al. v. Torrent Pharmaceuticals Limited, et al.*, Civ. A. No. 17-10273(ES)(SCM); *Forest Laboratories, LLC, et al. v. West-Ward Pharmaceuticals International Limited, et al.*, Civ. A. No. 17-10321(ES)(SCM); *Forest Laboratories, LLC, et al. v. Zydus Pharmaceuticals (USA) Inc.*, Civ. A. No. 17-10330(ES)(SCM) (collectively consolidated under *In re Fetzima*, Civ. A. No. 17-10230(ES)(SCM) because it involves the same Plaintiffs,¹ the same patents, and in all cases the Defendants are seeking approval to market generic versions of the same pharmaceutical product.

I further certify that the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this certification.

Dated: December 20, 2019

By: s/Liza M. Walsh

Liza M. Walsh
Eleonore Ofosu-Antwi
Hector D. Ruiz
Zahire D. Estrella-Chambers

¹ Pursuant to an internal corporate restructuring, Allergan Sales, LLC is the successor in interest to Forest Laboratories, LLC. Effective January 1, 2018, Forest Laboratories, LLC merged with and into Allergan Sales, LLC, with Allergan Sales, LLC as the surviving entity.

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RULE 201.1 CERTIFICATION

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

Dated: December 20, 2019

By: s/Liza M. Walsh

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