

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS	)
CORPORATION and	)
SUPERNUS PHARMACEUTICALS, INC.,	)
	)
Plaintiffs,	)
	)
v.	) C.A. No. 21-489-RGA
	)
ANI PHARMACEUTICALS, INC.,	)
	)
Defendant.	)

**DEFENDANT ANI PHARMACEUTICALS, INC.'S  
ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant ANI Pharmaceuticals, Inc. (“ANI”), by and through the undersigned attorneys, submits its answer to the Complaint of Plaintiff United Therapeutics Corporation (“UTC”) and Supernus Pharmaceuticals, Inc. (“Supernus,” and collectively with UTC, “Plaintiffs”) as follows. ANI denies all allegations in Plaintiffs’ Complaint except those admitted specifically below. This pleading is based upon ANI’s knowledge as to its own activities, and upon information and belief as to the activities of others:

**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).

**ANSWER:** ANI admits that the Complaint purports to bring an action for infringement of the patents listed in paragraph 1. ANI admits that what purport to be copies of the patents listed in paragraph 1 are attached as Exhibits A to L. ANI denies that Plaintiffs are entitled to any relief in this action.

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® (treprostинil) Extended-Release Tablets, which are approved by FDA for treatment of pulmonary arterial hypertension.

**ANSWER:** Paragraph 2 contains conclusions of law for which no response is required. To the extent a response is required, ANI admits that it filed ANDA No. 215667, seeking approval by the United States Food and Drug Administration to market generic products containing treprostинil prior to the expiration of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents. ANI denies the remaining allegations in paragraph 2.

### **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.

**ANSWER:** ANI admits, upon information and belief, that UTC is a corporation organized under the laws of the State of Delaware and has a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. ANI is without sufficient knowledge and information to form a belief as to the remaining allegations in paragraph 3 and therefore denies the same.

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.

**ANSWER:** ANI admits, upon information and belief, that Supernus is a corporation organized under the laws of the State of Delaware and has a place of business at 9715 Key West Avenue, Rockville, MD 20850. ANI is without sufficient knowledge and information to form a belief as to the remaining allegations in paragraph 4 and therefore denies the same.

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.

**ANSWER:** Admitted admits that ANI is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 210 Main Street West, Baudette, MN 56623. ANI denies the remaining allegations of paragraph 5.

#### **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.

**ANSWER:** Paragraph 6 contains conclusions of law for which no response is required. To the extent that a response is required, ANI admits that this action cites the patent laws of the United States generally. ANI further states that it does not contest that this Court has subject matter jurisdiction over Plaintiffs' claims. ANI denies any remaining allegations of paragraph 6.

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

**ANSWER:** Paragraph 7 contains conclusions of law for which no response is required. To the extent that a response is required, ANI does not contest personal jurisdiction in this judicial district for the limited purpose of this action only. ANI denies any remaining allegations of paragraph 7.

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

**ANSWER:** Paragraph 8 contains conclusions of law for which no response is required. To the extent that a response is required, ANI admits that Plaintiffs purport to base venue on

28 U.S.C. §1400(b). ANI does not contest that venue in this judicial district is proper for the limited purpose of this action only. ANI denies any remaining allegations of paragraph 8.

### **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®.

**ANSWER:** On information and belief, ANI admits that UTC is listed as the holder of NDA No. 203496 for treprostinil extended-release tablets, which it markets and sells under the name ORENITRAM®. ANI denies any remaining allegations in paragraph 9.

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.

**ANSWER:** On information and belief, ANI admits that ORENITRAM® was initially approved by the FDA in the United States in December 2013. ANI further admits upon information and belief that current prescribing information for ORENITRAM® states that it is indicated for “Treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.” ANI lacks knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 10, and therefore denies them.

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.

**ANSWER:** On information and belief, ANI admits that ORENITRAM® is marketed as extended-release tablets available in 0.125 mg, 0.25 mg, 1 mg, and 2.5 mg strengths. ANI lacks knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 11, and therefore denies them.

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.

**ANSWER:** ANI admits that the '070 patent is entitled "Compounds and methods for delivery of prostacyclin analogs," bears an issue date of August 26, 2008, and states the named inventors are Ken Phares and David Mottola. ANI denies that the '070 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 12.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 13, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '713 patent is entitled "Compounds and methods for delivery of prostacyclin analogs," bears an issue date of June 9, 2009, and states the named inventors are Ken Phares and David Mottola. ANI denies that the '713 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 14.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 15, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '839 patent is entitled "Compounds and methods for delivery of prostacyclin analogs," bears an issue date of August 28, 2012, and states the named inventors

are Ken Phares and David Mottola. ANI denies that the '839 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 16.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 17, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '892 patent is entitled "Solid formulations of prostacyclin analogs," bears an issue date of January 8, 2013, and states the named inventor is Kenneth R. Phares. ANI denies that the '892 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 18.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 19, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '169 patent is entitled "Compounds and methods for delivery of prostacyclin analogs," bears an issue date of April 2, 2013, and states the named inventors are Ken Phares and David Mottola. ANI denies that the '169 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 20.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 21, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '897 patent is entitled "Osmotic drug delivery system," bears an issue date of June 10, 2014, and states the named inventors are Argaw Kidane and Padmanabh P. Bhatt. ANI denies that the '897 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 22.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 23, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '311 patent is entitled "Compounds and methods for delivery of prostacyclin analogs," bears an issue date of June 9, 2015, and states the named inventors are Ken Phares, David Mottola, and Hitesh Batra. ANI denies that the '311 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 24.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 25, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '901 patent is entitled "Compounds and methods for delivery of prostacyclin analogs," bears an issue date of March 8, 2016, and states the named inventors are Ken Phares, David Mottola, and Roger Jeffs. ANI denies that the '901 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 26.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 27, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '203 patent is entitled "Osmotic drug delivery system," bears an issue date of July 19, 2016, and states the named inventors are Argaw Kidane and Padmanabh P. Bhatt. ANI denies that the '203 patent was duly and legally issued. ANI denies any remaining allegations of paragraph 28.

29. Supernus is the lawful owner of the '203 patent by 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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 29, and therefore denies the same.

30. The '223 patent, entitled "Compounds and methods of 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.

**ANSWER:** ANI admits that the '223 patent is entitled "Compound and Methods for Delivery of Prostacyclin Analogs," bears an issue date of August 23, 2016, and states the named inventors are Ken Phares, David Mottola, and Roger Jeffs. ANI denies that the '223 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 30.

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

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 31, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '066 patent is entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," bears an issue date of March 14, 2017, and states the named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh. ANI denies that the '066 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 32.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 33, and therefore denies the same.

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.

**ANSWER:** ANI admits that the '4901 patent is entitled "Process to prepare treprostinil, the active ingredient in Remodulin®," bears an issue date of March 28, 2017, and states the named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh. ANI denies that the '4901 patent was duly and legally issued. ANI denies any remaining allegations in paragraph 34.

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.

**ANSWER:** ANI lacks knowledge sufficient to confirm the truth of the allegations in paragraph 35, and therefore denies the same.

36. ORENITRAM® and its FDA-approved manufacture and 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").

**ANSWER:** Paragraph 36 contains legal conclusions to which no response is required. To the extent that a response is required, ANI admits that the patents identified in paragraph 36 are listed in the Orange Book in connection with ORENITRAM®, and denies any remaining allegations in paragraph 36.

#### **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 filed 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.

**ANSWER:** ANI admits that by letter dated February 19, 2021, it notified Plaintiffs that ANI had submitted ANDA No. 215667 to the FDA, seeking approval of a treprostinil extended-release 2.5 mg tablet prior to the expiration of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066 and '4901 patents, and that the asserted patents are invalid and/or not infringed. ANI admits, upon information and belief, that ANI's Notice Letter was delivered to Plaintiffs on or about February 23, 2021. ANI denies any remaining allegations in paragraph 37.

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.

**ANSWER:** ANI admits that it submitted ANDA No. 215667 to the FDA seeking approval of a treprostinil extended-release 2.5 mg tablet prior to the expiration of the '070, '713, '839, '892,

'169, '897, '311, '901, '203, '223, '066 and '4901 patents. ANI denies any remaining allegations in paragraph 38.

39. ANI's Notice Letter included a statement under 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to recite ANI's "factual and legal basis" 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.

**ANSWER:** ANI admits that the Notice Letter stated that the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066 and '4901 patents are "invalid, unenforceable, and/or not infringed." The Notice Letter speaks for itself and is the best evidence of its contents. ANI denies any remaining allegations in paragraph 39.

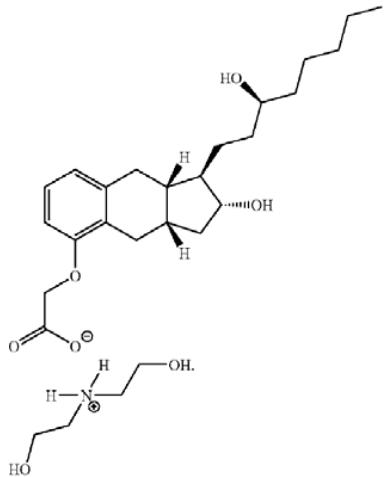
40. Plaintiffs are commencing this action before the expiration of forty-five days from the date Plaintiffs received ANI's Notice Letter.

**ANSWER:** Paragraph 40 contains conclusions of law for which no response is required. To the extent a response is required, ANI admits that the complaint in this action was filed April 1, 2021.

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

**ANSWER:** ANI admits that the active ingredient of ANI's ANDA Product is treprostinil diolamine. ANI lacks knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 41, and therefore denies them.

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



**ANSWER:** ANI admits that the active ingredient of ANI's ANDA Product is treprostinil diolamine. ANI denies any remaining allegations in paragraph 42.

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.

**ANSWER:** ANI states that the ANDA speaks for itself and is the best evidence of its contents. ANI denies any remaining allegations in paragraph 43.

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.

**ANSWER:** ANI states that the ANDA speaks for itself and is the best evidence of its contents. ANI denies any remaining allegations in paragraph 44.

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.

**ANSWER:** ANI denies the allegations in paragraph 45.

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, '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.

**ANSWER:** Admitted.

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).

**ANSWER:** ANI admits that as of or prior to the date of ANI's Notice Letter, certain ANI employees were aware of 21 U.S.C. §§ 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). ANI lacks knowledge and information sufficient to form a belief as to the truth or falsity of the remaining allegations in paragraph 47, and therefore denies them.

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

**ANSWER:** Paragraph 48 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 48.

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.

**ANSWER:** Paragraph 49 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 49.

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

**ANSWER:** Paragraph 50 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 50.

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.

**ANSWER:** Paragraph 51 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 51.

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.

**ANSWER:** Paragraph 52 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 52.

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

**ANSWER:** Paragraph 53 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 53.

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.

**ANSWER:** Paragraph 54 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 54.

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.

**ANSWER:** Paragraph 55 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 55.

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.

**ANSWER:** Paragraph 56 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 56.

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

**ANSWER:** Paragraph 57 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 57.

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

**ANSWER:** Paragraph 58 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 58.

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.

**ANSWER:** Paragraph 59 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 59.

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.

**ANSWER:** Paragraph 60 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 60.

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.

**ANSWER:** Paragraph 61 contains legal conclusions to which no response is required. To the extent that a response is required, ANI denies that it does or will infringe the asserted patents. ANI denies any remaining allegations in paragraph 61.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '070 patent. ANI denies the remaining allegations contained in paragraph 63.

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.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '070 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '070 patent. ANI denies the remaining allegations in paragraph 64.

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).

**ANSWER:** ANI denies the allegations in paragraph 65.

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).

**ANSWER:** ANI denies the allegations in paragraph 66.

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.

**ANSWER:** ANI denies the allegations in paragraph 67.

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.

**ANSWER:** ANI denies the allegations in paragraph 68.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '070 patent.

**ANSWER:** ANI denies the allegations in paragraph 69.

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.

**ANSWER:** ANI denies the allegations in paragraph 70.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '070 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '070 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 71.

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.

**ANSWER:** ANI denies the allegations in paragraph 72.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '713 patent. ANI denies the remaining allegations contained in paragraph 74.

75. 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 '713 patent creates an actual and justiciable controversy with respect to infringement of the '713 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '713 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '713 patent. ANI denies the remaining allegations in paragraph 75.

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).

**ANSWER:** ANI denies the allegations in paragraph 76.

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).

**ANSWER:** ANI denies the allegations in paragraph 77.

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.

**ANSWER:** ANI denies the allegations in paragraph 78.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 79.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '713 patent.

**ANSWER:** ANI denies the allegations in paragraph 80.

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.

**ANSWER:** ANI denies the allegations in paragraph 81.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '713 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '713 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 82.

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.

**ANSWER:** ANI denies the allegations in paragraph 83.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '839 patent. ANI denies the remaining allegations contained in paragraph 85.

86. 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 '839 patent creates an actual and justiciable controversy with respect to infringement of the '839 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '839 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '839 patent. ANI denies the remaining allegations in paragraph 86.

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).

**ANSWER:** ANI denies the allegations in paragraph 87.

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).

**ANSWER:** ANI denies the allegations in paragraph 88.

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.

**ANSWER:** ANI denies the allegations in paragraph 89.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 90.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '839 patent.

**ANSWER:** ANI denies the allegations in paragraph 91.

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.

**ANSWER:** ANI denies the allegations in paragraph 92.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '839 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '839 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 93.

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.

**ANSWER:** ANI denies the allegations in paragraph 94.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '892 patent. ANI denies the remaining allegations contained in paragraph 96.

97. 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 '892 patent creates an actual and justiciable controversy with respect to infringement of the '892 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '892 patent. ANI specifically denies

that the ANI ANDA Product does or will infringe the '892 patent. ANI denies the remaining allegations in paragraph 97.

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).

**ANSWER:** ANI denies the allegations in paragraph 98.

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).

**ANSWER:** ANI denies the allegations in paragraph 99.

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.

**ANSWER:** ANI denies the allegations in paragraph 100.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 101.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '892 patent.

**ANSWER:** ANI denies the allegations in paragraph 102.

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.

**ANSWER:** ANI denies the allegations in paragraph 103.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '892 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '892 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 104.

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.

**ANSWER:** ANI denies the allegations in paragraph 105.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '169 patent. ANI denies the remaining allegations contained in paragraph 107.

108. 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 '169 patent creates an actual and justiciable controversy with respect to infringement of the '169 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '169 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '169 patent. ANI denies the remaining allegations in paragraph 108.

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).

**ANSWER:** ANI denies the allegations in paragraph 109.

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).

**ANSWER:** ANI denies the allegations in paragraph 110.

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.

**ANSWER:** ANI denies the allegations in paragraph 111.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 112.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '169 patent.

**ANSWER:** ANI denies the allegations in paragraph 113.

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.

**ANSWER:** ANI denies the allegations in paragraph 114.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '169 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '169 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 115.

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.

**ANSWER:** ANI denies the allegations in paragraph 116.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '897 patent. ANI denies the remaining allegations contained in paragraph 118.

119. 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 '897 patent creates an actual and justiciable controversy with respect to infringement of the '897 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '897 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '897 patent. ANI denies the remaining allegations in paragraph 119.

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).

**ANSWER:** ANI denies the allegations in paragraph 120.

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).

**ANSWER:** ANI denies the allegations in paragraph 121.

122. 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 '897 patent.

**ANSWER:** ANI denies the allegations in paragraph 122.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 123.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '897 patent.

**ANSWER:** ANI denies the allegations in paragraph 124.

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.

**ANSWER:** ANI denies the allegations in paragraph 125.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '897 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '897 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 126.

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

**ANSWER:** ANI denies the allegations in paragraph 127.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '311 patent. ANI denies the remaining allegations contained in paragraph 129.

130. 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 '311 patent creates an actual and justiciable controversy with respect to infringement of the '311 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '311 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '311 patent. ANI denies the remaining allegations in paragraph 130.

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).

**ANSWER:** ANI denies the allegations in paragraph 131.

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).

**ANSWER:** ANI denies the allegations in paragraph 132.

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.

**ANSWER:** ANI denies the allegations in paragraph 133.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 134.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '311 patent.

**ANSWER:** ANI denies the allegations in paragraph 135.

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.

**ANSWER:** ANI denies the allegations in paragraph 136.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '311 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '311 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 137.

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.

**ANSWER:** ANI denies the allegations in paragraph 138.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '901 patent. ANI denies the remaining allegations contained in paragraph 140.

141. 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 '901 patent creates an actual and justiciable controversy with respect to infringement of the '901 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '901 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '901 patent. ANI denies the remaining allegations in paragraph 141.

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).

**ANSWER:** ANI denies the allegations in paragraph 142.

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).

**ANSWER:** ANI denies the allegations in paragraph 143.

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.

**ANSWER:** ANI denies the allegations in paragraph 144.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 145.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '901 patent.

**ANSWER:** ANI denies the allegations in paragraph 146.

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.

**ANSWER:** ANI denies the allegations in paragraph 147.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '901 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '901 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 148.

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.

**ANSWER:** ANI denies the allegations in paragraph 149.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '203 patent. ANI denies the remaining allegations contained in paragraph 151.

152. 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 '203 patent creates an actual and justiciable controversy with respect to infringement of the '203 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '203 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '203 patent. ANI denies the remaining allegations in paragraph 152.

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).

**ANSWER:** ANI denies the allegations in paragraph 153.

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).

**ANSWER:** ANI denies the allegations in paragraph 154.

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.

**ANSWER:** ANI denies the allegations in paragraph 155.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 156.

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

**ANSWER:** ANI denies the allegations in paragraph 157.

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.

**ANSWER:** ANI denies the allegations in paragraph 158.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '203 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '203 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 159.

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

**ANSWER:** ANI denies the allegations in paragraph 160.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to each of the following 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '223 patent. ANI denies the remaining allegations contained in paragraph 162.

163. 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 '223 patent creates an actual and justiciable controversy with respect to infringement of the '223 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '223 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '223 patent. ANI denies the remaining allegations in paragraph 163.

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).

**ANSWER:** ANI denies the allegations in paragraph 164.

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).

**ANSWER:** ANI denies the allegations in paragraph 165.

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.

**ANSWER:** ANI denies the allegations in paragraph 166.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 167.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '223 patent.

**ANSWER:** ANI denies the allegations in paragraph 168.

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.

**ANSWER:** ANI denies the allegations in paragraph 169.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '223 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '223 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 170.

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.

**ANSWER:** ANI denies the allegations in paragraph 171.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '066 patent. ANI denies the remaining allegations contained in paragraph 173.

174. 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 '066 patent creates an actual and justiciable controversy with respect to infringement of the '066 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '066 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '066 patent. ANI denies the remaining allegations in paragraph 174.

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).

**ANSWER:** ANI denies the allegations in paragraph 175.

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).

**ANSWER:** ANI denies the allegations in paragraph 176.

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.

**ANSWER:** ANI denies the allegations in paragraph 177.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 178.

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

noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '066 patent.

**ANSWER:** ANI denies the allegations in paragraph 179.

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.

**ANSWER:** ANI denies the allegations in paragraph 180.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '066 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '066 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 181.

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.

**ANSWER:** ANI denies the allegations in paragraph 182.

**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.

**ANSWER:** ANI repeats and re-incorporates its responses to 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.

**ANSWER:** ANI specifically denies that the ANI ANDA Product does or will infringe one or more claims of the '4901 patent. ANI denies the remaining allegations contained in paragraph 184.

185. 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 '4901 patent creates an actual and justiciable controversy with respect to infringement of the '4901 patent.

**ANSWER:** ANI admits based on the filing of this Complaint that there is an actual and justiciable controversy with respect to infringement of the '4901 patent. ANI specifically denies that the ANI ANDA Product does or will infringe the '4901 patent. ANI denies the remaining allegations in paragraph 185.

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).

**ANSWER:** ANI denies the allegations in paragraph 186.

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).

**ANSWER:** ANI denies the allegations in paragraph 187.

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.

**ANSWER:** ANI denies the allegations in paragraph 188.

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 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.

**ANSWER:** ANI denies the allegations in paragraph 189.

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 noninfringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '4901 patent.

**ANSWER:** ANI denies the allegations in paragraph 190.

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.

**ANSWER:** ANI denies the allegations in paragraph 191.

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.

**ANSWER:** ANI admits that, at the time it filed its ANDA, ANI was aware of the '4901 to such an extent that ANI was able to accurately and in good faith certify that the ANI ANDA Product does not infringe that patent, and/or that the '4901 patent is invalid and/or unenforceable. ANI otherwise denies the allegations in paragraph 192.

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.

**ANSWER:** ANI denies the allegations in paragraph 193.

#### **PRAYER FOR RELIEF**

The remainder of Plaintiffs' complaint is a prayer for relief, and does not require a response. To the extent any response is required, ANI denies that Plaintiffs are entitled to any remedy or relief.

## **AFFIRMATIVE DEFENSES**

ANI hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof. ANI reserves the right to assert additional defenses, as warranted by facts learned through investigation and discovery.

### **First Affirmative Defense**

Claims of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents are invalid under one or more provision of sections 101, 102, 103, and/or 112 of Title 35 of the United States Code.

### **Second Affirmative Defense**

The filing of ANI's ANDA No. 215667 has not infringed and does not infringe any valid and enforceable claim of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, or '4901 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

### **Third Affirmative Defense**

The manufacture, use, sale, or offer for sale of ANI's proposed generic products that are the subject of ANDA No. 215667 has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claims of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, or '4901 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

### **Fourth Affirmative Defense**

Plaintiffs are estopped from asserting claims that ANI's proposed generic products that are the subject of ANDA No. 215667 have infringed any valid or enforceable claims of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, or '4901 patents either directly or

indirectly, and either literally or under the doctrine of equivalents, on the basis of prosecution history estoppel.

**Fifth Affirmative Defense**

The Complaint fails to state a claim upon which relief can be granted.

**Sixth Affirmative Defense**

ANI's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

**Seventh Affirmative Defense**

ANI has not willfully infringed any claim of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, or '4901 patents.

**Eighth Affirmative Defense**

Any additional defenses that discovery may reveal.

## **COUNTERCLAIMS**

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, ANI Pharmaceuticals, Inc. (“ANI”) through its attorneys, brings the following Counterclaims against United Therapeutics Corporation (“UTC”) and Supernus Pharmaceuticals, Inc. (“Supernus,” and collectively with UTC, “Plaintiffs” or “Counterclaim Defendants”):

1. ANI repeats and incorporates by reference each of the foregoing paragraphs of ANI’s Answer and Affirmative Defenses to the Complaint.
2. These are ANI’s counterclaims for declaratory judgment of non-infringement and invalidity of one or more claims of United States Patent Nos. 7,417,070 (“the ’070 patent”), 7,544,713 (“the ’713 patent”), 8,252,839 (“the ’839 patent”), 8,349,892 (“the ’892 patent”), 8,410,169 (“the ’169 patent”), 8,747,897 (“the ’897 patent”), 9,050,311 (“the ’311 patent”), 9,278,901 (“the ’901 patent”), 9,393,203 (“the ’203 patent”), 9,422,223 (“the ’223 patent”), 9,593,066 (“the ’066 patent”), and 9,604,901 (“the ’4901 patent”) (collectively, the “Patents-in-Suit”) under 35 U.S.C. § 271(e)(5), 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(b)(2).

## **PARTIES**

3. ANI Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a place of business at 210 Main Street West, Baudette, MN 56623.

4. Upon information and belief, as stated in its complaint against ANI, UTC is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1040 Spring Street, Silver Spring, Maryland 20910.

5. Upon information and belief, as stated in its complaint against ANI, Supernus is a corporation organized under the laws of the State of Delaware, having a principal place of business at 9715 Key West Avenue, Rockville, MD 20850.

#### **JURISDICTION AND VENUE**

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, and/or 21 U.S.C. § 355(j), based on an actual controversy between the parties arising under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq.*

7. This Court has personal jurisdiction over the Plaintiffs because, among other reasons, they consented to the personal jurisdiction of the Court by commencing this action for patent infringement in this judicial district, as set forth in their Complaint.

8. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391(a) and 1400(a) based at least on the filing by Plaintiffs of this lawsuit in this venue.

9. There is an actual and justiciable controversy between the parties as to the infringement, validity, and enforceability of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents.

#### **FACTUAL BACKGROUND**

10. On information and belief, the '070 patent is titled "Compounds and methods for delivery of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on August 26, 2008. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '070 patent.

11. On information and belief, the '713 patent is titled "Compounds and methods for delivery of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on

June 9, 2009. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '713 patent.

12. On information and belief, the '839 patent is titled "Compounds and methods for delivery of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on August 28, 2012. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '839 patent.

13. On information and belief, the '892 patent is titled "Solid formulations of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on January 8, 2013. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '892 patent.

14. On information and belief, the '169 patent is titled "Compounds and methods for delivery of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on April 2, 2013. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '169 patent.

15. On information and belief, the '897 patent is titled "Osmotic drug delivery system," and it was issued by the U.S. Patent and Trademark Office on June 10, 2014. On information and belief, Plaintiff/Counterclaim Defendant Supernus is the owner of the '897 patent.

16. On information and belief and according to Plaintiffs/Counterclaim Defendants' Complaint, UTC is the exclusive licensee of the '897 patent.

17. On information and belief, the '311 patent is titled "Compounds and methods for delivery of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on

June 9, 2015. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '311 patent.

18. On information and belief, the '901 patent is titled "Compounds and methods for delivery of prostacyclin analogs," and it was issued by the U.S. Patent and Trademark Office on March 8, 2016. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '901 patent.

19. On information and belief, the '203 patent is titled "Osmotic Drug Delivery System," and it was issued by the U.S. Patent and Trademark Office on July 19, 2016. On information and belief, Plaintiff/Counterclaim Defendant Supernus Pharmaceuticals, Inc. is the owner of the '203 patent.

20. On information and belief and according to Plaintiffs/Counterclaim Defendants' Complaint, UTC is the exclusive licensee of the '203 patent.

21. On information and belief, the '223 patent is titled "Compounds and Methods for Delivery of Prostacyclin Analogs," and it was issued by the U.S. Patent and Trademark Office on August 23, 2016. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '223 patent.

22. On information and belief, the '066 patent is titled "Process to prepare treprostinil, the active ingredient in Remodulin®," and it was issued by the U.S. Patent and Trademark Office on March 28, 2017. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '066 patent.

23. On information and belief, the '4901 patent is titled "Process to prepare treprostinil, the active ingredient in Remodulin®," and it was issued by the U.S. Patent and

Trademark Office on March 28, 2017. On information and belief, Plaintiff/Counterclaim Defendant UTC is the owner of the '4901 patent.

24. On information and belief and according to Plaintiffs/Counterclaim Defendants' Complaint, UTC holds approved New Drug Application ("NDA") No. 203496 for treprostinil extended-release tablets. On information and belief and according to Plaintiffs/Counterclaim Defendants' Complaint, UTC markets and sells these tablets in the United States, including in this district, under the brand name ORENITRAM®.

25. On information and belief, UTC caused to be listed the '070 patent, '713 patent, '839 patent, '892 patent, '169 patent, '897 patent, '311 patent, '901 patent, '203 patent, '223 patent, '066 patent, and '4901 patent in the FDA publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") in connection with NDA No. 203496 as covering ORENITRAM® and/or its use.

26. ANI filed its Abbreviated New Drug Application ("ANDA") No. 215667 with FDA seeking approval to market its proposed generic treprostinil extended-release tablets ("ANDA Product").

27. ANI's ANDA No. 215667, as originally filed, contained a "Paragraph IV Certification" under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product.

28. In accordance with the requirements of 21 U.S.C. § 355(j)(2)(B), ANI sent UTC and Supernus a Notice Letter dated February 19, 2021, stating that ANDA No. 215667 included a Paragraph IV certification alleging that the Patents-in-Suit are invalid, unenforceable, and will

not be infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Product.

29. In response to ANDA No. 215667 and ANI's Paragraph IV certification, UTC and Supernus initiated the present litigation by filing a complaint against ANI on April 1, 2021.

30. UTC and Supernus have alleged in the present action that ANI has infringed and will infringe the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents by filing ANDA No. 215667 with the FDA and/or by manufacturing, using, or selling the products described in that ANDA.

31. As a consequence of the foregoing, there is an actual and justiciable controversy between ANI and the Plaintiffs as to whether the claims of the '070, '713, '839, '892, '169, '897, '311, '901, '203, '223, '066, and '4901 patents are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by ANI's ANDA No. 215667 or by the manufacture, use, or sale of the products described therein.

### **EXCEPTIONAL CASE**

32. This case is an exceptional one, and ANI is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

### **COUNT I (Declaration of Non-Infringement of the '070 Patent)**

33. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

34. UTC alleges ownership of the '070 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '070 patent.

35. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '070 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

36. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '070 patent.

37. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '070 patent.

**COUNT II**  
**(Declaration of Invalidity of the '070 Patent)**

38. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

39. UTC alleges ownership of the '070 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '070 patent.

40. One or more of the claims of the '070 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

41. One or more claims of the '070 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '070 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

42. Moreover, one or more claims of the '070 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement.

The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

43. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '070 patent.

44. ANI is entitled to a declaration that claims of the '070 patent are invalid.

**COUNT III**  
**(Declaration of Non-Infringement of the '713 Patent)**

45. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

46. UTC alleges ownership of the '713 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '713 patent.

47. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '713 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

48. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '713 patent.

49. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '713 patent.

**COUNT IV**  
**(Declaration of Invalidity of the '713 Patent)**

50. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

51. UTC alleges ownership of the '713 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '713 patent.

52. One or more of the claims of the '713 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

53. One or more claims of the '713 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '713 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

54. Moreover, one or more claims of the '713 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

55. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '713 patent.

56. ANI is entitled to a declaration that claims of the '713 patent are invalid.

**COUNT V**  
**(Declaration of Non-Infringement of the '839 Patent)**

57. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

58. UTC alleges ownership of the '839 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '839 patent.

59. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '839 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

60. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '839 patent.

61. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '839 patent.

**COUNT VI**  
**(Declaration of Invalidity of the '839 Patent)**

62. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

63. UTC alleges ownership of the '839 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '839 patent.

64. One or more of the claims of the '839 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

65. One or more claims of the '839 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '839 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

66. Moreover, one or more claims of the '839 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

67. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '839 patent.

68. ANI is entitled to a declaration that claims of the '839 patent are invalid.

**COUNT VII**  
**(Declaration of Non-Infringement of the '892 Patent)**

69. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

70. UTC alleges ownership of the '892 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '892 patent.

71. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '892 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

72. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '892 patent.

73. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '892 patent.

**COUNT VIII**  
**(Declaration of Invalidity of the '892 Patent)**

74. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

75. UTC alleges ownership of the '892 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '892 patent.

76. One or more of the claims of the '892 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

77. One or more claims of the '892 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '892 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

78. Moreover, one or more claims of the '892 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement.

The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

79. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '892 patent.

80. ANI is entitled to a declaration that claims of the '892 patent are invalid.

**COUNT IX**  
**(Declaration of Non-Infringement of the '169 Patent)**

81. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

82. UTC alleges ownership of the '169 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '169 patent.

83. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '169 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

84. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '169 patent.

85. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '169 patent.

**COUNT X**  
**(Declaration of Invalidity of the '169 Patent)**

86. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

87. UTC alleges ownership of the '169 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '169 patent.

88. One or more of the claims of the '169 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

89. One or more claims of the '169 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '169 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

90. Moreover, one or more claims of the '169 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

91. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '169 patent.

92. ANI is entitled to a declaration that claims of the '169 patent are invalid.

**COUNT XI**  
**(Declaration of Non-Infringement of the '897 Patent)**

93. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

94. UTC alleges ownership of the '897 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '897 patent.

95. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '897 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

96. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '897 patent.

97. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '897 patent.

**COUNT XII**  
**(Declaration of Invalidity of the '897 Patent)**

98. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

99. UTC alleges ownership of the '897 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '897 patent.

100. One or more of the claims of the '897 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

101. One or more claims of the '897 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '897 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

102. Moreover, one or more claims of the '897 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

103. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '897 patent.

104. ANI is entitled to a declaration that claims of the '897 patent are invalid.

**COUNT XIII**  
**(Declaration of Non-Infringement of the '311 Patent)**

105. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

106. UTC alleges ownership of the '311 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '311 patent.

107. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '311 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

108. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '311 patent.

109. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '311 patent.

**COUNT XIV**  
**(Declaration of Invalidity of the '311 Patent)**

110. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

111. UTC alleges ownership of the '311 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '311 patent.

112. One or more of the claims of the '311 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

113. One or more claims of the '311 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '311 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

114. Moreover, one or more claims of the '311 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement.

The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

115. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '311 patent.

116. ANI is entitled to a declaration that claims of the '311 patent are invalid.

**COUNT XV**  
**(Declaration of Non-Infringement of the '901 Patent)**

117. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

118. UTC alleges ownership of the '901 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '901 patent.

119. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '901 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

120. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '901 patent.

121. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '901 patent.

**COUNT XVI**  
**(Declaration of Invalidity of the '901 Patent)**

122. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

123. UTC alleges ownership of the '901 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '901 patent.

124. One or more of the claims of the '901 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

125. One or more claims of the '901 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '901 patent are invalid, see the ANI Second Notice Letter, all of which is incorporated by reference as if fully set forth herein.

126. Moreover, one or more claims of the '901 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the “written description” requirement, (2) failing to comply with the “enablement” requirement, and (3) failing to comply with the “definiteness” requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

127. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '901 patent.

128. ANI is entitled to a declaration that claims of the '901 patent are invalid.

**COUNT XVII**  
**(Declaration of Non-Infringement of the '203 Patent)**

129. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

130. Supernus alleges ownership of the '203 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '203 patent.

131. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '203 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

132. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '203 patent.

133. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '203 patent.

**COUNT XVIII**  
**(Declaration of Invalidity of the '203 Patent)**

134. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

135. Supernus alleges ownership of the '203 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '203 patent.

136. One or more of the claims of the '203 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

137. One or more claims of the '203 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letters that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '203 patent are invalid, see the ANI Notice Letters, all of which are incorporated by reference as if fully set forth herein.

138. Moreover, one or more claims of the '203 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

139. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '203 patent.

140. ANI is entitled to a declaration that claims of the '203 patent are invalid.

**COUNT XIX**  
**(Declaration of Non-Infringement of the '223 Patent)**

141. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

142. UTC alleges ownership of the '223 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '223 patent.

143. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '223 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

144. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '223 patent.

145. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '223 patent.

**COUNT XX**  
**(Declaration of Invalidity of the '223 Patent)**

146. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

147. UTC alleges ownership of the '223 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '223 patent.

148. One or more of the claims of the '223 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

149. One or more claims of the '223 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letters that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '223 patent are invalid, see the ANI Notice Letters, all of which are incorporated by reference as if fully set forth herein.

150. Moreover, one or more claims of the '223 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement.

The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

151. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '223 patent.

152. ANI is entitled to a declaration that claims of the '223 patent are invalid.

**COUNT XXI**  
**(Declaration of Non-Infringement of the '066 Patent)**

153. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

154. UTC alleges ownership of the '066 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '066 patent.

155. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '066 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

156. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '897 patent.

157. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '066 patent.

**COUNT XXII**  
**(Declaration of Invalidity of the '066 Patent)**

158. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

159. UTC alleges ownership of the '066 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '066 patent.

160. One or more of the claims of the '066 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

161. One or more claims of the '066 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '066 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

162. Moreover, one or more claims of the '066 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

163. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '066 patent.

164. ANI is entitled to a declaration that claims of the '066 patent are invalid.

**COUNT XXIII**  
**(Declaration of Non-Infringement of the '4901 Patent)**

165. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

166. UTC alleges ownership of the '4901 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '4901 patent.

167. The manufacture, use, or sale of ANI's ANDA product would not infringe any valid or enforceable claim of the '4901 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

168. A present, genuine, and justiciable controversy exists between ANI and UTC and Supernus regarding, *inter alia*, the issue of whether the manufacture, use, or sale of ANI's proposed ANDA product would infringe any valid or enforceable claim of the '897 patent.

169. ANI is entitled to a declaration that the manufacture, use, or sale of its ANDA product would not infringe any valid or enforceable claim of the '4901 patent.

**COUNT XXIV**  
**(Declaration of Invalidity of the '4901 Patent)**

170. ANI re-alleges and incorporates the allegations of each of the foregoing paragraphs as if fully set forth herein.

171. UTC alleges ownership of the '4901 patent, and Plaintiffs have brought claims against ANI alleging infringement of the '4901 patent.

172. One or more of the claims of the '4901 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112.

173. One or more claims of the '4901 patent are invalid under 35 U.S.C. §§ 102 and/or 103 in view of, at least, the prior art references identified in ANI's Notice Letter that Plaintiffs received. For additional explanation concerning exemplary reasons that the claims of the '4901 patent are invalid, see the ANI Notice Letter, all of which is incorporated by reference as if fully set forth herein.

174. Moreover, one or more claims of the '4901 patent are invalid under 35 U.S.C. §112 for (1) failing to comply with the "written description" requirement, (2) failing to comply with the "enablement" requirement, and (3) failing to comply with the "definiteness" requirement. The asserted claims do not satisfy the enablement requirement because the specification does not teach those skilled in the art how to make and how to use the full scope of the claimed invention without undue experimentation to any extent that could fairly be construed as covering the accused subject matter. Finally, the asserted claims do not satisfy the definiteness requirement because those skilled in the art would not understand the full scope of the asserted claims when read in the light of the specification.

175. A present, genuine, and justiciable controversy exists between ANI and Plaintiffs regarding, *inter alia*, the validity of claims of the '4901 patent.

176. ANI is entitled to a declaration that claims of the '4901 patent are invalid.

**PRAYER FOR RELIEF**

WHEREFORE, Defendant ANI Pharmaceuticals, Inc. respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs UTC and Supernus as follows:

- (a) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 7,417,070;
- (b) declaring that the claims of U.S. Patent No. 7,417,070 are invalid;

- (c) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 7,544,713;
- (d) declaring that the claims of U.S. Patent No. 7,544,713 are invalid;
- (e) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 8,252,839;
- (f) declaring that the claims of U.S. Patent No. 8,252,839 are invalid;
- (g) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 8,349,892;
- (h) declaring that the claims of U.S. Patent No. 8,349,892 are invalid;
- (i) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 8,410,169;
- (j) declaring that the claims of U.S. Patent No. 8,410,169 are invalid;
- (k) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 8,747,897;
- (l) declaring that the claims of U.S. Patent No. 8,747,897 are invalid;
- (m) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 9,050,311;
- (n) declaring that the claims of U.S. Patent No. 9,050,311 are invalid;
- (o) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 9,278,901;
- (p) declaring that the claims of U.S. Patent No. 9,278,901 are invalid;
- (q) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 9,393,203;

- (r) declaring that the claims of U.S. Patent No. 9,393,203 are invalid;
- (s) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 9,422,223;
- (t) declaring that the claims of U.S. Patent No. 9,422,223 are invalid;
- (u) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 9,593,066;
- (v) declaring that the claims of U.S. Patent No. 9,593,066 are invalid;
- (w) declaring that ANI has not infringed any valid and enforceable claim of U.S. Patent No. 9,604,901;
- (x) declaring that the claims of U.S. Patent No. 9,604,901 are invalid;
- (y) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding ANI its attorney's fees, costs, and expenses in this action; and
- (z) awarding ANI any further and additional relief as the Court deems just and proper.

Respectfully submitted,

/s/ Karen E. Keller

Karen E. Keller (No. 4489)

David M. Fry (No. 5486)

Nathan R. Hoeschen (No. 6232)

SHAW KELLER LLP

I.M. Pei Building

1105 North Market Street, 12th Floor  
Wilmington, DE 19801

(302) 298-0700

kkeller@shawkeller.com

dfry@shawkeller.com

nhoeschen@shawkeller.com

*Attorneys for ANI Pharmaceuticals, Inc.*

OF COUNSEL:  
Christopher B. Essig  
Kurt A. Mathas  
Michael A. Meneghini  
WINSTON & STRAWN LLP  
35 West Wacker Dr.  
Chicago, IL 60601-9703  
(312) 558-5600

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