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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

UNITED THERAPEUTICS CORPORATION and SUPERNUS PHARMACEUTICALS, INC., **Plaintiffs,** **v.** **ACTAVIS LABORATORIES FL, INC.,** **Defendant.**	**Civil Action No. _____** **COMPLAINT FOR PATENT INFRINGEMENT AND JURY DEMAND** **(Filed Electronically)**

Plaintiffs United Therapeutics Corporation ("UTC") and Supernus Pharmaceuticals, Inc. ("Supernus"), (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Actavis Laboratories FL, Inc. ("Actavis"), allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, involving United States Patent Nos. 7,417,070 ("the '070 patent") (attached as Exhibit A hereto), 7,544,713 ("the '713 patent") (attached as Exhibit B hereto), 8,252,839 ("the '839 patent") (attached as Exhibit C hereto), 8,349,892 ("the '892 patent") (attached as Exhibit D hereto), 8,410,169 ("the '169 patent") (attached as Exhibit E hereto), 8,497,393 ("the '393 patent") (attached as Exhibit F hereto), 9,050,311 ("the '311 patent") (attached as Exhibit G hereto), 8,747,897 ("the '897 patent") (attached as Exhibit H hereto), and 9,278,901 ("the '901 patent") (attached as Exhibit I hereto).

2. This action arises out of Actavis's submission of Abbreviated New Drug Application ("ANDA") No. 208906 to the United States Food and Drug Administration ("FDA") seeking approval, prior to the expiration of the '070, '713, '839, '892, '169, '393, '311,'897, and '901 patents, to manufacture, market, and sell a generic copy of UTC's ORENITRAM® (treprostinil) Extended-Release Tablets that is approved by FDA for treatment of pulmonary arterial hypertension.

THE PARTIES

3. UTC is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a pharmaceutical and biotechnology company focused on the development and

commercialization of products designed to address the needs of patients with chronic and life-threatening conditions.

4. Supernus is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1550 East Gude Drive, Rockville, MD 20850. Supernus is a specialty pharmaceutical company focused on developing and commercializing products for the treatment of central nervous system (CNS) disorders.

5. Upon information and belief, Actavis is a corporation organized and existing under the laws of the State of Florida, and having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

7. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

8. Upon information and belief, this Court has personal jurisdiction over Actavis with respect to this Complaint because of, *inter alia*, its continuous and systematic contacts with this Judicial District. The notice letter was sent from Actavis at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, NJ 07054. Upon information and belief, Actavis has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, NJ 07054. Upon information and belief, Actavis derives substantial revenue from articles used and consumed in this Judicial District and, consistent with its practice with respect to other generic products, following any FDA approval of Actavis's ANDA, Actavis will sell its generic product throughout the United States, including in this Judicial District. Upon information and belief, Actavis employs people throughout New Jersey, including at least

the following locations: Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054; 100 Enterprise Drive, Rockaway, New Jersey 07866; and 350 Mt. Kemble Avenue, Morristown, New Jersey 07960.

BACKGROUND

9. UTC holds an approved New Drug Application (No. 203496) for treprostinil extended-release tablets that UTC markets and sells under the registered trademark ORENITRAM®.

10. ORENITRAM® is a pharmaceutical product initially approved by FDA in the United States in December 2013, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and results in increased pressure in the pulmonary arteries, which increases strain on the heart, which, in turn, can lead to heart failure and death.

11. ORENITRAM® is an extended-release tablet available in four dosage strengths, 0.125 mg, 0.25 mg, 1 mg, and 2.5 mg. ORENITRAM® is designed to release treprostinil using an osmotic tablet technology.

12. The ’070 patent, entitled “Compounds and methods for delivery of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on August 26, 2008. The named inventors are Ken Phares and David Mottola.

13. UTC is the lawful owner of the ’070 patent by assignment of all right, title, and interest in and to the ’070 patent, including the right to bring infringement suits thereon.

14. The ’713 patent, entitled “Compounds and methods for delivery of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on June 9, 2009. The named inventors are Ken Phares and David Mottola.

15. UTC is the lawful owner of the ’713 patent by assignment of all right, title, and interest in and to the ’713 patent, including the right to bring infringement suits thereon.

16. The ’839 patent, entitled “Compounds and methods for delivery of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on August 28, 2012. The named inventors are Ken Phares and David Mottola.

17. UTC is the lawful owner of the ’839 patent by assignment of all right, title, and interest in and to the ’839 patent, including the right to bring infringement suits thereon.

18. The ’892 patent, entitled “Solid formulations of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on January 8, 2013. The named inventor is Kenneth R. Phares.

19. UTC is the lawful owner of the ’892 patent by assignment of all right, title, and interest in and to the ’892 patent, including the right to bring infringement suits thereon.

20. The ’169 patent, entitled “Compounds and methods for delivery of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on April 2, 2013. The named inventors are Ken Phares and David Mottola.

21. UTC is the lawful owner of the ’169 patent by assignment of all right, title, and interest in and to the ’169 patent, including the right to bring infringement suits thereon.

22. The ’393 patent, entitled “Process to prepare treprostinil, the active ingredient in Remodulin®,” was duly and legally issued by the United States Patent and Trademark Office on July 30, 2013. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

23. UTC is the lawful owner of the ’393 patent by assignment of all right, title, and interest in and to the ’393 patent, including the right to bring infringement suits thereon.

24. The ’311 patent, entitled “Compounds and methods for delivery of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on June 9, 2015. The named inventors are Ken Phares, David Mottola, and Hitesh Batra.

25. UTC is the lawful owner of the ’311 patent by assignment of all right, title, and interest in and to the ’311 patent, including the right to bring infringement suits thereon.

26. The ’897 patent, entitled “Osmotic drug delivery system,” was duly and legally issued by the United States Patent and Trademark Office on June 10, 2014. The named inventors are Argaw Kidane and Padmanabh P. Bhatt.

27. Supernus is the lawful owner of the ’897 patent by assignment of all right, title, and interest in and to the ’897 patent. UTC is the exclusive licensee of the ’897 patent, holding an exclusive license to develop, make, have made, use, offer for sale, sell, have sold, and import products covered by the ’897 patent.

28. The ’901 patent, entitled “Compounds and methods for delivery of prostacyclin analogs,” was duly and legally issued by the United States Patent and Trademark Office on March 8, 2016. The named inventors are Ken Phares, David Mottola, and Roger Jeffs.

29. UTC is the lawful owner of the ’901 patent by assignment of all right, title, and interest in and to the ’901 patent, including the right to bring infringement suits thereon.

30. ORENITRAM® and its FDA-approved manufacture and uses are covered by one or more claims of the ’070, ’713, ’839, ’892, ’169, ’393, ’311,’897, and ’901 patents, which have been listed in connection with ORENITRAM® in FDA’s *Approved Drug Products with Therapeutic Equivalents* publication (also known as the “Orange Book”).

ACTS GIVING RISE TO THIS ACTION

31. Actavis notified Plaintiffs by letter dated May 19, 2016 which was delivered to Plaintiffs on or about Monday, May 23, 2016 ("Actavis's Notice Letter"), that it had filed ANDA No. 208906 with FDA seeking approval to commercially manufacture, market, use, and sell generic copies of ORENITRAM® (treprostinil) Extended-Release Tablets, 0.25 mg and 1 mg ("Actavis's ANDA Products") prior to the expiration of the '070, '713, '839, '892, '169, '393, '311, '897 and '901 patents.

32. Actavis previously provided notice to UTC regarding its ANDA for another strength, 2.5 mg, and that notice gave rise to *United Therapeutics Corp. v. Actavis Labs. FL, Inc.*, 3:16-cv-01816-PGS-LHG. Actavis's Notice Letter and referenced "Paragraph IV" certifications provide the basis for this second infringement suit and concomitant new 30-month stay under 21 U.S.C. § 355(c)(3)(C).

33. Actavis's Notice Letter included a statement under 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to recite Actavis's "factual and legal basis" for its opinion that the '070, '713, '839, '892, '169, '393, '311, '897, and '901 patents are not valid, are unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of Actavis's ANDA Products. Yet, that statement did not include any explanation as to why claims 2 and 3 of the '070 patent, claims 1-22 and 24-26 of the '713 patent, claim 5 of the '839 patent, claims 1-7 of the '169 patent, any claim of the '393 patent, and any claim of the '311 patent are allegedly invalid. The statement also did not include any explanation as to why independent claim 1 of the '070 patent, independent claim 23 of the '713 patent, independent claim 1 of the '839 patent, independent claim 8 of the '169 patent, the claims of the '897 patent and independent claims 1 and 7 of the '901 patent are allegedly not infringed. Actavis's Notice Letter also did not include anything beyond conclusory

statements regarding alleged non-infringement. Actavis provided no explanation as to any alleged unenforceability.

34. Upon information and belief, Actavis submitted ANDA No. 208906 with FDA seeking approval to commercially manufacture, market, use, and sell generic copies of UTC's approved ORENITRAM® product prior to the expiration of the '070, '713, '839, '892, '169, '393, '311,'897, and '901 patents.

35. Plaintiffs are commencing this action before the expiration of forty-five days from the date Plaintiffs received Actavis's Notice Letter.

36. Upon information and belief, Actavis's ANDA Products contain the same active compound as UTC's approved ORENITRAM® product.

37. Upon information and belief, Actavis's ANDA No. 208906 seeks approval from FDA to market Actavis's ANDA Products for the same indication as UTC's approved ORENITRAM® product.

38. Upon information and belief, Actavis represented to FDA in ANDA No. 208906 that Actavis's ANDA Products are bioequivalent to UTC's approved ORENITRAM® product.

39. Upon information and belief, Actavis intends to commercially manufacture, use, sell, offer for sale, and/or import Actavis's ANDA Products upon, or in anticipation of, FDA approval.

40. According to Actavis's Notice Letter, Actavis's ANDA No. 208906 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in Actavis's opinion the '070, '713, '839, '892, '169, '393, '311, '897, and '901 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use or sale of Actavis's ANDA Products.

41. Upon information and belief, as of the date of Actavis's Notice Letter, Actavis was aware of the statutory provisions and regulations set forth in 21 U.S.C. §§ 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

42. In Actavis's Notice Letter, Actavis offered confidential access to portions of the Actavis ANDA on terms and conditions set forth in paragraph VII of the Actavis Notice Letter ("Actavis Offer"). Actavis requested that Plaintiffs accept the Actavis Offer before receiving access to any portion of the Actavis ANDA. The Actavis Offer contained sweeping, unreasonable restrictions that differ materially from restrictions found under protective orders, such as those protective orders in pending, related cases in the United States District Court for the District of New Jersey. For example, the Actavis Offer required that Plaintiffs' outside counsel "do not engage, formally or informally, in *any* patent prosecution for UTC or Supernus, or *any* FDA counseling, litigation or other work before or involving the FDA" (emphasis added).

43. Under 21 U.S.C. § 355(j)(5)(C)(i)(III), an "offer of confidential access shall contain such restrictions . . . on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

44. UTC attempted to negotiate with Actavis to obtain relevant information from the Actavis ANDA under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful. For example, Actavis, relying on previous correspondence, insisted that attorneys representing Plaintiffs and in-house counsel and the staff of such counsel agree not to be engaged in any patent prosecution or any FDA counseling, litigation or other work before or involving the FDA, though such a restrictions have not been present in any prior protective order relating to any other UTC treprostinil-containing product, such as

REMODULIN® (treprostinil) Injection and TYVASO® (treprostinil) Inhalation Solution, including litigation involving corporate affiliates of Actavis. *See United Therapeutics Corp. v. Watson Labs., Inc.*, 3:15-cv-05723-PGS-LHG, Protective Order, Docket No. 36 (D.N.J. Jan. 13, 2016); *United Therapeutics Corp. v. Sandoz, Inc.*, 3:14-cv-05499-PGS-LHG, Stipulated Protective Order and Cross Use Agreement, Docket No. 23 (D.N.J. Jan. 15, 2015); *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, 3:14-cv-05498-PGS-LHG, Amended Stipulated Protective Order, Docket No. 41 (D.N.J. Apr. 10, 2015); *United Therapeutics Corp. v. Sandoz, Inc.*, 3:12-cv-01617-PGS-LHG, Protective Order, Docket No. 32 (D.N.J. Sept. 12, 2012). UTC objected to this provision of Actavis's Offer as unreasonable and in violation of 21 U.S.C. § 355(j)(5)(C)(i)(III).

45. Plaintiffs are not aware of any other means of obtaining information regarding Actavis's ANDA Products within the 45-day statutory period. Without such information, Plaintiffs will use the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that Actavis's ANDA Products fall within the scope of one or more claims of the '070, '713, '839, '892, '169, '393, '311, '897, and '901 patents.

COUNT 1: INFRINGEMENT OF THE '070 PATENT UNDER 35 U.S.C. § 271 (e)

46. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

47. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '070 patent creates an actual and justiciable controversy with respect to infringement of the '070 patent.

48. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '070 patent, and will indirectly infringe by actively inducing infringement by others.

49. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '070 patent was an act of infringement of the '070 patent under 35 U.S.C. § 271(e)(2).

50. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '070 patent.

51. Upon information and belief, Actavis was and is aware of the existence of the '070 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '070 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

52. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '070 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE '713 PATENT UNDER 35 U.S.C. § 271(e)

53. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

54. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '713 patent creates an actual and justiciable controversy with respect to infringement of the '713 patent.

55. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '713 patent, and will indirectly infringe by actively inducing infringement by others.

56. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '713 patent was an act of infringement of the '713 patent under 35 U.S.C. § 271(e)(2).

57. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '713 patent.

58. Upon information and belief, Actavis was and is aware of the existence of the '713 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '713 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

59. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '713 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE '839 PATENT UNDER 35 U.S.C. § 271(e)

60. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

61. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '839 patent creates an actual and justiciable controversy with respect to infringement of the '839 patent.

62. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '839 patent, and will indirectly infringe by actively inducing infringement by others.

63. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '839 patent was an act of infringement of the '839 patent under 35 U.S.C. § 271(e)(2).

64. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '839 patent.

65. Upon information and belief, Actavis was and is aware of the existence of the '839 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '839 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

66. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '839 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 4: INFRINGEMENT OF THE '892 PATENT UNDER 35 U.S.C. § 271 (e)

67. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

68. Actavis's submission of ANDA 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '892 patent creates an actual and justiciable controversy with respect to infringement of the '892 patent.

69. Upon information and belief, Actavis's submission of ANDA No. 208906 and upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '892 patent, and will indirectly infringe by actively inducing infringement by others.

70. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '892 patent was an act of infringement of the '892 patent under 35 U.S.C. § 271(e)(2).

71. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '892 patent.

72. Upon information and belief, Actavis was and is aware of the existence of the '892 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '892 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

73. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '892 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 5: INFRINGEMENT OF THE '169 PATENT UNDER 35 U.S.C. § 271(e)

74. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

75. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '169 patent creates an actual and justiciable controversy with respect to infringement of the '169 patent.

76. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '169 patent, and will indirectly infringe by actively inducing infringement by others.

77. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '169 patent was an act of infringement of the '169 patent under 35 U.S.C. § 271(e)(2).

78. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '169 patent.

79. Upon information and belief, Actavis was and is aware of the existence of the '169 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '169 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

80. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '169 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 6: INFRINGEMENT OF THE '393 PATENT UNDER 35 U.S.C. § 271 (e)

81. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

82. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '393 patent creates an actual and justiciable controversy with respect to infringement of the '393 patent.

83. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '393 patent, and will indirectly infringe by actively inducing infringement by others.

84. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '393 patent was an act of infringement of the '393 patent under 35 U.S.C. § 271(e)(2).

85. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '393 patent.

86. Upon information and belief, Actavis was and is aware of the existence of the '393 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '393 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

87. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '393 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 7: INFRINGEMENT OF THE '311 PATENT UNDER 35 U.S.C. § 271 (e)

88. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

89. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '311 patent creates an actual and justiciable controversy with respect to infringement of the '311 patent.

90. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for

sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '311 patent, and will indirectly infringe by actively inducing infringement by others.

91. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '311 patent was an act of infringement of the '311 patent under 35 U.S.C. § 271(e)(2).

92. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '311 patent.

93. Upon information and belief, Actavis was and is aware of the existence of the '311 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '311 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

94. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '311 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 8: INFRINGEMENT OF THE '897 PATENT UNDER 35 U.S.C. § 271 (e)

95. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

96. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA

Products upon receiving FDA approval prior to the expiration of the '897 patent creates an actual and justiciable controversy with respect to infringement of the '897 patent.

97. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '897 patent, and will indirectly infringe by actively inducing infringement by others.

98. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '897 patent was an act of infringement of the '897 patent under 35 U.S.C. § 271(e)(2).

99. Upon information and belief, Actavis's ANDA Products as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '897 patent.

100. Upon information and belief, Actavis was and is aware of the existence of the '897 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '897 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

101. Plaintiffs will be substantially and irreparably damaged and harmed if Actavis's infringement of the '897 patent is not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 9: INFRINGEMENT OF THE '901 PATENT UNDER 35 U.S.C. § 271 (e)

102. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

103. Actavis's submission of ANDA No. 208906 and Actavis's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of Actavis's ANDA Products upon receiving FDA approval prior to the expiration of the '901 patent creates an actual and justiciable controversy with respect to infringement of the '901 patent.

104. Upon information and belief, Actavis's submission of ANDA No. 208906 and, upon FDA approval of Actavis's ANDA, Actavis's commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Actavis's ANDA Products currently infringes and will directly infringe one or more claims of the '901 patent, and will indirectly infringe by actively inducing infringement by others.

105. Actavis's submission of ANDA No. 208906 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Actavis's ANDA Products prior to expiration of the '901 patent was an act of infringement of the '901 patent under 35 U.S.C. § 271(e)(2).

106. Upon information and belief, Actavis's ANDA Products or an intermediate in their manufacture as described in and/or directed by Actavis's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Actavis's ANDA Products would infringe one or more claims of the '901 patent.

107. Upon information and belief, Actavis was and is aware of the existence of the '901 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '901 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

108. UTC will be substantially and irreparably damaged and harmed if Actavis's infringement of the '901 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

1. A Judgment that Actavis:

   A. has infringed the ’070 patent, the ’713 patent, the ’839 patent, the ’892 patent, the ’169 patent, the ’393 patent, the ’311 patent, the ’897 patent, and the ’901 patent;

   B. will induce infringement of the ’070 patent, the ’713 patent, the ’839 patent, the ’892 patent, the ’169 patent, the ’393 patent, the ’311 patent, the ’897 patent, and the ’901 patent; and

   C. will contribute to the infringement by others of the ’070 patent, the ’713 patent, the ’839 patent, the ’892 patent, the ’169 patent, the ’393 patent, the ’311 patent, the ’897 patent, and the ’901 patent;

2. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of Actavis’s ANDA Products be not earlier than the latest of the expiration dates of the ’070 patent, the ’713 patent, the ’839 patent, the ’892 patent, the ’169 patent, the ’393 patent, the ’311 patent, the ’897 patent, and the ’901 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC and/or Supernus are or may become entitled;

3. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Actavis, its officers, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, their successors, and assigns, from infringing, contributorily infringing, or inducing others to infringe the ’070 patent, the ’713 patent, the ’839 patent, the ’892 patent, the

'169 patent, the '393 patent, the '311 patent, the '897 patent, and the '901 patent, including engaging in the commercial manufacture, use, sale, sale, offer for sale, and/or importation in the United States of the product that is the subject of ANDA No. 208906 and/or any applicable DMF until the expiration of the '070 patent, the '713 patent, the '839 patent, the '892 patent, the '169 patent, the '393 patent, the '311 patent, the '897 patent, and the '901 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC and/or Supernus are or may become entitled;

4. A Judgment declaring that making, using, selling, offering for sale, or importing into the United States of Actavis's ANDA Products, or any product or compound that infringes one or more of the '070 patent, the '713 patent, the '839 patent, the '892 patent, the '169 patent, the '393 patent, the '311 patent, the '897 patent, and the '901 patent, prior to the expiration dates of the respective patents, will infringe, actively induce infringement of, and will contribute to the infringement by others of the '070 patent, the '713 patent, '839 patent, the '892 patent, the '169 patent, the '393 patent, the '311 patent, the '897 patent, and the '901 patent;

5. Temporary, preliminary, permanent, or other injunctive relief as necessary or appropriate should Actavis seek to commercially manufacture, use, sell, offer to sell, or import Actavis's ANDA Products prior to disposition of this action and/or the expiration of the '070 patent, the '713 patent, the '839 patent, the '892 patent, the '169 patent, the '393 patent, the '311 patent, the '897 patent, and the '901 patent;

6. A Judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Actavis commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 208906 that infringes one or more of

the ’070 patent, the ’713 patent, the ’839 patent, the ’892 patent, the ’169 patent, the ’393 patent, the ’311 patent, the ’897 patent, and the ’901 patent;

7. A Judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding Plaintiffs their attorneys’ fees;

8. Costs and expenses in this action; and

9. Such further and other relief as this Court may deem just and proper.

JURY DEMAND

Plaintiffs request trial by jury for any issues so triable.

Dated: June 17, 2016

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LOCAL CIVIL RULE 11.2 & 40.1 CERTIFICATION

Plaintiffs hereby certify that, to their knowledge, the matter in controversy in this action is not the subject of any other pending lawsuit, arbitration, or administrative proceeding other than the following proceedings:

- *United Therapeutics Corporation, et al. v. Actavis Laboratories FL, Inc.*, Civil Action No. 3:16-cv-01816-PGS-LHG (D.N.J.); and
- *United Therapeutics Corporation v. Watson Laboratories, Inc.*, Civil Action No. 15-5723 (PGS)(LHG) (D.N.J.); and
- *Supernus Pharmaceuticals, Inc. v. Hon. Michelle K. Lee*, Civil Action No. 16-342 (GBL)(IDD) (E.D. Va.).

The first case is listed as a related case because it involves the same parties, the same asserted patents, and the same ANDA as the present case. The second case is identified as related because one of the nine patents being asserted in the present case, the ’393 patent, was asserted by United Therapeutics Corporation in that case. The present case involves a product, Orenitram® (treprostinil) Extended-Release Tablets, which is not at issue in that case. The remaining eight patents in the present case are not related to the ’393 patent. The third case is listed as a related case because it is an action seeking to correct the patent term adjustment under 35 U.S.C. § 154 for one of the other nine asserted patents, the ’897 patent.

Dated: June 17, 2016

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