

Leda Dunn Wettre
ROBINSON, WETTRE & MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
Telephone: (973) 690-5400
Facsimile: (973) 466-2760
Lwettre@rwmlegal.com

OF COUNSEL:
William G. Gaede, III
Bhanu K. Sadasivan
Shane G. Smith
Evan Boetticher
MCDERMOTT WILL & EMERY LLP
275 Middlefield Road, Suite 100
Menlo Park, CA 94025
Telephone: (650) 815-7400
Facsimile: (650) 815-7401

Attorneys for Plaintiff Depomed, Inc.

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

DEPOMED, INC.

Plaintiff,

v.

IMPAX LABORATORIES, INC., PAR
PHARMACEUTICAL COMPANIES, INC.
and PAR PHARMACEUTICAL, INC.

Defendants.

CIVIL ACTION NO: 12-02154 (JAP)(TJB)

**SECOND AMENDED COMPLAINT FOR
PATENT INFRINGEMENT**

Plaintiff Depomed, Inc., complains against defendants Impax Laboratories, Inc. (“Impax”) and Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, “Par”) as follows:

THE PARTIES

1. Plaintiff Depomed, Inc. (“Depomed”), is a corporation organized under the laws of California, having its principal place of business in Menlo Park, California.

2. Upon information and belief, Impax is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, California 94544. On information and belief, Impax is in the business of developing, manufacturing, distributing and/or selling generic pharmaceutical products for the U.S. market, including in this judicial district.

3. Upon information and belief, Par Pharmaceutical Companies, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. On information and belief, Par Pharmaceutical Companies, Inc. is a holding company that operates principally through its wholly-owned subsidiary, Par Pharmaceutical, Inc. and is in the business of developing, manufacturing, and distributing generic pharmaceutical products for the U.S. market, including in this judicial district. On information and belief, Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. are agents of each other and/or work in concert with each other with respect to the development, regulatory approval, marketing, sale and distribution of generic pharmaceuticals products throughout the United States, including in this district.

4. Upon information and belief, Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 300 Tice Boulevard, Woodcliff Lake, New Jersey 07677. On information and belief, Par Pharmaceutical, Inc. is in the business of developing, manufacturing, and distributing generic pharmaceutical products for the U.S. market, including in this judicial district. On information

and belief, Par Pharmaceutical, Inc.'s preparation and submission of Abbreviated New Drug Application ("ANDA") No. 203757 was done collaboratively with, and for the benefit of, Par Pharmaceutical Companies, Inc. On information and belief, Par Pharmaceutical, Inc. is the alter ego of Par Pharmaceutical Companies, Inc. where a unity of interest and ownership exists between Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. such that separate personalities of the two do not in reality exist.

JURISDICTION AND VENUE

5. This is an action for patent infringement arising under the patent laws of the United States (Title 35 of the United States Code) and arising from each of Impax and Par filing an ANDA with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Depomed's product Gralise[®] prior to the expiration of U.S. Patent Nos. 6,340,475, 6,488,962, 6,635,280, 6,723,340, 7,438,927, 7,731,989, 8,192,756 and 8,252,332. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Impax because, *inter alia*, Impax has purposely availed itself of the benefits and protections of New Jersey's laws such that it should reasonably anticipate being haled into court here. On information and belief, Impax has had persistent, systematic and continuous contacts with New Jersey as set forth below.

7. Impax has a past practice of consenting to personal jurisdiction in this Court for other litigation matters. For example, Impax has consented to personal jurisdiction in *Abbott Laboratories v. Impax Laboratories, Inc.*, Civil Action No. 2:10-cv-01322; *Elan Pharma Int'l Ltd. v. Impax Laboratories, Inc.*, Civil Action 2:09-cv-05541; *Pfizer Inc. v. Impax Laboratories,*

Inc., Civil Action 2:11-cv-03130 and *Warner Chilcott Labs. Ireland Ltd. v. Impax Laboratories, Inc.*, Civil Action 2:09-cv-01233.

8. According to Impax's website, Impax currently manufactures and markets 102 generic pharmaceutical products. Upon information and belief, Impax sells generic pharmaceutical products to wholesalers, large retail drug chains as well as other third party customers for sale in New Jersey and elsewhere in the United States and earns revenue from the distribution and sale in New Jersey of its generic pharmaceutical products.

9. According to Impax's website, Impax has 66 approved ANDAs and currently has 39 pending ANDAs. Upon information and belief, Impax is the named applicant on ANDAs for numerous generic drugs, including many that are sold and used in New Jersey and elsewhere in the United States.

10. Upon information and belief, Impax will manufacture, market, and/or sell within the United States the generic 300 mg and 600 mg Gabapentin Tablets described in Impax's ANDA no. 203666 if FDA approval is granted. If ANDA no. 203666 is approved, the generic 300 mg and 600 mg Gabapentin Tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.

11. This Court has personal jurisdiction over Par because, *inter alia*, Par resides in New Jersey, conducts business in the State of New Jersey, has availed itself of the rights and benefits under New Jersey law, and has engaged in substantial and continuous contacts in the State of New Jersey. Moreover, Par has a past practice of consenting to personal jurisdiction in this Court for other litigation matters. For example, Par consented to personal jurisdiction in

Sanofi-Aventis U.S. LLC v. Mustafa Nevzat Ilac Sanayii A.S., Civil Action No. 3:08-cv-00263-JAP-DEA; *Novartis Corp. v. Par Pharmaceutical Companies, Inc.*, Civil Action No. 2:06-cv-06283-HAA-ES; and *Ortho-McNeil Pharmaceutical Inc. v. Kali Laboratories, Inc.*, Civil Action No. 2:06-cv-03533-DMC-MF.

12. Upon information and belief, Par Pharmaceutical Companies, Inc. operates in the United States as two business segments: Par Pharmaceutical, the generic products division and Strativa Pharmaceuticals, the branded products division. As of December 31, 2011, the generic product lines included approximately 55 product names each with an associated ANDA. On information and belief, Par Pharmaceutical, Inc. is the named applicant on ANDAs for numerous generic drugs, including many that are sold and used in New Jersey and elsewhere in the United States.

13. Upon information and belief, Par Pharmaceutical Companies, Inc. participated in, contributed to, aided, abetted and/or induced the submission to the FDA of ANDA No. 203757, the ANDA at issue in this litigation.

14. Upon information and belief, Par will manufacture, market, and/or sell within the United States the generic 300 mg and 600 mg Gabapentin Tablets described in Par's ANDA no. 203757 if FDA approval is granted. If ANDA no. 203757 is approved, the generic 300 mg and 600 mg Gabapentin Tablets charged with infringing the patents-in-suit, would, among other things, be marketed and distributed in New Jersey, prescribed by physicians in New Jersey, and dispensed by pharmacies located within New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.

15. A related lawsuit involving three different defendants but the same branded product and some of the same patents are currently pending in this Court. On March 2, 2012,

Depomed filed suit in this Court against Actavis Elizabeth LLC and Actavis Inc. (collectively “Actavis”), Watson Laboratories, Inc. – Florida, Watson Pharma, Inc. and Watson Pharmaceuticals, Inc. (collectively “Watson”) and Incepta Pharmaceuticals Co. Ltd. (“Incepta”) seeking a judgment of infringement of the same six patents at issue in this case. Each of the defendants in that case have also filed an ANDA seeking approval to market a generic version of Depomed’s product Gralise[®] prior to the expiration of the patents in suit.

16. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391(b) and 1400.

THE PATENTS-IN-SUIT

17. On January 22, 2002, United States Patent No. 6,340,475 (the “‘475 Patent”) entitled “Extending the Duration of Drug Release Within the Stomach During the Fed Mode” issued to Depomed as assignee of the inventors. (A copy of the ‘475 Patent is attached as Exhibit 1.)

18. On December 3, 2002, United States Patent No. 6,488,962 (the “‘962 Patent”) entitled “Tablet Shapes To Enhance Gastric Retention of Swellable Controlled-Release Oral Dosage Forms” issued to Depomed as assignee of the inventors. (A copy of the ‘962 Patent is attached as Exhibit 2.)

19. On October 21, 2003, United States Patent No. 6,635,280 (the “‘280 Patent”) entitled “Extending the Duration of Drug Release Within the Stomach During the Fed Mode” issued to Depomed as assignee of the inventors. (A copy of the ‘280 Patent is attached as Exhibit 3.)

20. On April 20, 2004, United States Patent No. 6,723,340 (the “‘340 Patent”) entitled “Optimal Polymer Mixtures for Gastric Retentive Tablets” issued to Depomed as assignee of the inventors. (A copy of the ‘340 Patent is attached as Exhibit 4.)

21. On October 21, 2008, United States Patent No. 7,438,927 (the “‘927 Patent”) entitled “Methods of Treatment Using a Gastric Retained Gabapentin Dosage” issued to Depomed as assignee of the inventors. (A copy of the ‘927 Patent is attached as Exhibit 5.)

22. On June 8, 2010, United States Patent No. 7,731,989 (the “‘989 Patent”) entitled “Gastric Retained Gabapentin Dosage Form” issued to Depomed as assignee of the inventors. (A copy of the ‘989 Patent is attached as Exhibit 6.)

23. On June 5, 2012, United States Patent No. 8,192,756 (the “‘756 Patent”) entitled “Gastric Retained Gabapentin Dosage Form” issued to Depomed as assignee of the inventors. (A copy of the ‘756 Patent is attached as Exhibit 7.)

24. On August 28, 2012, United States Patent No. 8,252,332 (the “‘332 Patent”) entitled “Gastric Retained Gabapentin Dosage Form” issued to Depomed as assignee of the inventors. (A copy of the ‘332 Patent is attached as Exhibit 8.)

GRALISE®

25. Depomed holds approved New Drug Application No. 022544 (the “Depomed NDA”) for gabapentin extended-release tablets in 300 and 600 mg dosage strengths, which are sold under the trade name Gralise®.

26. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the ‘475, ‘962, ‘280, ‘340, ‘927, ‘989, ‘756, and ‘332 Patents are listed in the FDA publication, “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Gralise® in the 300 mg dosage.

27. Pursuant to 21 U.S.C. §§ 355(b)(1) and 355(c)(2), and attendant FDA regulations, the ‘475, ‘962, ‘280, ‘340, ‘927, ‘989, ‘756, and ‘332 patents are listed in the FDA publication,

“Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”), with respect to Gralise[®] in the 600 mg dosage.

IMPAX’S ANDA

28. On information and belief, Impax submitted ANDA No. 203666 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of Gabapentin Tablets in the 300 and 600 mg dosage strengths. The Gabapentin Tablets described in the Impax ANDA are herein referred to as the “Impax Products,” the 300 mg dosage strength is referred to as the “Impax 300 mg Product,” and the 600 mg dosage strength is referred to as the “Impax 600 mg Product.”

29. On information and belief, Impax contends that the Impax 300 mg Product is bioequivalent to the 300 mg dosage form of Gralise and that the Impax 600 mg Product is bioequivalent to the 600 mg dosage form of Gralise.

30. On information and belief, the Impax ANDA refers to and relies upon the Gralise[®] NDA and contains data that demonstrate the bioequivalence of the Impax Products and Gralise[®].

31. Depomed received from Impax a letter, dated March 26, 2012, stating that Impax had included a certification in the Impax ANDA that the claims of the ‘475, ‘280, ‘989, ‘927, ‘340, and ‘962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Impax Products (the “Impax Notification Letter”). (A true and correct copy of the Impax Notification Letter is attached hereto as Exhibit 9.)

PAR’S ANDA

32. On information and belief, Par submitted ANDA No. 203757 to the FDA, seeking approval to engage in the commercial manufacture, use or sale of Gabapentin Tablets in the 300

and 600 mg dosage strengths. The Gabapentin Tablets described in the Par ANDA are herein referred to as the “Par Products,” the 300 mg dosage strength is referred to as the “Par 300 mg Product,” and the 600 mg dosage strength is referred to as the “Par 600 mg Product.”

33. On information and belief, Par contends that the Par 300 mg Product is bioequivalent to the 300 mg dosage form of Gralise and that the Par 600 mg Product is bioequivalent to the 600 mg dosage form of Gralise.

34. On information and belief, the Par ANDA refers to and relies upon the Gralise® NDA and contains data that demonstrate the bioequivalence of the Par Products and Gralise®.

35. Depomed received from Par a letter, dated March 27, 2012, stating that Par had included a certification in the Par ANDA that the claims of the ‘475, ‘280, ‘989, ‘927, ‘340, and ‘962 Patents are invalid or will not be infringed by the commercial manufacture, use, or sale of the Par Products (the “Par Notification Letter”). (A true and correct copy of the Par Notification Letter is attached hereto as Exhibit 10.)

36. Depomed received from Par a letter, dated August 22, 2012, stating that Par had included a certification that in Par’s opinion the claims of the ‘756 Patent are invalid or will not be infringed by the commercial manufacture, use, or sale of the Par Products (the “Par Notification Letter”). (A true and correct copy of the Par Notification Letter is attached hereto as Exhibit 11.)

FIRST CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the ‘475 Patent by Impax)

37. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

38. On information and belief, Impax has infringed the ‘475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from

the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the '475 Patent.

39. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax's infringement of the asserted claims of the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

40. Impax's commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the term of the '475 Patent, would further infringe the asserted claims of the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

41. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the asserted claims of the '475 Patent.

42. Plaintiff has no adequate remedy at law.

43. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**SECOND CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '475 Patent by Par)**

44. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

45. On information and belief, Par has infringed the '475 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '475 Patent.

46. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

47. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '475 Patent, would further infringe the asserted claims of the asserted claims of the '475 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

48. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '475 Patent.

49. Plaintiff has no adequate remedy at law.

50. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**THIRD CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '962 Patent by Impax)**

51. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

52. On information and belief, Impax has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the '962 Patent.

53. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax

ANDA. Accordingly, an actual and immediate controversy exists regarding Impax's infringement of the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

54. Impax's commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the term of the '962 Patent, would further infringe the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

55. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the '962 Patent.

56. Plaintiff has no adequate remedy at law.

57. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**FOURTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '962 Patent by Par)**

58. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

59. On information and belief, Par has infringed the '962 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '962 Patent.

60. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

61. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '962 Patent, would further infringe the asserted claims of the '962 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

62. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '962 Patent.

63. Plaintiff has no adequate remedy at law.

64. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**FIFTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '280 Patent by Impax)**

65. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

66. On information and belief, Impax has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the '280 Patent.

67. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax's infringement of the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

68. Impax's commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the

term of the '280 Patent, would further infringe the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

69. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the '280 Patent.

70. Plaintiff has no adequate remedy at law.

71. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**SIXTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '280 Patent by Par)**

72. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

73. On information and belief, Par has infringed the '280 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '280 Patent.

74. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

75. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '280 Patent, would further infringe the asserted claims of the '280 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

76. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '280 Patent.

77. Plaintiff has no adequate remedy at law.

78. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**SEVENTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '340 Patent by Par)**

79. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

80. On information and belief, Par has infringed the '340 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '340 Patent.

81. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

82. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '340 Patent, would further infringe the asserted claims of the '340 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

83. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '340 Patent.

84. Plaintiff has no adequate remedy at law.

85. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**EIGHTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '927 Patent by Impax)**

86. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

87. On information and belief, Impax has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the '927 Patent.

88. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax's infringement of the asserted claims of the '927 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

89. Impax's commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the term of the '927 Patent, would further infringe the asserted claims of the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

90. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the '927 Patent.

91. Plaintiff has no adequate remedy at law.

92. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**NINTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '927 Patent by Par)**

93. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

94. On information and belief, Par has infringed the '927 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '927 Patent.

95. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the '927 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

96. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '927 Patent, would further infringe the asserted claims of the '927 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

97. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '927 Patent.

98. Plaintiff has no adequate remedy at law.

99. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

TENTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '989 Patent by Impax)

100. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

101. On information and belief, Impax has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the '989 Patent.

102. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax's infringement of the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

103. Impax's commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the term of the '989 Patent, would further infringe the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

104. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the '989 Patent.

105. Plaintiff has no adequate remedy at law.

106. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**ELEVENTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '989 Patent by Par)**

107. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

108. On information and belief, Par has infringed the '989 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '989 Patent.

109. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

110. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '989 Patent, would further infringe the asserted claims of the '989 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

111. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '989 Patent.

112. Plaintiff has no adequate remedy at law.

113. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

TWELFTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the ‘756 Patent by Impax)

114. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

115. On information and belief, Impax has infringed the ‘756 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the ‘756 Patent.

116. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax’s infringement of the asserted claims of the ‘756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

117. Impax’s commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the term of the ‘756 Patent, would further infringe the asserted claims of the ‘756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

118. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the ‘756 Patent.

119. Plaintiff has no adequate remedy at law.

120. This case is exceptional, and Plaintiff is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

**THIRTEENTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the '756 Patent by Par)**

121. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

122. On information and belief, Par has infringed the '756 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the '756 Patent.

123. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par's infringement of the asserted claims of the '756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

124. Par's commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the '756 Patent, would further infringe the asserted claims of the '756 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

125. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the '756 Patent.

126. Plaintiff has no adequate remedy at law.

127. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

**FOURTEENTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the ‘332 Patent by Impax)**

128. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

129. On information and belief, Impax has infringed the ‘332 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Impax ANDA, by which Impax seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Impax Products prior to the expiration of the ‘332 Patent.

130. Impax has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Impax Products in the event that the FDA approves the Impax ANDA. Accordingly, an actual and immediate controversy exists regarding Impax’s infringement of the asserted claims of the ‘332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

131. Impax’s commercial manufacture, use, offer to sell, or sale of the Impax Products within the United States, or importation of the Impax Products into the United States during the term of the ‘332 Patent, would further infringe the asserted claims of the ‘332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

132. Plaintiff will be substantially and irreparably harmed if Impax is not enjoined from infringing the asserted claims of the ‘332 Patent.

133. Plaintiff has no adequate remedy at law.

134. This case is exceptional, and Plaintiff is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

**FIFTEENTH CAUSE OF ACTION
(Infringement and Declaratory Judgment of Infringement of the ‘332 Patent by Par)**

135. Plaintiff realleges and incorporates by reference the allegations contained in paragraphs 1-36.

136. On information and belief, Par has infringed the ‘332 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Par ANDA, by which Par seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale, or importation of the Par Products prior to the expiration of the ‘332 Patent.

137. Par has declared its intent to manufacture, use, offer to sell, or sell in the U.S. or to import into the U.S., the Par Products in the event that the FDA approves the Par ANDA. Accordingly, an actual and immediate controversy exists regarding Par’s infringement of the asserted claims of the ‘332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

138. Par’s commercial manufacture, use, offer to sell, or sale of the Par Products within the United States, or importation of the Par Products into the United States during the term of the ‘332 Patent, would further infringe the asserted claims of the ‘332 Patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

139. Plaintiff will be substantially and irreparably harmed if Par is not enjoined from infringing the asserted claims of the ‘332 Patent.

140. Plaintiff has no adequate remedy at law.

141. This case is exceptional, and Plaintiff is entitled to an award of attorneys’ fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment against defendants Impax Laboratories, Inc. (“Impax”) and Par Pharmaceutical Companies, Inc. and Par Pharmaceutical, Inc. (collectively, “Par”), and respectfully request the following relief:

1. A judgment that the asserted claims of the ‘475, ‘962, ‘280, ‘927, ‘989, ‘756, and ‘332 Patents have been infringed by Impax;

2. A judgment that the asserted claims of the '475, '962, '280, '340, '927, '989, '756, and '332 Patents have been infringed by Par;

3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Impax, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Impax Products within the United States, or importing the Impax Products into the United States, prior to the expiration of the '475, '962, '280, '927, '989, '756, and/or '332 Patents, including any extensions;

4. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Par, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Par Products within the United States, or importing the Par Products into the United States, prior to the expiration of the '475, '962, '280, '340, '927, '989, '756, and/or '332 Patents, including any extensions;

5. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203666 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '927, '989, '756, and/or '332 Patents, including any extensions;

6. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 203757 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '475, '962, '280, '340, '927, '989, '756, and/or '332 Patents, including any extensions;

7. A judgment declaring and enjoining Impax, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Impax Products within the United States, or importing the Impax Products into the United States, prior to the expiration dates of the '475, '962, '280, '927, '989, '756, and/or '332 Patents, including any extensions;

8. A judgment declaring and enjoining Par, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling Par Products within the United States, or importing the Par Products into the United States, prior to the expiration dates of the '475, '962, '280, '340, '927, '989, '756, and/or '332 Patents, including any extensions;

9. If Impax commercially manufactures, uses, offers to sell, or sells the Impax Products within the United States, or imports the Impax Products into the United States, prior to the expiration of any of the '475, '962, '280, '927, '989, '756, and/or '332 Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

10. If Par commercially manufactures, uses, offers to sell, or sells the Par Products within the United States, or imports the Par Products into the United States, prior to the expiration of any of the '475, '962, '280, '340, '927, '989, '756, and/or '332 Patents, including any extensions, a judgment awarding Plaintiff monetary relief together with interest;

11. An award of damages together with interest, and a judgment that the damages so adjudged be trebled pursuant to 35 U.S.C. §§ 283 and 284;

12. Judgment that this is an exceptional case and that Plaintiff be awarded its attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285;

13. Costs and expenses in this action; and

14. Such other and further relief as the Court deems just and appropriate.

Dated: September 28, 2012

Respectfully submitted,

By: s/ Leda Dunn Wettre
Leda Dunn Wettre
ROBINSON, WETTRE & MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
Telephone: (973) 690-5400
Facsimile: (973) 466-2760
Lwettre@rwmlegal.com

OF COUNSEL:
William G. Gaede III
Bhanu K. Sadasivan
Shane G. Smith
MCDERMOTT WILL & EMERY LLP
275 Middlefield Road, Suite 100
Menlo Park, CA 94025
Telephone: (650) 815-7400
Facsimile: (650) 815-7401

Attorneys for Plaintiff Depomed, Inc.

CERTIFICATE OF SERVICE

I certify that on September 28, 2012, I caused a copy of the attached Second Amended Complaint and all of the exhibits referenced herein to be served upon Defendants' counsel of record via the Court's electronic filing system.

s/ Leda Dunn Wettre
Leda Dunn Wettre