UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VALEANT PHARMACEUTICALS INTERNATIONAL, INC., SALIX PHARMACEUTICALS, INC., PROGENICS PHARMACEUTICALS, INC., and WYETH LLC Plaintiffs, v. MYLAN PHARMACEUTICALS, INC., MYLAN LABORATORIES LTD., AND MYLAN INC., Defendants.	Civil Action No.: 17-06714 (SRC) (CLW) *Document Electronically Filed.*

FIRST AMENDED COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Valeant Pharmaceuticals International, Inc. ("Valeant"), Salix Pharmaceuticals, Inc. ("Salix"), Progenics Pharmaceuticals, Inc. ("Progenics"), and Wyeth LLC (collectively "Plaintiffs") by way of Amended Complaint against Defendants Mylan Pharmaceuticals, Inc. ("Mylan Pharmaceuticals"), Mylan Laboratories Ltd. ("Mylan Labs"), and Mylan Inc. (collectively "Mylan" or "Defendants") allege as follows:

THE PARTIES

1. Plaintiff Valeant is a corporation organized and existing under the laws of Canada. Its United States headquarters are located at 400 Somerset Corporate Blvd., Bridgewater, New Jersey 08807.

2. Plaintiff Salix is a corporation organized and existing under the laws of California, having its principal place of business at 8510 Colonnade Center Drive, Raleigh,

North Carolina 27615. Salix is the registered holder of approved New Drug Application No. 021964, which covers subcutaneous Relistor®.

3. Plaintiff Progenics is a corporation organized and existing under the laws of Delaware, having its principal place of business at One World Trade Center, 47th Floor, New York, New York 10007.

4. Plaintiff Wyeth LLC, formerly Wyeth, is a Delaware LLC, having places of business at 235 East 42nd Street, New York, New York 10017, and One Giralda Farms, Madison, New Jersey 07940.

5. Upon information and belief, Defendant Mylan Pharmaceuticals is a corporation organized and existing under the laws of West Virginia, having a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. Upon information and belief, Mylan Pharmaceuticals is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Labs.

6. Upon information and belief, Defendant Mylan Labs is a corporation organized and existing under the laws of India, having a place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India. Upon information and belief, Mylan Labs is a wholly-owned subsidiary of Mylan Inc. and an agent or affiliate of Mylan Pharmaceuticals.

7. Upon information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

NATURE OF THE ACTION

8. This is an action for infringement of United States Patent Nos. 9,669,096 ("the '096 patent") and 9,492,445 ("the '445 patent") arising under the United States patent laws, Title

35, United States Code, § 100 et seq., including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202. This action relates to Mylan's filing of an Abbreviated New Drug Applications ("ANDA") under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to market its generic methylnaltrexone bromide formulations for subcutaneous injection, 12 mg/0.6 mL single-use vial ("Mylan's generic methylnaltrexone vial product") and 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes ("Mylan's generic methylnaltrexone pre-filled syringe products") (collectively "Mylan's generic methylnaltrexone injectable products").

JURISDICTION AND VENUE

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. Upon information and belief, this court has jurisdiction over Mylan Pharmaceuticals. Upon information and belief, Mylan Pharmaceuticals is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Pharmaceuticals directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone injectable products. Upon information and belief Mylan Pharmaceuticals is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

11. Upon information and belief, this court has jurisdiction over Mylan Labs. Upon information and belief, Mylan Labs is in the business of manufacturing, marketing, importing,

and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Labs directly, or indirectly, manufactures, markets, and sells generic drug products throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone injectable products. Upon information and belief Mylan Labs purposefully has conducted and continues to conduct business in this judicial district.

12. Upon information and belief, this court has jurisdiction over Mylan Inc. Upon information and belief, Mylan Inc. is in the business of manufacturing, marketing, importing, and selling pharmaceutical products, including generic drug products. Upon information and belief, Mylan Inc. directly, or indirectly, manufactures, markets, and sells generic drug products, including generic products manufactured by Mylan Pharmaceuticals and/or Mylan Labs, throughout the United States and in this judicial district, and this judicial district is a likely destination for Mylan's generic methylnaltrexone injectable products. Upon information and belief Mylan Inc. is registered to do business in New Jersey and purposefully has conducted and continues to conduct business in this judicial district.

13. Upon information and belief, Mylan Pharmaceuticals is registered to do business in New Jersey under business ID 0100214277, is registered as a drug manufacturer and wholesale drug distributer under registration number 5003762, and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for the receipt of process.

14. Upon information and belief, Mylan Inc. is registered to do business in New Jersey under business ID 010097192 and has appointed Corporation Service Company, 830 Bear Tavern Road, West Trenton, NJ 08628, as its registered agent for the receipt of process.

15. Mylan's ANDA Nos. 208592 and 208594 are the subject of an on-going infringement litigation in the District of New Jersey: *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 2:15-cv-08180 (consolidated).

16. Mylan Pharmaceuticals and Mylan Inc. avail themselves of the rights, benefits, and privileges of this Court by filing complaints in the District of New Jersey: *Mylan Pharmaceuticals, Inc. v. Celgene Corporations,* Civil Action No. 2:14-cv-02094; and *Mylan Inc. et al. v. Apotex Inc. et al.*, Civil Action No. 3:14-cv-04560.

17. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceutical and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); and *Janssen Products, L.P. et al. v. Lupin Limited et al.,* Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

18. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. availed themselves of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following prior District of New Jersey actions: *Baxter Healthcare Corp. et al. v. Agila Specialties Private Limited et al.*, Civil Action No. 1:14-cv-07094 (Mylan Pharmaceuticals and Mylan Labs); *Horizon Pharma, Inc., et al. v. Mylan Pharmaceuticals Inc.*, et al., Civil Action No. 3:15-cv-03327 (Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc.); *Astrazeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 3:13-cv-04022 (Mylan Pharmaceuticals, Mylan

Labs, and Mylan Inc.); and *Janssen Products, L.P. et al. v. Lupin Limited et al.*, Civil Action No. 2:10-cv-05954 (Mylan Pharmaceuticals and Mylan Inc.).

19. Upon information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and § 1400(b).

20. Mylan Pharmaceuticals, Mylan Labs, and Mylan Inc. did not contest venue in this judicial district in at least the following actions: *Sanofi-Aventis U.S. LLC, et al. v. Mylan Laboratories Ltd.*, Civil Action No. 3:15-cv-3392 (Mylan Labs); *Astrazeneca AB et al. v. Mylan Laboratories Limited et al.*, Civil Action No. 3:12-cv-01378 (Mylan Labs, Mylan Inc.); *Ortho-McNeil-Janssen Pharmaceuticals, Inc. v. Mylan Inc. et al.*, Civil Action No. 2:10-cv-06018 (Mylan Inc., Mylan Pharmaceuticals); *Schering Corporation et al. v. Mylan Pharmaceuticals Inc. et al.,* Civil Action No. 2:10-cv-03085 (Mylan Pharmaceuticals); *Hoffman-La Roche Inc. v. Mylan Inc. et al.*, Civil Action No. 09-cv-1692 (Mylan Inc., Mylan Pharmaceuticals); *Warner Chilcott Company, LLC v. Impax Laboratories, Inc. et al.*, Civil Action No. 08-cv-6034 (Mylan Pharmaceuticals, Mylan Inc.).

THE PATENTS IN SUIT

21. The PTO issued the ’096 patent on June 6, 2017. The ’096 patent claims, *inter alia*, pharmaceutical preparations of methylnaltrexone. Plaintiffs hold all substantial rights in the ’096 patent and have the right to sue for infringement thereof. A copy of the ’096 patent is attached hereto as Exhibit A.

22. The PTO issued the ’445 patent on November 15, 2016. The ’445 patent claims, *inter alia*, compositions of methylnaltrexone and methods of using the same. Plaintiffs hold all substantial rights in the ’445 patent and have the right to sue for infringement thereof. A copy of the ’445 patent is attached hereto as Exhibit B.

23. Salix is the holder of New Drug Application ("NDA") No. 021964 for subcutaneous Relistor®. In conjunction with NDA No. 021964, the '096 and '445 patents are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book"), together with U.S. Patent Nos. 8,247,425, 8,420,663, 8,552,025, 8,822,490, and 9,180,125, which are the subject of an on-going infringement litigation in the District of New Jersey: *Valeant Pharmaceuticals et al. v. Mylan Pharmaceuticals Inc., et al.*, Civil Action No. 2:15-cv-08180 (consolidated).

24. Methylnaltrexone bromide formulations for subcutaneous injection, 12 mg/0.6 mL single-use vial, and 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes are sold in the United States under the trademark Relistor®.

MYLAN'S INFRINGING ANDA NO. 208592 SUBMISSION

25. Upon information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 208592, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

26. Upon information and belief, Mylan's ANDA No. 208592 seeks FDA approval to sell in the United States Mylan's generic methylnaltrexone bromide formulation for subcutaneous injection, 12 mg/0.6 mL single-use vial, intended to be a generic version of Relistor® 12 mg/0.6 mL single-use vials.

27. Salix, Progenics and Wyeth received a letter from Mylan Pharmaceuticals dated July 19, 2017, purporting to be a Notice of Certification for ANDA No. 208592 ("Mylan's ANDA No. 208592 notice letter") under Section 505(j)(2)(B)(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv), and 21 C.F.R. § 314.95. Mylan's ANDA No. 208592 notice letter was addressed to Wyeth at Madison, New Jersey.

28. Mylan's ANDA No. 208592 notice letter states that "Mylan Pharmaceuticals Inc. is the authorized U.S. contact for applicant Mylan Laboratories Limited . . . with respect to ANDA No. 208-592 and related ANDA No. 208-594." Mylan's notice letter refers to Mylan Pharmaceuticals and Mylan Labs collectively as "Mylan."

29. Mylan's ANDA No. 208592 notice letter alleges that Mylan has submitted to the FDA ANDA No. 208592 seeking FDA approval to sell Mylan's generic methylnaltrexone vial product, intended to be a generic version of Relistor® 12 mg/0.6 mL single-use vials.

30. Mylan's ANDA No. 208592 notice letter states that the "FDA received Mylan's ANDA, which contained the required bioavailability or bioequivalence data or information" for Mylan's generic methylnaltrexone vial product and Relistor® 12 mg/0.6 mL single-use vials.

31. Mylan's ANDA No. 208592 notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claim of the '096 patent.

32. The '445 patent is listed in the Orange Book in conjunction with NDA No. 021964 for subcutaneous Relistor®.

33. Upon information and belief, ANDA No. 208592 seeks approval of Mylan's generic methylnaltrexone vial product that is the same, or substantially the same, as Relistor® 12 mg/0.6 mL single-use vials.

34. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 208592 complained of herein were done with the cooperation, the participation, the assistance of, and at least in part for the benefit of Mylan Inc. and Mylan Labs.

MYLAN'S INFRINGING ANDA NO. 208594 SUBMISSION

35. Upon information and belief, Mylan filed or caused to be filed with the FDA ANDA No. 208594, under Section 505(j) of the Act and 21 U.S.C. § 355(j).

36. Upon information and belief, Mylan's ANDA No. 208594 seeks FDA approval to sell in the United States Mylan's generic methylnaltrexone bromide for subcutaneous injection, 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes, intended to be a generic version of Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes.

37. Salix, Progenics and Wyeth received a letter from Mylan Pharmaceuticals dated July 19, 2017, purporting to be a Notice of Certification for ANDA No. 208594 ("Mylan's ANDA No. 208594 notice letter") Section 505(j)(2)(B)(iv) of the Act, 21 U.S.C. § 355(j)(2)(B)(iv), and 21 C.F.R. § 314.95. Mylan's ANDA No. 208594 notice letter was addressed to Wyeth at Madison, New Jersey.

38. Mylan's ANDA No. 208594 notice letter states that "Mylan Pharmaceuticals Inc. is the authorized U.S. contact for applicant Mylan Laboratories Limited . . . with respect to ANDA No. 208-594 and related ANDA No. 208-592." Mylan's ANDA No. 208594 notice letter refers to Mylan Pharmaceuticals and Mylan Labs collectively as "Mylan."

39. Mylan's ANDA No. 208594 notice letter alleges that Mylan has submitted to the FDA ANDA No. 208594 seeking FDA approval to sell Mylan's generic methylnaltrexone pre-filled syringe products, intended to be generic versions of Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes.

40. Mylan's ANDA No. 208594 notice letter states that the "FDA received Mylan's ANDA, which contained the required bioavailability or bioequivalence data or information" for

Mylan's generic methylnaltrexone pre-filled syringe products and Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL single-use pre-filled syringes.

41. Mylan's ANDA No. 208594 notice letter, which is required by statute and regulation to provide a full and detailed explanation regarding any non-infringement defenses, does not allege non-infringement of any claim of the '096 patent.

42. The '445 patent is listed in the Orange Book in conjunction with NDA No. 021964 for subcutaneous Relistor®.

43. Upon information and belief, ANDA No. 208594 seeks approval of Mylan's generic methylnaltrexone pre-filled syringe products that are the same, or substantially the same, as Relistor® 8 mg/0.4 mL and 12 mg/0.6 mL pre-filled syringes.

44. Upon information and belief, Mylan Pharmaceuticals' actions relating to ANDA No. 208594 complained of herein were done with the cooperation, the participation, the assistance of, and at least in art for the benefit of Mylan Inc. and Mylan Labs.

COUNT I AGAINST MYLAN

Infringement of the '096 Patent under § 271(e)(2) (ANDA No. 208592)

45. Paragraphs 1-44 are incorporated herein as set forth above.

46. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone vial product before the expiration date of the '096 patent.

47. Upon information and belief, Mylan's generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '096 patent.

48. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

COUNT II AGAINST MYLAN

Declaratory Judgment of Infringement of the '096 Patent (ANDA No. 208592)

49. Paragraphs 1-48 are incorporated herein as set forth above.

50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

51. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

52. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone vial product before the expiration date of the '096 patent, including Mylan's filing of ANDA No. 208592.

53. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

54. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will constitute infringement of at least one claim of the '096 patent.

COUNT III AGAINST MYLAN

Infringement of the '096 Patent under § 271(e)(2) (ANDA No. 208594)

55. Paragraphs 1-54 are incorporated herein as set forth above.

56. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '096 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208594 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '096 patent.

57. Upon information and belief, Mylan's generic methylnaltrexone pre-filled syringe products will, if approved and marketed, infringe at least one claim of the '096 patent.

58. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone pre-filled syringe products, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

COUNT IV AGAINST MYLAN

Declaratory Judgment of Infringement of the '096 Patent (ANDA No. 208594)

59. Paragraphs 1-58 are incorporated herein as set forth above.

60. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

61. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

62. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '096 patent, including Mylan's filing of ANDA No. 208594.

63. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '096 patent.

64. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will constitute infringement of at least one claim of the '096 patent.

COUNT V AGAINST MYLAN

Infringement of the '445 Patent under § 271(e)(2) (ANDA No. 208592)

65. Paragraphs 1-64 are incorporated herein as set forth above.

66. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208592 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone vial product before the expiration date of the '445 patent.

67. Upon information and belief, Mylan's generic methylnaltrexone vial product will, if approved and marketed, infringe at least one claim of the '445 patent.

68. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone vial product, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

COUNT VI AGAINST MYLAN

Declaratory Judgment of Infringement of the '445 Patent (ANDA No. 208592)

69. Paragraphs 1-68 are incorporated herein as set forth above.

70. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

71. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

72. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone vial product before the expiration date of the '445 patent, including Mylan's filing of ANDA No. 208592.

73. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

74. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone vial product will constitute infringement of at least one claim of the '445 patent.

COUNT VII AGAINST MYLAN

Infringement of the '445 Patent under § 271(e)(2) (ANDA No. 208594)

75. Paragraphs 1-74 are incorporated herein as set forth above.

76. Under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '445 patent by submitting, or causing to be submitted to the FDA, ANDA No. 208594 seeking approval for the commercial marketing of Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '445 patent.

77. Upon information and belief, Mylan's generic methylnaltrexone pre-filled syringe products will, if approved and marketed, infringe at least one claim of the '445 patent.

78. Upon information and belief, Mylan will, through the manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone pre-filled syringe products, directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

COUNT IV AGAINST MYLAN

Declaratory Judgment of Infringement of the '445 Patent (ANDA No. 208594)

79. Paragraphs 1-78 are incorporated herein as set forth above.

80. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

81. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

82. Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Mylan's generic methylnaltrexone pre-filled syringe products before the expiration date of the '445 patent, including Mylan's filing of ANDA No. 208594.

83. Upon information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '445 patent.

84. Plaintiffs are entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's generic methylnaltrexone pre-filled syringe products will constitute infringement of at least one claim of the '445 patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment in their favor and against Mylan on the patent infringement claims set forth above and respectfully request that this Court:

1. Enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '096 patent by submitting or causing to be submitted ANDA No. 208592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone vial product before the expiration of the '096 patent;

2. Enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '096 patent by submitting or causing to be submitted ANDA No. 208594 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone pre-filled syringe products before the expiration of the '096 patent;

3. Enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '445 patent by submitting or causing to be submitted ANDA No. 208592 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone vial product before the expiration of the '445 patent;

4. Enter judgment that, under 35 U.S.C. § 271(e)(2), Mylan has infringed at least one claim of the '445 patent by submitting or causing to be submitted ANDA No. 208594 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of Mylan's generic methylnaltrexone pre-filled syringe products before the expiration of the '445 patent;

5. Order that the effective date of any approval by the FDA of Mylan's generic methylnaltrexone vial product be a date that is not earlier than the expiration of the '096 and '445 patents or such later date as the Court may determine;

6. Order that the effective date of any approval by the FDA of Mylan's generic methylnaltrexone pre-filled syringe products be a date that is not earlier than the expiration of the '096 and '445 patents or such later date as the Court may determine;

7. Enjoin Mylan from the commercial manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone vial product until expiration of the '096 and '445 patents or such later date as the Court may determine;

8. Enjoin Mylan from the commercial manufacture, use, import, offer for sale, and/or sale of Mylan's generic methylnaltrexone pre-filled syringe products until expiration of the '096 and '445 patents or such later date as the Court may determine;

9. Enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of Mylan's ANDA No. 208592 until expiration of the '096 and '445 patents;

10. Enjoin Mylan and all persons acting in concert with Mylan from seeking, obtaining, or maintaining approval of Mylan's ANDA No. 208594 until expiration of the '096 and '445 patents;

11. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs costs, expenses, and disbursements in this action, including reasonable attorney's fees; and

12. Award Plaintiffs such further and additional relief as this Court deems just and proper.

Dated: September 18, 2017
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

William P. Deni, Jr.
Charles H. Chevalier
J. Brugh Lower
GIBBONS P.C.
One Gateway Center
Newark, New Jersey 07102
Tel: (973) 596-4500
Fax: (973) 596-0545
wdeni@gibbonslaw.com
cchevalier@gibbonslaw.com
jlower@gibbonslaw.com

Bryan C. Diner
M. Andrew Holtman
Justin J. Hasford
Megan Leinen Johns
Kristi L. McIntyre
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, NW
Washington, DC 20001-4413
Tel: (202) 408-4000

Jessica M. Lebeis
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
271 17th Street, NW
Suite 1400
Atlanta, GA 30363-6209
Tel: (404) 653-6400

Attorneys for Plaintiffs