IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION and SUPERNUS PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ANI PHARMACEUTICALS, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs United Therapeutics Corporation ("UTC") and Supernus Pharmaceuticals, Inc. ("Supernus") (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against ANI Pharmaceuticals, Inc. ("ANI"), 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), 8,747,897 ("the '897 patent") (attached as Exhibit F hereto), 9,050,311 ("the '311 patent") (attached as Exhibit G hereto), 9,278,901 ("the '901 patent") (attached as Exhibit H hereto), 9,393,203 ("the '203 patent") (attached as Exhibit I hereto), 9,422,223 ("the '223 patent") (attached as Exhibit J hereto), 9,593,066 ("the '066 patent") (attached as Exhibit K hereto), and 9,604,901 ("the '4901 patent") (attached as Exhibit L hereto).

2. This action arises out of ANI's submission of Abbreviated New Drug Application ("ANDA") No. 215667 ("ANI's ANDA") to the United States Food and Drug Administration ("FDA") seeking approval, prior to the expiration of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents, to manufacture, market, and sell generic copies of UTC's ORENITRAM® (treprostinil) Extended-Release Tablets, which are 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 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 having a place of business at 9715 Key West Avenue, 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, ANI is a corporation organized and existing under the laws of the State of Delaware having a principal place of business at 210 Main Street West, Baudette, MN 56623.

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. This Court has personal jurisdiction over ANI because, upon information and belief, ANI is incorporated and resides in Delaware.

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

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 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 sue for infringement thereof.

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 sue for infringement thereof.

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 sue for infringement thereof.

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 sue for infringement thereof.

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 sue for infringement thereof.

22. 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.

23. Supernus is the lawful owner of the ’897 patent by assignment of all right, title and interest in and to the ’897 patent, including the right to sue for infringement thereof. UTC is the exclusive licensee of the ’897 patent, with the exclusive right to develop, make, have made, use, offer for sale, sell, have sold, and import products covered by the ’897 patent.

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 sue for infringement thereof.

26. 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.

27. 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 sue for infringement thereof.

28. The ’203 patent, entitled “Osmotic drug delivery system,” was duly and legally issued by the United States Patent and Trademark Office on July 19, 2016. The named inventors are Argaw Kidane and Padmanabh P. Bhatt.

29. Supernus is the lawful owner of the ’203 patent assignment of all right, title and interest in and to the ’203 patent, including the right to sue for infringement thereof. UTC is the exclusive licensee of the ’203 patent, with the exclusive right to develop, make, have made, use, offer for sale, sell, have sold, and import products covered by the ’203 patent.

30. The ’223 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 23, 2016. The named inventors are Ken Phares, David Mottola, and Roger Jeffs.

31. UTC is the lawful owner of the ’223 patent assignment of all right, title and interest in and to the ’223 patent, including the right to sue for infringement thereof.

32. The ’066 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 March 14, 2017. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

33. UTC is the lawful owner of the ’066 patent assignment of all right, title and interest in and to the ’066 patent, including the right to sue for infringement thereof.

34. The ’4901 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 March 28, 2017. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

35. UTC is the lawful owner of the ’4901 patent assignment of all right, title and interest in and to the ’4901 patent, including the right to sue for infringement thereof.

36. ORENITRAM® and its FDA-approved uses are covered by one or more claims of the ’070, ’713, ’839, ’892, ’169, ’897, ’311, ’901, ’203, ’223, ’066, and ’4901 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

37. ANI notified Plaintiffs by letter dated February 19, 2021, which was delivered to Plaintiffs on or about February 23, 2021 (“ANI’s Notice Letter”), that it had submitted ANDA No. 215667 (“ANI’s ANDA”) to the FDA, seeking approval to commercially manufacture, market, use, and sell generic copies of ORENITRAM® (treprostinil) Extended-Release Tablets, 2.5 mg (“ANI’s ANDA Product”) prior to the expiration of the ’070, ’713, ’839, ’892, ’169, ’897, ’311, ’901, ’203, ’223, ’066 and ’4901 patents.

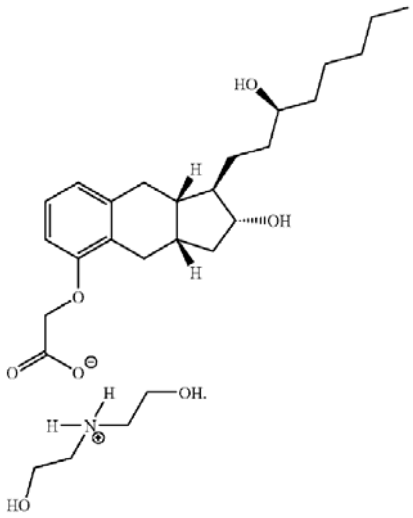
38. Upon information and belief, ANI submitted ANI's ANDA to the FDA seeking approval to commercially manufacture, market, use, and sell ANI's ANDA Product prior to the expiration of the '070, '713, '839, '892, '169, '897,'311, '901, '203, '223, '066 and '4901 patents.

39. ANI's Notice Letter included a statement under 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to set forth ANI's "factual and legal bases" for its opinion that the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066 and '4901 patents are "invalid, unenforceable, and/or not infringed" by the commercial manufacture, use, or sale of ANI's ANDA Product. That statement did not include any contention that any claim of the '070 patent, claims 23-25 of the '713 patent, claims 1 and 3-5 of the '839 patent, claims 8 and 9 of the '169 patent, claims 1, 5, 6, and 10 of the '311 patent, or any claim of the '223 patent are not infringed. That statement also did not include any contention that claims 1-22 and 26 of the '713 patent, claim 2 of the '839 patent, any claim of the '892 patent, claims 1-7 and 10-11 of the '169 patent, claims 2-4 and 7-9 of the '311 patent, claim 12 of the '901 patent, or any claim of the '203 patent are invalid. ANI did not allege the unenforceability of any claim except claims 1-5 of the '839 patent and claims 8-9 of the '169 patent.

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

41. Upon information and belief, ANI's ANDA Product contains the same active compound as UTC's approved ORENITRAM® product.

42. Upon information and belief, the active pharmaceutical ingredient ("API") of ANI's ANDA Product is treprostinil diethanolamine, which has the following structure:



43. Upon information and belief, ANI's ANDA seeks approval from the FDA to market ANI's ANDA Product for the same indication as UTC's approved ORENITRAM® product.

44. Upon information and belief, ANI represented to the FDA in ANI's ANDA that ANI's ANDA Product is bioequivalent to UTC's approved ORENITRAM® product.

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

46. According to ANI's Notice Letter, ANI's ANDA contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in ANI's opinion, the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066 and '4901 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use or sale of ANI's ANDA Product.

47. Upon information and belief, as of the date of ANI's Notice Letter, ANI 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).

48. Upon information and belief, the API of ANI's ANDA Product melts at about 107° C.

49. Upon information and belief, the API of ANI's ANDA Product has an x-ray powder diffraction pattern having a pattern peak at about 17.2 degrees 2 theta.

50. Upon information and belief, the API of ANI's ANDA Product comprises a diethanolamine salt of (+)-treprostinil.

51. Upon information and belief, the API of ANI's ANDA Product comprises a polymorph of a diethanolamine salt of (+)-treprostinil, which polymorph melts at 107° C.

52. Upon information and belief, ANI's ANDA product is a pharmaceutical formulation comprising a therapeutically effective amount of a diethanolamine salt of treprostinil and a pharmaceutically acceptable carrier.

53. Upon information and belief, ANI's ANDA product is formulated as a tablet.

54. Upon information and belief, ANI's ANDA product provides an oral bioavailability of treprostinil at least 50% greater than the oral bioavailability of a composition with treprostinil as a free acid.

55. Upon information and belief, ANI's ANDA product provides an oral bioavailability of treprostinil at least 100% greater than the oral bioavailability of a composition with treprostinil as a free acid.

56. Upon information and belief, the API of ANI's ANDA product is prepared by a method comprising dissolving treprostinil in a solvent, adding diethanolamine, heating, and cooling in an antisolvent to form the diethanolamine salt of treprostinil as a crystalline solid.

57. Upon information and belief, ANI's ANDA Product has an absolute bioavailability of at least 15%.

58. Upon information and belief, ANI's ANDA Product has an absolute bioavailability of between 21% and 25%.

59. Upon information and belief, ANI's ANDA Product, if used as described in ANI's proposed labelling, results in a C_{max} in the plasma of the person to whom it is administered that increases in a linear fashion over 8 hours.

60. Upon information and belief, ANI's ANDA Product, if used as described in ANI's proposed labelling, results in a AUC_{inf} in the plasma of the person to whom it is administered that increases in a linear fashion over 8 hours.

61. Upon information and belief, ANI's ANDA Product, if used as described in ANI's proposed labelling, results in a concentration of treprostinil in the person's plasma of at least 50 pg/ml for at least 8 hours.

COUNT 1: INFRINGEMENT OF THE '070 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

63. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '070 patent.

64. ANI's submission of ANI's ANDA and its intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

65. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale, and/or

importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '070 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

66. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '070 patent was an act of infringement of the '070 patent under 35 U.S.C. § 271(e)(2).

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

68. Upon information and belief, ANI will induce others to infringe one or more claims of the '070 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API or subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '070 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '070 patent and intent to induce the infringement thereof.

69. Upon information and belief, ANI will also contributorily infringe one or more claims of the '070 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell,

and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '070 patent.

70. Upon information and belief, ANI will also infringe one or more claims of the '070 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

71. Upon information and belief, ANI 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.

72. UTC will be substantially and irreparably damaged and harmed if ANI'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(a)-(c), (e) and (g)

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

74. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '713 patent.

75. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

76. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '713 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

77. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '713 patent was an act of infringement of the '713 patent under 35 U.S.C. § 271(e)(2).

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

79. Upon information and belief, ANI will induce others to infringe one or more claims of the '713 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '713 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '713 patent and intent to induce the infringement thereof.

80. Upon information and belief, ANI will also contributorily infringe one or more claims of the '713 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '713 patent.

81. Upon information and belief, ANI will also infringe one or more claims of the '713 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

82. Upon information and belief, ANI 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.

83. UTC will be substantially and irreparably damaged and harmed if ANI'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(a)-(c), (e) and (g)

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

85. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '839 patent.

86. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

87. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '839 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

88. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '839 patent was an act of infringement of the '839 patent under 35 U.S.C. § 271(e)(2).

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

90. Upon information and belief, ANI will induce others to infringe one or more claims of the '839 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '839 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of

infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '839 patent and intent to induce the infringement thereof.

91. Upon information and belief, ANI will also contributorily infringe one or more claims of the '839 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '839 patent.

92. Upon information and belief, ANI will also infringe one or more claims of the '839 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

93. Upon information and belief, ANI 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.

94. UTC will be substantially and irreparably damaged and harmed if ANI'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(a)-(c), (e) and (g)

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

96. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '892 patent.

97. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

98. Upon information and belief, ANI's submission of ANI's ANDA and upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '892 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

99. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '892 patent was an act of infringement of the '892 patent under 35 U.S.C. § 271(e)(2).

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

101. Upon information and belief, ANI will induce others to infringe one or more claims of the '892 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '892 patent. Upon

information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '892 patent and intent to induce the infringement thereof.

102. Upon information and belief, ANI will also contributorily infringe one or more claims of the '892 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '892 patent.

103. Upon information and belief, ANI will also infringe one or more claims of the '892 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

104. Upon information and belief, ANI 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.

105. UTC will be substantially and irreparably damaged and harmed if ANI'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(a)-(c), (e) and (g)

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

107. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '169 patent.

108. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

109. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '169 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

110. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '169 patent was an act of infringement of the '169 patent under 35 U.S.C. § 271(e)(2).

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

112. Upon information and belief, ANI will induce others to infringe one or more claims of the '169 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding

and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '169 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '169 patent and intent to induce the infringement thereof.

113. Upon information and belief, ANI will also contributorily infringe one or more claims of the '169 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '169 patent.

114. Upon information and belief, ANI will also infringe one or more claims of the '169 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

115. Upon information and belief, ANI 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.

116. UTC will be substantially and irreparably damaged and harmed if ANI'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 '897 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

118. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '897 patent.

119. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

120. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '897 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

121. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '897 patent was an act of infringement of the '897 patent under 35 U.S.C. § 271(e)(2).

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

123. Upon information and belief, ANI will induce others to infringe one or more claims of the '897 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '897 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '897 patent and intent to induce the infringement thereof.

124. Upon information and belief, ANI will also contributorily infringe one or more claims of the '897 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '897 patent.

125. Upon information and belief, ANI will also infringe one or more claims of the '897 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

126. Upon information and belief, ANI 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.

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

COUNT 7: INFRINGEMENT OF THE '311 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

129. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '311 patent.

130. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

131. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '311 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

132. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '311 patent was an act of infringement of the '311 patent under 35 U.S.C. § 271(e)(2).

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

134. Upon information and belief, ANI will induce others to infringe one or more claims of the '311 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '311 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '311 patent and intent to induce the infringement thereof.

135. Upon information and belief, ANI will also contributorily infringe one or more claims of the '311 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '311 patent.

136. Upon information and belief, ANI will also infringe one or more claims of the '311 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

137. Upon information and belief, ANI 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.

138. UTC will be substantially and irreparably damaged and harmed if ANI'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 '901 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

140. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '901 patent.

141. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product 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.

142. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '901 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

143. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '901 patent was an act of infringement of the '901 patent under 35 U.S.C. § 271(e)(2).

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

145. Upon information and belief, ANI will induce others to infringe one or more claims of the '901 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '901 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '901 patent and intent to induce the infringement thereof.

146. Upon information and belief, ANI will also contributorily infringe one or more claims of the '901 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '901 patent.

147. Upon information and belief, ANI will also infringe one or more claims of the '901 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

148. Upon information and belief, ANI 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.

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

COUNT 9: INFRINGEMENT OF THE '203 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

151. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '203 patent.

152. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product upon receiving FDA approval prior to the expiration of the '203 patent creates an actual and justiciable controversy with respect to infringement of the '203 patent.

153. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe

one or more claims of the '203 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

154. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '203 patent was an act of infringement of the '203 patent under 35 U.S.C. § 271(e)(2).

155. Upon information and belief, ANI's ANDA Product or an intermediate in its manufacture as described in and/or directed by ANI's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for ANI's ANDA Product would infringe one or more claims of the '203 patent.

156. Upon information and belief, ANI will induce others to infringe one or more claims of the '203 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '203 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '203 patent and intent to induce the infringement thereof.

157. Upon information and belief, ANI will also contributorily infringe one or more claims of the '203 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-

infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '203 patent.

158. Upon information and belief, ANI will also infringe one or more claims of the '203 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

159. Upon information and belief, ANI was and is aware of the existence of the '203 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '203 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

160. Plaintiffs will be substantially and irreparably damaged and harmed if ANI's infringement of the '203 patent is not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 10: INFRINGEMENT OF THE '223 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

162. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '223 patent.

163. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product upon receiving FDA approval prior to the expiration of the '223 patent creates an actual and justiciable controversy with respect to infringement of the '223 patent.

164. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '223 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

165. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '223 patent was an act of infringement of the '223 patent under 35 U.S.C. § 271(e)(2).

166. Upon information and belief, ANI's ANDA Product or an intermediate in its manufacture as described in and/or directed by ANI's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for ANI's ANDA Product would infringe one or more claims of the '223 patent.

167. Upon information and belief, ANI will induce others to infringe one or more claims of the '223 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '223 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '223 patent and intent to induce the infringement thereof.

168. Upon information and belief, ANI will also contributorily infringe one or more claims of the '223 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '223 patent.

169. Upon information and belief, ANI will also infringe one or more claims of the '223 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

170. Upon information and belief, ANI was and is aware of the existence of the '223 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '223 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

171. UTC will be substantially and irreparably damaged and harmed if ANI's infringement of the '223 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 11: INFRINGEMENT OF THE '066 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

173. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '066 patent.

174. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product upon

receiving FDA approval prior to the expiration of the '066 patent creates an actual and justiciable controversy with respect to infringement of the '066 patent.

175. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '066 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

176. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '066 patent was an act of infringement of the '066 patent under 35 U.S.C. § 271(e)(2).

177. Upon information and belief, ANI's ANDA Product or an intermediate in its manufacture as described in and/or directed by ANI's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for ANI's ANDA Product would infringe one or more claims of the '066 patent.

178. Upon information and belief, ANI will induce others to infringe one or more claims of the '066 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '066 patent. Upon information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of

infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '066 patent and intent to induce the infringement thereof.

179. Upon information and belief, ANI will also contributorily infringe one or more claims of the '066 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '066 patent.

180. Upon information and belief, ANI will also infringe one or more claims of the '066 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

181. Upon information and belief, ANI was and is aware of the existence of the '066 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '066 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

182. UTC will be substantially and irreparably damaged and harmed if ANI's infringement of the '066 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 12: INFRINGEMENT OF THE '4901 PATENT
UNDER 35 U.S.C. §§ 271(a)-(c), (e) and (g)

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

184. Upon information and belief, upon FDA approval, ANI will manufacture, market, sell, offer to sell, import, and distribute ANI's ANDA Products, which will result in infringement of one or more claims of the '4901 patent.

185. ANI's submission of ANI's ANDA and ANI's intention to engage in the commercial manufacture, use, sale, offer for sale, or importation of ANI's ANDA Product upon receiving FDA approval prior to the expiration of the '4901 patent creates an actual and justiciable controversy with respect to infringement of the '4901 patent.

186. Upon information and belief, ANI's submission of ANI's ANDA and, upon FDA approval of ANI's ANDA, ANI's commercial manufacture, use, sale, offer for sale and/or importation into the United States of ANI's ANDA Product has infringed and will directly infringe one or more claims of the '4901 patent, and will indirectly infringe by actively inducing infringement by others, under one or more of 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c), 35 U.S.C. § 271(e), and/or 35 U.S.C. § 271(g).

187. ANI's submission of ANI's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of ANI's ANDA Product prior to expiration of the '4901 patent was an act of infringement of the '4901 patent under 35 U.S.C. § 271(e)(2).

188. Upon information and belief, ANI's ANDA Product or an intermediate in its manufacture as described in and/or directed by ANI's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for ANI's ANDA Product would infringe one or more claims of the '4901 patent.

189. Upon information and belief, ANI will induce others to infringe one or more claims of the '4901 patent under 35 U.S.C. § 271(b) by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to, the manufacturer of ANI's ANDA Product, or its API, or other subsequent purchasers, distributors, or users thereof, which product or its use constitutes direct infringement of one or more claims of the '4901 patent. Upon

information and belief, ANI's aiding and abetting includes ANI's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to ANI's ANDA. ANI will do so with knowledge of the '4901 patent and intent to induce the infringement thereof.

190. Upon information and belief, ANI will also contributorily infringe one or more claims of the '4901 patent under 35 U.S.C. § 271(c) in that ANI will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which ANI knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '4901 patent.

191. Upon information and belief, ANI will also infringe one or more claims of the '4901 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell, or using ANI's ANDA Product or the API or an intermediate thereof which is neither materially changed by subsequent process nor a trivial or non-essential component of another product.

192. Upon information and belief, ANI was and is aware of the existence of the '4901 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '4901 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

193. UTC will be substantially and irreparably damaged and harmed if ANI's infringement of the '4901 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 ANI:

   A. has infringed the '070 patent, the '713 patent, '839 patent, the '892 patent, the '169 patent, the '897 patent, the '311 patent, the '901 patent, the '203 patent, the '223 patent, the '066 patent, and the '4901 patent under 35 U.S.C. § 271 (e)(2);

   B. will induce infringement by others of the '070 patent, the '713 patent, '839 patent, the '892 patent, the '169 patent, the '897 patent, the '311 patent, the '901 patent, the '203 patent, the '223 patent, the '066 patent, and the '4901 patent; and

   C. will contribute to the infringement by others of the '070 patent, the '713 patent, '839 patent, the '892 patent, the '169 patent, the '897 patent, the '311 patent, the '901 patent, the '203 patent, the '223 patent, the '066 patent, and the '4901 patent;

2. A Judgment pursuant to 35 U.S.C. § 271(e)(4)(A) ordering that the effective date of any FDA approval of ANI's ANDA Product be not earlier than the latest of the expiration dates of the '070 patent, the '713 patent, '839 patent, the '892 patent, the '169 patent, the '897 patent, the '311 patent, the '901 patent, the '203 patent, the '223 patent, the '066 patent, and the '4901 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 ANI, 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, ’839 patent, the ’892 patent, the ’169 patent, the ’897 patent, the ’311 patent, the ’901 patent, the ’203 patent, the ’223 patent, the ’066 patent, and the ’4901 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 ANI’s ANDA and/or any applicable DMF until the expiration of the ’070 patent, the ’713 patent, ’839 patent, the ’892 patent, the ’169 patent, the ’897 patent, the ’311 patent, the ’901 patent, the ’203 patent, the ’223 patent, the ’066 patent, and the ’4901 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 ANI’s ANDA Product, or any product or compound that infringes one or more of the ’070 patent, the ’713 patent, ’839 patent, the ’892 patent, the ’169 patent, the ’897 patent, the ’311 patent, the ’901 patent, the ’203 patent, the ’223 patent, the ’066 patent, and the ’4901 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 ’897 patent, the ’311 patent, the ’901 patent, the ’203 patent, the ’223 patent, the ’066 patent, and the ’4901 patent;

5. A Judgment awarding Plaintiffs damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if ANI commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANI’s ANDA that infringes one or more of the ’070 patent, the ’713 patent, ’839 patent, the ’892 patent, the ’169 patent, the ’897 patent, the ’311 patent, the ’901 patent, the ’203 patent, the ’223 patent, the ’066 patent, and the ’4901 patent;

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

7. Awarding Plaintiffs their costs and expenses in this action; and

8. Granting such further and other relief as this Court may deem just and proper.

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