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

FOREST LABORATORIES HOLDINGS, LTD., ALLERGAN SALES, LLC and ALLERGAN USA, INC. **Plaintiffs,** **v.** **STRIDES PHARMA GLOBAL PTE LIMITED, and STRIDES PHARMA INC.** **Defendants.**	**C.A. No.:**

COMPLAINT FOR PATENT INFRINGEMENT

Forest Laboratories Holdings, LTD., Allergan Sales, LLC and Allergan USA, Inc. (collectively, "Plaintiffs" or "Forest") file this Complaint for patent infringement against Defendants Strides Pharma Global PTE Limited and Strides Pharma Inc. (collectively "Strides") under 35 U.S.C. §§ 271(e)(2), (b), and (c). This patent action concerns the pharmaceutical drug product Savella®. Forest hereby alleges as follows:

JURISDICTION AND PARTIES

1. Plaintiff Forest Laboratories Holdings, Ltd. ("Forest Holdings") is a corporation organized under the laws of the Republic of Ireland having offices at Canon's Court, 22 Victoria Street, Hamilton HM 12 Bermuda.

2. Allergan Sales, LLC ("Allergan Sales") is a limited liability company organized and existing under the laws of the State of Delaware, with a place of business at 2525 DuPont Drive, Irvine, California 92612.

3. Allergan USA, Inc. ("Allergan USA") is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

4. Upon information and belief, Defendant Strides Pharma Global PTE Limited ("Strides Global") is a Singapore corporation, having a principal place of business at No. 8 Eu Tong Sen Street, #15-93, The Central, Singapore—059818.

5. Upon information and belief, Defendant Strides Pharma Inc. ("Strides Inc.") is a New Jersey company, having its principal place of business at 2 Tower Center Blvd., Suite 1102, East Brunswick, NJ 08816.

6. Upon information and belief, Strides Inc. is an agent or affiliate of Strides Global and is acting as the agent of Strides Global with respect to Abbreviated New Drug Application ("ANDA") No. 207399.

7. This action contains the same patents and claims at issue in *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD. and Royalty Pharma Collection Trust v. Apotex Corp. and Apotex Inc.*, 1:13-cv-1602 (D. Del.) finding that all the asserted claims of U.S. Patent Nos. 6,602,911, 7,888,342, and 7,994,220 were valid and infringed by defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (*See* D.I. 287, D.I. 288, and D.I. 295 in 1:13-cv-1602.) (D. Del.)

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

9. Upon information and belief, Strides Inc. is a generic pharmaceutical company in the business of marketing, researching, and developing generic drug products. Upon information and belief, Strides Inc. directly and through its affiliates markets and sells drug products in and throughout the State of New Jersey and throughout the United States. Upon information and belief, Strides Inc. is incorporated in the State of New Jersey.

10. Strides "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*, 2017 WL 69716 (U.S. Jan. 9, 2017). Strides' "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. Upon information and belief, Strides "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, Strides will engage in marketing of its proposed ANDA products in New Jersey upon approval of its ANDA.

11. Strides' ANDA filing regarding the '911, '342, and '220 patents have a substantial connection with this district because it reliably and non-speculatively predicts activities by Strides Inc. in this district.

12. For the reasons stated above, this Court has personal jurisdiction over Strides. This Court also has personal jurisdiction over Strides because Strides has affirmatively availed itself of this Court's jurisdiction by filing counterclaims in this district, and has previously been sued in this district and has not challenged personal jurisdiction. *See, e.g., Takeda GMBH et al. v. Strides Pharma Inc., Strides Pharma Global PTE Limited*, 1:15-cv-03378 (D.N.J.) (D.I. 13).

13. Upon information and belief venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because Strides Global is incorporated in Singapore 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. Upon information and belief venue is proper in this Court under 28 U.S.C. § 1391(b) and (c), and § 1400(b) because on information and belief, Strides Inc. is incorporated in, has its principal place of business in, and currently sells over-the-counter medications in and throughout New Jersey.

15. Plaintiffs believe this case belongs in Delaware, and previously filed a suit against Strides in that district, but is concurrently filing this case in New Jersey out of an abundance of caution.

16. 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 '911 Patent Under 35 U.S.C. § 271(e)(2))

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

18. The '911 patent, titled "Methods of Treating Fibromyalgia," was duly and legally issued to inventors Jay D. Kranzler and Srinivas G. Rao by the United States Patent and Trademark Office ("PTO") on August 5, 2003. The '911 patent is currently assigned to Forest Holdings and expires on January 14, 2023. This expiration date includes a 435-day patent term extension granted by the PTO pursuant to 35 U.S.C. § 156(b). A true and correct copy of the '911 patent is attached as Exhibit A. A true and correct copy of the Certificate Extending Patent Term is attached as Exhibit B.

19. New Drug Application ("NDA") No. 022256 is directed to the use of Savella® in the management of fibromyalgia. The FDA approved NDA No. 022256 on January 14, 2009. The '911 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 022256. Allergan Sales is the NDA holder.

20. Allergan USA is the exclusive distributor of tablets containing 12.5 mg, 25 mg, 50 mg, and 100 mg of the active ingredient milnacipran hydrochloride in the United States, which are sold under the brand name Savella®.

21. Upon information and belief, Strides filed, or caused to be filed, ANDA No. 207399 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of milnacipran hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States before the expiration of the '911 patent.

22. Upon information and belief, ANDA No. 207399 contains a Paragraph IV certification alleging that all the claims of the '911 patents are invalid and one of the claims is not infringed.

23. Strides sent, or caused to be sent, to Plaintiffs a letter dated August 23, 2017 ("the Strides Notice Letter") notifying Plaintiffs that Strides had submitted ANDA No. 207399, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Strides Notice Letter alleges that claims 1-7 of the '911 patent are invalid and claim 4 of the '911 patent is not infringed.

24. Upon information and belief, Strides seeks approval of an indication for Strides' generic milnacipran product that is claimed in the '911 patent.

25. Under 35 U.S.C. § 271(e)(2)(A), Strides infringed one or more claims of the '911 patent in violation of Plaintiffs' patent rights, by submitting to the FDA an ANDA that seeks approval to commercially market—before the expiration date of the '911 patent—Strides' generic milnacipran product, the use of which would directly infringe one or more claims of the '911 patent, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the '911 patent, by users of Strides' generic milnacipran product.

26. Upon information and belief, Strides has knowledge of the '911 patent and has filed ANDA No. 207399 seeking authorization to commercially manufacture, use, offer for sale, and sell Strides' generic milnacipran product in the United States. Upon information and belief, if the FDA approves ANDA No. 207399, physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by Strides and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '911 patent.

27. Upon information and belief, Strides knows and intends that physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by Strides, and will therefore induce infringement of one or more of the claims of the '911 patent with the requisite intent.

28. Upon information and belief, if the FDA approves ANDA No. 207399, Strides will sell or offer to sell Strides' generic milnacipran product specifically labeled for use in practicing one or more of the method claims of the '911 patent, wherein Strides' generic milnacipran product is a material part of the method claimed, wherein Strides knows that

physicians will prescribe and patients will use Strides' generic milnacipran product in practicing one or more of the methods claimed in the '911 patent, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Strides will thus contribute to the infringement of the '911 patent.

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

30. The District of Delaware previously issued a final judgment in *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD. and Royalty Pharma Collection Trust v. Apotex Corp. and Apotex Inc.*, 1:13-cv-1602 finding that all the asserted claims of U.S. Patent Nos. 6,602,911, 7,888,342, and 7,994,220 were valid and infringed by defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (*See* D.I. 287, D.I. 288, and D.I. 295 in 1:13-cv-1602 (D. Del.).)

COUNT II FOR PATENT INFRINGEMENT
(Infringement of the '342 Patent Under 35 U.S.C. § 271(e)(2))

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

32. The '342 patent, titled "Methods of Treating Fibromyalgia Syndrome, Chronic Fatigue Syndrome and Pain," was duly and legally issued to inventors Jay D. Kranzler and Srinivas G. Rao by the PTO on February 15, 2011. The '342 patent is currently assigned to Forest Holdings and expires on November 5, 2021. A true and correct copy of the '342 patent is attached as Exhibit C.

33. NDA No. 022256 is directed to the use of Savella® in the management of fibromyalgia. The FDA approved NDA No. 022256 on January 14, 2009. The '342 patent is listed in the Orange Book for NDA No. 022256. Allergan Sales is the NDA holder.

34. Allergan USA is the exclusive distributor of tablets containing 12.5 mg, 25 mg, 50 mg, and 100 mg of the active ingredient milnacipran hydrochloride in the United States, which are sold under the brand name Savella®.

35. Upon information and belief, Strides filed, or caused to be filed, ANDA No. 207399 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of milnacipran hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States before the expiration of the '342 patent.

36. Upon information and belief, ANDA No. 207399 contains a Paragraph IV certification alleging that all the claims of the '342 patent are invalid and that one of the claims is not infringed.

37. Strides sent, or caused to be sent, to Plaintiffs the Strides Notice Letter notifying Plaintiffs that Strides had submitted ANDA No. 207399, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Strides Notice Letter alleges that claims 1-10 of the '342 patent are invalid and claim 10 of the '342 patent is not infringed.

38. Upon information and belief, Strides seeks approval of an indication for Strides' generic milnacipran product that is claimed in the '342 patent.

39. Under 35 U.S.C. § 271(e)(2)(A), Strides infringed one or more claims of the '342 patent in violation of Plaintiffs' patent rights, by submitting to the FDA an ANDA that seeks

approval to commercially market—before the expiration date of the ’342 patent—Strides’ generic milnacipran product, the use of which would directly infringe one or more claims of the ’342 patent, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the ’342 patent, by users of Strides’ generic milnacipran product.

40. Upon information and belief, Strides has knowledge of the ’342 patent and has filed ANDA No. 207399 seeking authorization to commercially manufacture, use, offer for sale, and sell Strides’ generic milnacipran product in the United States. Upon information and belief, if the FDA approves ANDA No. 207399, physicians, health care providers, and/or patients will use Strides’ generic milnacipran product in accordance with the instructions and/or label provided by Strides and will directly infringe, literally and/or through the doctrine of equivalents one or more claims of the ’342 patent.

41. Upon information and belief, Strides knows and intends that physicians, health care providers, and/or patients will use Strides’ generic milnacipran product in accordance with the instructions and/or label provided by Strides, and will therefore induce infringement of one or more of the claims of the ’342 patent with the requisite intent.

42. Upon information and belief, if the FDA approves ANDA No. 207399, Strides will sell or offer to sell Strides’ generic milnacipran product specifically labeled for use in practicing one or more of the method claims of the ’342 patent, wherein Strides’ generic milnacipran product is a material part of the method claimed, wherein Strides knows that physicians will prescribe and patients will use Strides’ generic milnacipran product in practicing one or more of the methods claimed in the ’342 patent, and wherein milnacipran is not a staple

article or commodity of commerce suitable for substantial noninfringing use. Strides will thus contribute to the infringement of the '342 patent.

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

44. The District of Delaware previously issued a final judgment in *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD. and Royalty Pharma Collection Trust v. Apotex Corp. and Apotex Inc.*, 1:13-cv-1602 finding that all the asserted claims of U.S. Patent Nos. 6,602,911, 7,888,342, and 7,994,220 were valid and infringed by defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (*See* D.I. 287, D.I. 288, and D.I. 295 in 1:13-cv-1602 (D. Del.).)

COUNT III FOR PATENT INFRINGEMENT
(Infringement of the '220 Patent Under 35 U.S.C. § 271(e)(2))

45. Plaintiffs reallege and incorporate by reference paragraphs 1-44.

46. The '220 patent, titled "Milnacipran for the Long-Term Treatment of Fibromyalgia Syndrome," was duly and legally issued to inventors Srinivas G. Rao, Michael Gendreau, and Jay D. Kranzler by the PTO on August 9, 2011. The '220 patent is currently assigned to Forest Holdings and expires on September 19, 2029. This expiration date includes a 1089 day patent term adjustment granted by the PTO pursuant to 35 U.S.C. § 154(b). A true and correct copy of the '220 patent is attached as Exhibit D. A true and correct copy of the Issue Notification reflecting the patent term adjustment is attached as Exhibit E.

47. NDA No. 022256 is directed to the use of Savella® in the management of fibromyalgia. The FDA approved NDA No. 022256 on January 14, 2009. The '220 patent is listed in the Orange Book for NDA No. 022256. Allergan Sales is the NDA holder.

48. Allergan USA is the exclusive distributor of tablets containing 12.5 mg, 25 mg, 50 mg, and 100 mg of the active ingredient milnacipran hydrochloride in the United States, which are sold under the brand name Savella®.

49. Upon information and belief, Strides filed, or caused to be filed, ANDA No. 207399 with the FDA under 21 U.S.C. § 355(j), seeking to obtain approval for the commercial manufacture, use, and sale of milnacipran hydrochloride tablets in 12.5 mg, 25 mg, 50 mg, and 100 mg dosage strengths in the United States before the expiration of the '220 patent.

50. Upon information and belief, ANDA No. 207399 contains a Paragraph IV certification alleging that all the claims of the '220 patent are invalid.

51. Strides sent, or caused to be sent, to Plaintiffs the Strides Notice Letter notifying Plaintiffs that Strides had submitted ANDA No. 207399, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B)(ii). The Strides Notice Letter alleges that claims 1-7 of the '220 patent are invalid. The Strides Notice Letter does not allege that any claims of the '220 patent are not infringed by Strides.

52. Upon information and belief, Strides seeks approval of an indication for Strides' generic milnacipran product that is claimed in the '220 patent.

53. Under 35 U.S.C. § 271(e)(2)(A), Strides infringed one or more claims of the '220 patent in violation of Plaintiffs' patent rights, by submitting to the FDA an ANDA that seeks

approval to commercially market—before the expiration date of the ’220 patent—Strides’ generic milnacipran product, the use of which would directly infringe one or more claims of the ’220 patent, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the ’220 patent, by users of Strides’ generic milnacipran product..

54. Upon information and belief, Strides has knowledge of the ’220 patent and has filed ANDA No. 207399 seeking authorization to commercially manufacture, use, offer for sale, and sell Strides’ generic milnacipran product in the United States. Upon information and belief, if the FDA approves ANDA No. 207399, physicians, health care providers, and/or patients will use Strides’ generic milnacipran product in accordance with the instructions and/or label provided by Strides and will directly infringe, literally and/or through the doctrine of equivalents one or more claims of the ’220 patent.

55. Upon information and belief, Strides knows and intends that physicians, health care providers, and/or patients will use Strides’ generic milnacipran product in accordance with the instructions and/or label provided by Strides, and will therefore induce infringement of one or more of the claims of the ’220 patent with the requisite intent.

56. Upon information and belief, if the FDA approves ANDA No. 207399, Strides will sell or offer to sell Strides’ generic milnacipran product specifically labeled for use in practicing one or more of the method claims of the ’220 patent, wherein Strides’ generic milnacipran product is a material part of the method claimed, wherein Strides knows that physicians will prescribe and patients will use Strides’ generic milnacipran product in practicing one or more of the methods claimed in the ’220 patent, and wherein milnacipran is not a staple

article or commodity of commerce suitable for substantial noninfringing use. Strides will thus contribute to the infringement of the '220 patent.

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

58. The District of Delaware previously issued a final judgment in *Forest Laboratories, Inc., Forest Laboratories Holdings, LTD. and Royalty Pharma Collection Trust v. Apotex Corp. and Apotex Inc.*, 1:13-cv-1602 finding that all the asserted claims of U.S. Patent Nos. 6,602,911, 7,888,342, and 7,994,220 were valid and infringed by defendants Mylan Inc. and Mylan Pharmaceuticals Inc. (*See* D.I. 287, D.I. 288, and D.I. 295 in 1:13-cv-1602 (D. Del.).)

COUNT IV FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '911 Patent Under 35 U.S.C. § 271(b), and/or (c))

59. Plaintiffs reallege and incorporate by reference paragraphs 1-58.

60. 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.

61. Upon information and belief, Strides, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Strides' generic milnacipran product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '911 patent under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

62. Upon information and belief, Strides has knowledge of the '911 patent and has filed ANDA No. 207399 seeking authorization to commercially manufacture, use, offer for sale, and sell Strides' generic milnacipran product in the United States. Upon information and belief, if the FDA approves ANDA No. 207399, physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by Strides and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '911 patent in violation of Plaintiffs' patent rights.

63. Upon information and belief, Strides knows and intends that physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by the '911 patent with the requisite intent under 35 U.S.C. § 271(b).

64. Upon information and belief, if the FDA approves ANDA No. 207399, Strides will sell or offer to sell Strides' generic milnacipran product specifically labeled for use in practicing one or more claims of the '911 patent, wherein Strides' generic milnacipran product is a material part of the invention claimed in the '911 patent, wherein Strides knows that physicians will prescribe and patients will use Strides' generic milnacipran product for practicing one or more claims in the '911 patent, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Strides will thus contribute to the infringement of the '911 patent under 35 U.S.C. § 271(c).

65. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Strides as to liability for Strides' infringement of the '911 patent claims. Strides' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Strides' threatened imminent actions.

COUNT V FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the '342 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. Upon information and belief, Strides, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Strides' generic milnacipran product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the '342 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs' patent rights.

69. Upon information and belief, Strides has knowledge of the '342 patent and has filed ANDA No. 207399 seeking authorization to commercially manufacture, use, offer for sale, and sell Strides' generic milnacipran product in the United States. Upon information and belief, if the FDA approves ANDA No. 207399, physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by Strides and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '342 patent, in violation of Plaintiffs' patent rights.

70. Upon information and belief, Strides knows and intends that physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by the '342 patent with the requisite intent under 35 U.S.C. § 271(b).

71. Upon information and belief, if the FDA approves ANDA No. 207399, Strides will sell or offer to sell Strides' generic milnacipran product specifically labeled for use in

practicing one or more claims of the ’342 patent, wherein Strides’ generic milnacipran product is a material part of the invention claimed in the ’342 patent, wherein Strides knows that physicians will prescribe and patients will use Strides’ generic milnacipran product for practicing one or more claims in the ’342 patent, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Strides will thus contribute to the infringement of the ’342 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 Strides as to liability for Strides’ infringement of the ’342 patent claims. Strides’ actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Strides’ threatened imminent actions.

COUNT VI FOR DECLARATORY JUDGMENT
(Declaratory Judgment of Patent Infringement of the ’220 Patent Under 35 U.S.C. § 271(b), and/or (c))

73. Plaintiffs reallege and incorporate by reference paragraphs 1-72.

74. 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.

75. Upon information and belief, Strides, upon the manufacture, sale, offer for sale, or sale within the United States, or importation into the United States of Strides’ generic milnacipran product so labeled, if approved by the FDA, will induce and contribute to the infringement of one or more claims of the ’220 patent, under 35 U.S.C. § 271(b) and/or (c), in violation of Plaintiffs’ patent rights.

76. Upon information and belief, Strides has knowledge of the ’220 patent and has filed ANDA No. 207399 seeking authorization to commercially manufacture, use, offer for sale,

and sell Strides' generic milnacipran product in the United States. Upon information and belief, if the FDA approves ANDA No. 207399, physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by Strides and will directly infringe, literally and/or through the doctrine of equivalents, one or more claims of the '220 patent in violation of Plaintiffs' patent rights.

77. Upon information and belief, Strides knows and intends that physicians, health care providers, and/or patients will use Strides' generic milnacipran product in accordance with the instructions and/or label provided by the '220 patent with the requisite intent under 35 U.S.C. § 271(b).

78. Upon information and belief, if the FDA approvesANDA No. 207399, Strides will sell or offer to sell Strides' generic milnacipran product specifically labeled for use in practicing one or more claims of the '220 patent, wherein Strides' generic milnacipran product is a material part of the invention claimed in the '220 patent, wherein Strides knows that physicians will prescribe and patients will use Strides' generic milnacipran product for practicing one or more claims in the '342 patent, and wherein milnacipran is not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Strides will thus contribute to the infringement of the '220 patent under 35 U.S.C. § 271(c).

79. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and Strides as to liability for Strides' infringement of the '220 patent claims. Strides' actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from Strides' threatened imminent actions.

PRAYER FOR RELIEF

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

a) declare that United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 are valid;

b) declare that, under 35 U.S.C. § 271(e)(2)(A), Strides infringed United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 by submitting ANDA No. 207399 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Strides' generic milnacipran product prior to the expiration of said patents;

c) declare that Strides' commercial manufacture, use or sale, or offer for sale in, or importation into the United States of Strides' generic milnacipran product prior to the expiration of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220 would constitute infringement of one or more claims of said patents under 35 U.S.C. § 271(b) and/or (c);

d) order that the effective date of any FDA approval of Strides' generic milnacipran product shall be no earlier than the expiration date of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) enjoin Strides, and all persons acting in concert with Strides, from seeking, obtaining, or maintaining final approval of ANDA No. 207399 until the expiration of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled;

f) enjoin Strides and all persons acting in concert with Strides, from commercially manufacturing, using, offering for sale, or selling Strides' generic milnacipran product within the United States, or importing Strides' generic milnacipran product into the United States, until the expiration of United States Patent Nos. 6,602,911, 7,888,342, and 7,994,220, including any exclusivities or extensions to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B);

g) 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

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

Respectfully submitted,

Dated: October 6, 2017

By: *s/Liza M. Walsh*

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RULE 11.2 CERTIFICATION

We hereby certify that, the matter in controversy is the subject of an action filed on October 5, 2017 and pending in the District Court for the District of Delaware 1:17-cv-01394.

Dated: October 6, 2017

By: *s/Liza M. Walsh*

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RULE 201.1 CERTIFICATION

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

Dated: October 6, 2017

By: *s/Liza M. Walsh*

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