Donald A. Robinson
Keith J. Miller
Justin T. Quinn
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, NJ 07102
(973) 690-5400

Imron T. Aly (admitted *pro hac vice*)
SCHIFF HARDIN LLP
233 South Wacker Drive, Suite 6600
Chicago, Illinois 60606
(312) 258-5500

John K. Hsu (*pro hac vice*)
SCHIFF HARDIN LLP
901 K Street NW, Suite 700
Washington, DC 20001

Christine W. Feller (*pro hac vice*)
Ahmed M. T. Riaz
SCHIFF HARDIN LLP
666 Fifth Avenue, Suite 1700
New York, NY 10103

Attorneys for Plaintiff
Fresenius Kabi USA, LLC

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, Plaintiff, v. PAR STERILE PRODUCTS, LLC, PAR PHARMACEUTICAL, INC., and PAR PHARMACEUTICAL COMPANIES, INC., Defendants.	)	**Civil Action No. 2:15-cv-03852-KM-MAH**

FIRST AMENDED COMPLAINT

Plaintiff Fresenius Kabi USA, LLC ("Fresenius Kabi"), by its undersigned attorneys, for its first amended complaint against Defendants Par Sterile Products, LLC; Par Pharmaceutical, Inc.; and Par Pharmaceutical Companies, Inc. (collectively, "Par")

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, in response to the submission of an Abbreviated New Drug Application ("ANDA") with the U.S. Food and Drug Administration ("FDA"), seeking approval to manufacture and sell generic versions of levothyroxine sodium powder for injection prior to the expiration of U.S. Patent Nos. 9,006,289 ("the '289 Patent"), 9,168,238 ("the '238 Patent") and 9,168,239 ("the '239 Patent").

THE PARTIES

2. Plaintiff Fresenius Kabi is a corporation organized and existing under the laws of the state of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. On information and belief, Par Sterile Products, LLC (formerly known as JHP Pharmaceuticals, LLC) is a limited liability company organized and existing under the laws of the state of Delaware, having a principal place of business in Parsippany, New Jersey.

4. On 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 in Woodcliff Lake, New Jersey.

5. On 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 in Woodcliff Lake, New Jersey.

6. On information and belief, Par Sterile Products, LLC is an indirect wholly-owned subsidiary of Par Pharmaceutical, Inc., which is a wholly owned subsidiary of Par Pharmaceutical Companies, Inc.

JURISDICTION AND VENUE

7. This action for patent infringement arises under 35 U.S.C. § 1 *et seq.* generally and 35 U.S.C. § 271 specifically.

8. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. Personal jurisdiction over all Par entities is proper because, upon information and belief, Par, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district. Upon information and belief, Par is in the business of licensing and distributing generic drug products throughout the United States and in this judicial district. Upon information and belief, Par has purposefully conducted and continues to conduct business in New Jersey, including by maintaining its corporate headquarters in New Jersey, and, thus, New Jersey is a likely destination of Par's generic products. Upon information and belief, Par has purposely availed itself of the rights and benefits of the laws of the State of New Jersey, having engaged in systematic and continuous contacts with the State of New Jersey and having previously submitted to personal jurisdiction in this Court, including in the following cases: *Novartis Pharmaceuticals Corp. v. Par Sterile Prods. Inc.*, Case No. 2:14-cv-07558-SDW-SCM;

Par Sterile Products, LLC v. Hospira, Inc., Case No. 3:14-cv-05343-MJC-TJB; and *In re Certain Consolidated Zoledronic Acid Cases*, Case No. 2:12-cv-03967-SDW-SCM.

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

THE PATENTS-IN-SUIT

11. The '289 Patent, entitled "Levothyroxine Formulations," was duly and legally issued on April l4, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '289 Patent is attached hereto as Exhibit A.

12. The '238 Patent, entitled "Levothyroxine Formulations," was duly and legally issued on October 27, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '238 Patent is attached hereto as Exhibit B.

13. The '239 Patent, entitled "Levothyroxine Formulations," was duly and legally issued on October 27, 2015, naming Zhi-Qiang Jiang, Arunya Usayapant, and George Monen as the inventors. A true and correct copy of the '239 Patent is attached hereto as Exhibit C.

14. Plaintiff Fresenius Kabi is the assignee and lawfully owns all rights, title and interest in the '289 Patent, the '238 Patent, and the '239 Patent ("the patents-in-suit"), including the right to sue and to recover for past infringement thereof.

15. The FDA issues a publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book").

16. Fresenius Kabi is the holder of New Drug Application ("NDA") No. 202231 for Levothyroxine Sodium, which the FDA approved on June 24, 2011. In accordance with 21 U.S.C. § 355(b)(1), the '289 Patent, the '238 Patent, and the '239 Patent are each listed in the Orange Book in connection with approved NDA No. 202231, as a patent "with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale" of Fresenius Kabi's NDA drug product.

17. Fresenius Kabi currently sells in the United States Levothyroxine Sodium. According to the Orange Book, the '289 Patent is currently not due to expire until October 3, 2032; the '238 Patent is currently not due to expire until August 29, 2032; and the '239 Patent is also currently not due to expire until August 29, 2032.

PAR'S ANDA NO. 205366

18. On information and belief, Par submitted ANDA No. 205366 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of generic 100 mcg/vial, 200 mcg/vial, and 500 mcg/vial levothyroxine sodium powder for injection (the "ANDA Products").

19. On information and belief, ANDA No. 205366 contains a Paragraph IV certification that the '289 Patent, the '238 Patent, and the '239 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described by Par's ANDA No. 205366.

20. On information and belief, Par is the owner of ANDA No. 205366.

21. On information and belief, if ANDA No. 205366 is approved by the FDA before the expiration of the '289 Patent, the '238 Patent, and/or the '239 Patent, Par will begin manufacturing, using, importing, offering for sale, and/or selling the ANDA Products, despite the patents.

22. On information and belief, if ANDA No. 205366 is approved by the FDA, Par will begin marketing the ANDA Products for treatment of myxedema coma, and doctors and patients will use each of the dosage strengths of the ANDA Products for the indications marketed by Par.

23. Pursuant to FDA regulation 21 C.F.R. § 314.94, in order to secure FDA approval, each of the ANDA Products' dosage strengths must have the same strength as one of the approved

dosages for Fresenius Kabi's NDA levothyroxine sodium products ("the NDA products"). In addition, the ANDA Products must be bioequivalent to the NDA products.

24. Fresenius Kabi received a letter ("the Notice Letter"), purporting to be a Notice of Certification for ANDA No. 205366 under Section 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95(c). The Paragraph IV certification alleged that the claims of the '289 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

25. On information and belief, ANDA No. 205366 seeks approval of a generic levothyroxine product that is the same, or substantially the same, as Fresenius Kabi's commercially marketed and approved Levothyroxine Sodium product.

26. On information and belief, Par was aware of the at least the '289 Patent when ANDA No. 205366 was submitted to the FDA, containing the above-described Paragraph IV certifications concerning this specific patent.

27. On information and belief, JHP Pharmaceuticals, LLC (n/k/a Par Sterile Products, LLC) submitted the ANDA No. 205366 to the FDA. On information and belief, Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. both participated in, assisted or cooperated with, or provided material support to Par Sterile Products, LLC.

28. On information and belief, if the ANDA No. 205366 is approved, then the named defendants will act in concert to license, manufacture, sell, distribute, and develop generic versions of Fresenius Kabi's Levothyroxine Sodium product and market it before expiration of the '289 Patent, the '238 Patent, and the '239 Patent.

COUNT I: INFRINGEMENT OF THE '289 PATENT – ANDA SUBMISSION

29. Fresenius Kabi incorporates and realleges paragraphs 1-28 above.

30. The submission of ANDA No. 205366 including a Paragraph IV certification regarding the '289 Patent was an act of infringement by Par of one or more claims of the '289 Patent under 35 U.S.C. § 271(e)(2).

31. On information and belief, the use of ANDA Products in accordance with and as directed by the instructions contained in the proposed package insert of Par's ANDA No. 205366 is covered by one or more claims of the '289 Patent.

32. On information and belief, Par's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Products before the expiration of the '289 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '289 Patent.

33. On information and belief, the use of Par's ANDA Products in accordance with and as directed by Par's proposed labeling will infringe one or more claims of the '289 Patent.

34. On information and belief, by seeking approval to distribute the ANDA Products with their proposed labeling, Par intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Par knows will infringe one or more claims of the '289 Patent.

35. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, actively induce infringement of one or more claims of the '289 Patent immediately following approval of ANDA No. 205366.

36. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, contribute to the infringement of one or more claims of the '289 Patent immediately following approval of ANDA No. 205366.

37. On information and belief, Par knows that its ANDA No. 205366 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’289 Patent, and that the Par ANDA Products and their proposed labeling are not suitable for any noninfringing use.

38. On information and belief, Par’s actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 205366 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’289 patent.

39. On information and belief, Par has been aware of the existence of the application resulting in the ’289 Patent since before the submission of ANDA No. 205366.

40. On information and belief, Par has no reasonable basis for believing that its ANDA Products will not infringe one or more valid claims of the ’289 Patent and no reasonable basis for believing that the infringed claims are invalid. Par posited no theory of non-infringement in its Notice Letter.

41. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

42. On information and belief, unless enjoined by this Court, Par plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Products with their proposed labeling immediately following approval of ANDA No. 205366 and before the expiration of the ‘289 Patent.

43. The acts of infringement by Par set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

44. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Par's ANDA No. 205366 to be a date which is not any earlier than the expiration date of the '289 Patent, including any extensions of that date.

COUNT II: INFRINGEMENT OF THE '289 PATENT – DECLARATORY JUDGMENT

45. Fresenius Kabi incorporates and realleges paragraphs 1-44 above.

46. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

47. There is an actual case or controversy such that the Court may entertain Fresenius Kabi's 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.

48. Par Sterile Products, LLC has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import its generic levothyroxine sodium product before the expiration of the '289 patent, including Par Sterile Products, LLC's filing of ANDA No. 205366.

49. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's generic levothyroxine sodium product will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '289 patent.

50. Par has refused to stipulate that it will not launch a generic levothyroxine product while this matter is in litigation waiting to be resolved by the Court.

51. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and Par as to liability for the infringement of the '289 patent claims. Par's actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

52. Fresenius Kabi is entitled to declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or important of Par's generic levothyroxine sodium product will constitute infringement of one or more claims of the '289 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

COUNT III: INFRINGEMENT OF THE '238 PATENT – ANDA SUBMISSION

53. Fresenius Kabi incorporates and realleges paragraphs 1-52 above.

54. The submission of ANDA No. 205366 including a Paragraph IV certification regarding the '238 Patent was an act of infringement by Par of one or more claims of the '238 Patent under 35 U.S.C. § 271(e)(2).

55. On information and belief, the use of ANDA Products in accordance with and as directed by the instructions contained in the proposed package insert of Par's ANDA No. 205366 is covered by one or more claims of the '238 Patent.

56. On information and belief, Par's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Products before the expiration of the '238 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '238 Patent.

57. On information and belief, the use of Par's ANDA Products in accordance with and as directed by Par's proposed labeling will infringe one or more claims of the '238 Patent.

58. On information and belief, by seeking approval to distribute the ANDA Products with their proposed labeling, Par intends to cause others, specifically, for example, medical professionals and patients, to perform acts that Par knows will infringe one or more claims of the '238 Patent.

59. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, actively induce infringement of one or more claims of the ’238 Patent immediately following approval of ANDA No. 205366.

60. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, contribute to the infringement of one or more claims of the ’238 Patent immediately following approval of ANDA No. 205366.

61. On information and belief, Par knows that its ANDA No. 205366 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the ’238 Patent, and that the Par ANDA Products and their proposed labeling are not suitable for any noninfringing use.

62. On information and belief, Par’s actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 205366 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the ’238 patent.

63. On information and belief, Par has been aware of the existence of the application resulting in the ’238 Patent since the submission of ANDA No. 205366.

64. On information and belief, Par has no reasonable basis for believing that its ANDA Products will not infringe one or more valid claims of the ’238 Patent and no reasonable basis for believing that the infringed claims are invalid. This case is “exceptional,” as that term is used in 35 U.S.C. § 285.

65. On information and belief, unless enjoined by this Court, Par plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of

the ANDA Products with their proposed labeling immediately following approval of ANDA No. 205366 and before the expiration of the '238 Patent.

66. The acts of infringement by Par set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

67. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Par's ANDA No. 205366 to be a date which is not any earlier than the expiration date of the '238 Patent, including any extensions of that date.

COUNT IV: INFRINGEMENT OF THE '238 PATENT – DECLARATORY JUDGMENT

68. Fresenius Kabi incorporates and realleges paragraphs 1-67 above.

69. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

70. There is an actual case or controversy such that the Court may entertain Fresenius Kabi's 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.

71. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's generic levothyroxine sodium product before the expiration of the '238 patent, including Par's filing of ANDA No. 205366.

72. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's generic levothyroxine sodium product by Par will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '238 patent.

73. Par has refused to stipulate that it will not launch a generic levothyroxine product while this matter is in litigation waiting to be resolved by the Court.

74. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and Par as to liability for the infringement of the '238 patent claims. Par's actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

75. Fresenius Kabi is entitled to declaratory judgment that Par's future commercial manufacture, use, offer for sale, sale, and/or import of Par's generic levothyroxine sodium product will constitute infringement of one or more claims of the '238 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

COUNT V: INFRINGEMENT OF THE '239 PATENT – ANDA SUBMISSION

76. Fresenius Kabi incorporates and realleges paragraphs 1-75 above.

77. The submission of ANDA No. 205366 including a Paragraph IV certification regarding the '239 Patent was an act of infringement by Par of one or more claims of the '239 Patent under 35 U.S.C. § 271(e)(2).

78. On information and belief, the use of ANDA Products in accordance with and as directed by the instructions contained in the proposed package insert of Par's ANDA No. 205366 is covered by one or more claims of the '239 Patent.

79. On information and belief, Par's commercial importation, manufacture, use, sale, and/or offer for sale of the ANDA Products before the expiration of the '239 Patent would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '239 Patent.

80. On information and belief, the use of Par's ANDA Products in accordance with and as directed by Par's proposed labeling will infringe one or more claims of the '239 Patent.

81. On information and belief, by seeking approval to distribute the ANDA Products with their proposed labeling, Par intends to cause others, specifically, for example, medical

professionals and patients, to perform acts that Par knows will infringe one or more claims of the '239 Patent.

82. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, actively induce infringement of one or more claims of the '239 Patent immediately following approval of ANDA No. 205366.

83. On information and belief, unless enjoined by this Court, Par plans and intends to, and will, contribute to the infringement of one or more claims of the '239 Patent immediately following approval of ANDA No. 205366.

84. On information and belief, Par knows that its ANDA No. 205366 and its proposed labeling are especially made or adapted for use in infringing one or more claims of the '239 Patent, and that the Par ANDA Products and their proposed labeling are not suitable for any noninfringing use.

85. On information and belief, Par's actions through the licensing, manufacture, use, import, offer for sale, and/or sale a generic levothyroxine sodium product pursuant to ANDA No. 205366 will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '239 patent.

86. On information and belief, Par has been aware of the existence of the application resulting in the '239 Patent since the submission of ANDA No. 205366.

87. On information and belief, Par has no reasonable basis for believing that its ANDA Products will not infringe one or more valid claims of the '239 Patent and no reasonable basis for believing that the infringed claims are invalid. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

88. On information and belief, unless enjoined by this Court, Par plans and intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of the ANDA Products with their proposed labeling immediately following approval of ANDA No. 205366 and before the expiration of the '239 Patent.

89. The acts of infringement by Par set forth above will cause Fresenius Kabi irreparable harm for which it has no adequate remedy at law, and those acts will continue unless enjoined by this Court.

90. Fresenius Kabi is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Par's ANDA No. 205366 to be a date which is not any earlier than the expiration date of the '239 Patent, including any extensions of that date.

COUNT VI: INFRINGEMENT OF THE '239 PATENT – DECLARATORY JUDGMENT

91. Fresenius Kabi incorporates and realleges paragraphs 1-90 above.

92. Fresenius Kabi brings claims arising under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

93. There is an actual case or controversy such that the Court may entertain Fresenius Kabi's 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.

94. Par has made, and will continue to make, substantial preparation in the United States to manufacture, use, offer to sell, sell, and/or import Par's generic levothyroxine sodium product before the expiration of the '239 patent, including Par's filing of ANDA No. 205366.

95. On information and belief, any commercial manufacture, use, offer for sale, sale, and/or importation of Par's generic levothyroxine sodium product by Par will directly infringe, contributorily infringe, and/or induce infringement of at least one claim of the '239 patent.

96. Par has refused to stipulate that it will not launch a generic levothyroxine product while this matter is in litigation waiting to be resolved by the Court.

97. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Fresenius Kabi and Par as to liability for the infringement of the '239 patent claims. Par's actions have created for Fresenius Kabi a reasonable apprehension of irreparable harm and loss resulting from Par's threatened imminent actions.

98. Fresenius Kabi is entitled to declaratory judgment that Par's future commercial manufacture, use, offer for sale, sale, and/or import of Par's generic levothyroxine sodium product will constitute infringement of one or more claims of the '239 patent under one or more provisions of 35 U.S.C. § 271, including §§ 271(a), (b), and/or (c).

RELIEF SOUGHT

WHEREFORE, Fresenius Kabi respectfully requests the following relief:

A. Judgment in favor of Fresenius Kabi and against Par;

B. Judgment that Par has infringed, literally or by the doctrine of equivalents, '289 Patent, the '238 Patent, and the '239 Patent by the submission of ANDA No. 205366, and that the commercial importation, sale, offer for sale, use, and/or manufacture of the ANDA Products, in the United States, would infringe, induce infringement of, and/or contribute to the infringement of '289 Patent, the '238 Patent, and the '239 Patent;

C. Judgment, pursuant to 35 U.S.C. § 271(e)(4)(A) and other provisions of 35 U.S.C. § 271, that the effective date of approval of ANDA No. 205366 under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), shall be a date not earlier than the date of expiration of '289 Patent, the '238 Patent, and the '239 Patent plus any additional periods of exclusivity;

D. A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271 and 283 and Federal Rule of Civil Procedure 65, enjoining Par and its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any ANDA Product, and any product that is similar to or only colorably different from those products, before the date of expiration of '289 Patent, the '238 Patent, and the '239 Patent and any additional periods of exclusivity;

E. A declaration that this is an exceptional case and an award to Fresenius Kabi of its reasonable attorneys' fees and expenses, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

F. Damages or other monetary relief, including prejudgment interest, if Par engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of ANDA Products, or any other products that the use of which would infringe '289 Patent, the '238 Patent, and the '239 Patent, or the inducement of or contribution to the foregoing, prior to the expiration of '289 Patent, the '238 Patent, and the '239 Patent;

G. An award of pre-judgment and post-judgment interest on each and every award;

H. An award of Fresenius Kabi's taxable costs in bringing and prosecuting this action; and.

I. Such other and further relief to Fresenius Kabi as this Court may deem just and proper.

Dated: December 8, 2015

By: s/ Donald A. Robinson

Donald A. Robinson
Keith J. Miller
Justin T. Quinn
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, NJ 07102
(973) 690-5400

OF COUNSEL

Imron T. Aly (*pro hac vice*)
SCHIFF HARDIN LLP
233 South Wacker Drive,
Suite 6600
Chicago, Illinois 60606
(312) 258-5500

John K. Hsu (*pro hac vice*)
SCHIFF HARDIN LLP
901 K Street NW, Suite 700
Washington, DC 20001

Christine W. Feller (*pro hac vice*)
Ahmed M.T. Riaz
SCHIFF HARDIN LLP
666 Fifth Avenue, Suite 1700
New York, NY 10103

Attorneys for Plaintiff
Fresenius Kabi USA, LLC