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Attorneys for Plaintiff
United Therapeutics Corporation

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

UNITED THERAPEUTICS CORPORATION	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.: _____
	)	
SANDOZ, INC.,	)	
	)	
Defendant.	)	

COMPLAINT AND JURY DEMAND

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Defendant Sandoz, Inc. ("Sandoz"), alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, involving United States Patent Nos. 5,153,222 ("the '222 patent") (attached as Exhibit A hereto); 6,765,117 ("the '117 patent") (attached as Exhibit B hereto); and 7,999,007 ("the '007 patent") (attached as Exhibit C hereto).

2. This action arises out of Sandoz's submission of Abbreviated New Drug Application ("ANDA") No. 203649 to the United States Food and Drug Administration (the "FDA") seeking approval, prior to the expiration of the '222, '117, and '007 patents, to manufacture, market, and sell a generic copy of UTC's REMODULIN® (Treprostinil Sodium) Injection product which is approved by the FDA for treatment of pulmonary arterial hypertension.

THE PARTIES

3. UTC is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotech company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions.

4. Upon information and belief, Sandoz is a corporation organized and existing under the laws of the State of Colorado and has its principal place of business at 506 Carnegie Center, Suite 400, Princeton, New Jersey 08540.

JURISDICTION AND VENUE

5. 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.

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

7. Upon information and belief, this Court has personal jurisdiction over Sandoz with respect to this Complaint because, *inter alia*, of its continuous and systematic contacts with this judicial district where it maintains its principal place of business. Upon information and belief, Sandoz derives substantial revenue from articles used and consumed in this judicial district and, consistent with its practice with respect to other generic products, following any FDA approval of Sandoz's ANDA, Sandoz will sell its generic product throughout the United States, including in New Jersey. In addition, Sandoz has previously availed itself of this Court as a forum in which to bring patent litigation against others. *See Sandoz v. Eli Lilly and Co.*, Civil Action No. 2:07-cv-04100-DMC-MF (D.N.J.).

8. The acts giving rise to this action are centered in New Jersey and Sandoz has consented to the jurisdiction and venue of New Jersey. By letter dated February 2, 2012, Sandoz "of 506 Carnegie Center, Suite 400, Princeton, NJ 08540," gave notice of the acts giving rise to this action. The letter identified the relevant contact for "any inquiries concerning or for any service of process or legal information" as the Head of U.S. Patent Litigation of Sandoz Inc. located in Sandoz's Princeton, NJ offices. Sandoz's accompanying Offer of Confidential Access Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) requested that UTC agree that any claims for breach of that agreement granting confidential access may be brought in courts located in the State of New Jersey "and consent to the jurisdiction and venue of such courts for any such claims." Sandoz accordingly is availing itself of New Jersey in connection with its ANDA, making jurisdiction and venue proper in New Jersey.

BACKGROUND

9. UTC holds an approved New Drug Application (No. 21-272) for Treprostinil Sodium Injection, which UTC markets and sells under the registered trademark REMODULIN®.

10. REMODULIN® is a pharmaceutical product initially approved in the United States in May 2002, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease involving the narrowing of the arteries of the lungs, and resulting in high pressure in the pulmonary arteries and decreased blood flow from the heart to the lungs, thereby depriving the body of oxygen.

11. REMODULIN® is an injectable product approved for sale in concentrations including 10 mg/mL.

12. The ’222 patent, entitled “Method of treating pulmonary hypertension with benzidine prostaglandins,” was duly and legally issued by the United States Patent and Trademark Office on October 6, 1992 and is scheduled to expire on October 5, 2014. The named inventors are Anjaneyulu S. Tadepalli, Walker A. Long, James W. Crow, and Kenneth B. Klein.

13. UTC is the lawful owner of the ’222 patent by assignment of all right, title and interest in and to the ’222 patent, including the right to bring infringement suits thereon.

14. The ’117 patent, entitled “Process for stereoselective synthesis of prostacyclin derivatives,” was duly and legally issued by the United States Patent and Trademark Office on July 20, 2004 and is scheduled to expire on October 24, 2017. The named inventors are Robert M. Moriarty, Raju Penmasta, Liang Guo, Mungala S. Rao, and James P. Staszewski.

15. UTC is the lawful owner of the ’117 patent by assignment of all right, title and interest in and to the ’117 patent, including the right to bring infringement suits thereon.

16. The ’007 patent, entitled “Buffer solutions having selective bactericidal activity against gram negative bacteria,” was duly and legally issued by the United States Patent and Trademark Office on August 16, 2011 and is scheduled to expire March 20, 2029. The named inventors are Roger Jeffs and David Zaccardelli.

17. UTC is the lawful owner of the ’007 patent by assignment of all right, title and interest in and to the ’007 patent, including the right to bring infringement suits thereon.

18. REMODULIN® and its FDA approved uses and manufacture are covered by one or more claims of the ’222 patent, the ’117 patent, and the ’007 patent, which have all been listed in connection with REMODULIN® in the FDA’s *Approved Drug Products with Therapeutic Equivalents* publication (also known as the “Orange Book”).

ACTS GIVING RISE TO THIS ACTION

19. Sandoz notified UTC on February 3, 2012 (“Sandoz’s Notice Letter”) that it had filed ANDA No. 203649 with the FDA seeking approval to commercially manufacture, market, use and sell a generic copy of REMODULIN® treprostinil sodium injection, 200mg/20mL (10mg/mL) (“Sandoz’s ANDA Product”) prior to the expiration of the ’222, ’117, and ’007 patents.

20. Upon information and belief, Sandoz submitted ANDA No. 203649 with the FDA seeking approval to commercially manufacture, market, use and sell a generic copy of REMODULIN® treprostinil sodium injection, 200mg/20mL (10mg/mL) (“Sandoz’s ANDA Product”) prior to the expiration of the ’222, ’117, and ’007 patents.

21. Sandoz’s Notice Letter was accompanied by an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). On February 22, 2012, counsel for UTC responded to Sandoz that Sandoz’s Offer of Confidential Access did not follow the statutory requirements that the offer “shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for protecting trade secrets and other confidential business information.” UTC proposed an amended Offer of Confidential Access seeking access to the relevant sections of the ANDA and any Drug Master File (“DMF”) referenced in the ANDA. As of the filing of this Complaint, Sandoz has informed UTC

that Sandoz is represented by outside counsel, but neither Sandoz nor its counsel has provided any substantive response to UTC's amended Offer of Confidential access.

22. Upon information and belief, Sandoz submitted ANDA No. 203649 to obtain FDA approval to engage in the commercial manufacture, use and sale of Sandoz's ANDA Product prior to the expiration of the '222, '117, and '007 patents.

23. Sandoz's Notice Letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to recite Sandoz's "factual and legal bases" for its opinion that the '222, '117, and '007 patents are not valid and/or would not be infringed by the commercial manufacture, use, or sale of Sandoz's ANDA Product.

24. UTC is commencing this action before the expiration of forty-five days from the date UTC received Sandoz's Notice Letter.

25. Upon information and belief, Sandoz's ANDA Product contains the same active compound as UTC's approved REMODULIN® product.

26. Upon information and belief, Sandoz's ANDA No. 203649 seeks approval from the FDA to market Sandoz's ANDA Product for the same indication as UTC's approved REMODULIN® product.

27. Upon information and belief, Sandoz represented to the FDA in ANDA No. 203649 that Sandoz's ANDA Product is bioequivalent to UTC's approved REMODULIN® product.

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

29. According to Sandoz's Notice Letter, Sandoz's ANDA No. 203649 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in Sandoz's

opinion the ’222, ’117, and ’007 patents are invalid and/or would not be infringed by the manufacture, use or sale of Sandoz’s ANDA Product.

30. Upon information and belief, Sandoz was aware of the ’222, ’117, and ’007 patents when Sandoz filed ANDA No. 203649 containing the Paragraph IV certification.

31. Upon information and belief, as of the date of Sandoz’s Notice Letter, Sandoz 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).

COUNT 1: INFRINGEMENT OF THE ’222 PATENT UNDER 35 U.S.C. § 271(e)

32. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

33. Upon information and belief, use of Sandoz’s ANDA Product is covered by one or more claims of the ’222 patent.

34. Sandoz had knowledge of the ’222 patent when it submitted ANDA No. 203649.

35. Sandoz’s Notice Letter does not provide any contention that, or explanation why, the claims of the ’222 patent are not infringed by Sandoz’s ANDA Product, as would be required under 21 C.F.R. § 314.95(c)(6)(i) if Sandoz contended that the claims were not infringed.

36. Sandoz’s submission of ANDA No. 203649 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of Sandoz’s ANDA Product was an act of infringement of the ’222 patent under 35 U.S.C. § 271(e)(2).

37. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz’s ANDA Product would directly or indirectly infringe one or more claims of the ’222 patent.

38. Upon information and belief, Sandoz will induce others to infringe one or more claims of the ’222 patent by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Sandoz’s ANDA Product for the treatment of pulmonary hypertension, which use constitutes direct infringement of one or more claims of the ’222 patent. Upon information and belief, Sandoz’s aiding and abetting includes Sandoz’s active steps to promote its ANDA Product for infringing uses and to encourage and to instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Sandoz’s ANDA.

39. Upon information and belief, Sandoz will also contributorily infringe one or more claims of the ’222 patent in that Sandoz will make, use, sell, offer to sell, and/or import its ANDA Product, which Sandoz knows has no substantial non-infringing uses and is especially adapted to carry out the method claimed in one or more claims of the ’222 patent. Upon information and belief, others such as without limitation health care providers or patients will use Sandoz’s ANDA Product in a manner which constitutes direct infringement of one or more claims of the ’222 patent.

40. Upon information and belief, Sandoz was and is aware of the existence of the ’222 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’222 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

41. UTC will be substantially and irreparably damaged and harmed if Sandoz’s infringement of the ’222 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE ’222 PATENT UNDER 35 U.S.C. §§ 271(a)-(c)

42. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

43. Upon information and belief, upon FDA approval Sandoz will manufacture, market, sell, offer to sell, import, and distribute Sandoz's ANDA Product which will result in infringement of one or more claims of the '222 patent.

44. Sandoz's ANDA and Sandoz's intention to engage in the commercial manufacture, use, offer for sale, sale, importation and distribution of Sandoz's ANDA Product upon receiving FDA approval prior to the expiration of the '222 patent creates an actual and justiciable controversy with respect to infringement of the '222 patent.

45. Upon information and belief, the use of Sandoz's ANDA Product as described in and/or directed by documents including without limitation Sandoz's proposed labeling, ANDA, and/or other corporate documents for Sandoz's ANDA Product would infringe one or more claims of the '222 patent.

46. Upon information and belief, Sandoz knows that Sandoz's ANDA Product and its proposed labeling are especially made for and adapted for use in infringing the '222 patent, and that Sandoz's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use.

47. Upon information and belief, Sandoz will induce others to infringe one or more claims of the '222 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 patients or health care providers that administer Sandoz's ANDA Product for the treatment of pulmonary hypertension, which use constitutes direct infringement of one or more claims of the '222 patent. Upon information and belief, Sandoz's aiding and abetting includes Sandoz's active steps to promote its ANDA Product for infringing uses and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Sandoz's ANDA.

48. Upon information and belief, Sandoz will also contributorily infringe one or more claims of the ’222 patent under 35 U.S.C. § 271(c) in that Sandoz will make, use, sell, offer to sell, and/or import its ANDA Product, which Sandoz knows has no substantial non-infringing uses and is especially adapted to carry out the method claimed in one or more claims of the ’222 patent. Upon information and belief, others such as without limitation health care providers or patients will use Sandoz’s ANDA Product in a manner which constitutes direct infringement of one or more claims of the ’222 patent.

49. Upon information and belief, upon FDA approval of Sandoz’s ANDA, Sandoz’s commercial manufacture, use, sale offer for sale and/or importation into the United States of the Sandoz’s ANDA Product will infringe one or more claims of the ’222 patent, and by actively inducing and contributing to infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b) and/or 35 U.S.C. § 271(c).

50. Upon information and belief, Sandoz was and is aware of the existence of the ’222 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’222 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

51. UTC will be substantially and irreparably damaged and harmed if Sandoz’s infringement of the ’222 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE ’117 PATENT UNDER 35 U.S.C. § 271(e)

52. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

53. Upon information and belief, Sandoz’s ANDA Product or an intermediate in its manufacture is covered by one or more claims of the ’117 patent.

54. Sandoz had knowledge of the '117 patent when it submitted ANDA No. 203649.

55. Sandoz's submission of ANDA No. 203649 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Sandoz's ANDA Product was an act of infringement of the '117 patent under 35 U.S.C. § 271(e)(2).

56. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA Product would infringe one or more claims of the '117 patent.

57. Upon information and belief, Sandoz was and is aware of the existence of the '117 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '117 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

58. UTC will be substantially and irreparably damaged and harmed if Sandoz's infringement of the '117 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 4: INFRINGEMENT OF THE '117 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

59. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

60. Upon information and belief, upon FDA approval Sandoz will manufacture, market, sell, offer to sell, import, and distribute Sandoz's ANDA Product which will result in infringement of one or more claims of the '117 patent.

61. Sandoz's ANDA and Sandoz's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz's ANDA Product upon receiving FDA approval prior to the expiration of the '117 patent creates an actual and justiciable controversy with respect to infringement of the '117 patent.

62. Upon information and belief, upon FDA approval of Sandoz's ANDA, Sandoz's commercial manufacture, use, sale offer for sale and/or importation into the United States of Sandoz's ANDA Product will directly infringe one or more claims of the '117 patent, and will indirectly infringe by actively inducing infringement by others, under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), 35 U.S.C. § 271(c) and/or 35 U.S.C. § 271(g).

63. Upon information and belief, Sandoz's ANDA Product or an intermediate in its manufacture as described in and/or directed by Sandoz's proposed labeling, ANDA, applicable DMF, and/or other corporate documents for Sandoz's ANDA Product would infringe one or more claims of the '117 patent.

64. Upon information and belief, Sandoz will induce others to infringe one or more claims of the '117 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 Sandoz's ANDA Product, or its Active Pharmaceutical Ingredient ("API"), or other subsequent purchasers, distributors, or users thereof, which product or its manufacture constitutes direct infringement of one or more claims of the '117 patent. Upon information and belief, Sandoz's aiding and abetting includes Sandoz's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Sandoz's ANDA.

65. Upon information and belief, Sandoz will also contributorily infringe one or more claims of the '117 patent under 35 U.S.C. § 271(c) in that Sandoz will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which Sandoz knows has no substantial non-infringing uses. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '117 patent.

66. Upon information and belief, Sandoz will also infringe one or more claims of the '117 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Sandoz'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.

67. Upon information and belief, Sandoz was and is aware of the existence of the '117 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '117 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

68. UTC will be substantially and irreparably damaged and harmed if Sandoz's infringement of the '117 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 5: INFRINGEMENT OF THE '007 PATENT UNDER 35 U.S.C. § 271(e)

69. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

70. Upon information and belief, use of Sandoz's ANDA Product is covered by one or more claims of the '007 patent.

71. Sandoz had knowledge of the '007 patent when it submitted ANDA No. 203649.

72. Sandoz's submission of ANDA No. 203649 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale and/or offer for sale of Sandoz's ANDA Product was an act of infringement of the '007 patent under 35 U.S.C. § 271(e)(2).

73. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Sandoz's ANDA Product would directly or indirectly infringe the one or more claims of the '007 patent.

74. Upon information and belief, Sandoz will induce others to infringe one or more claims of the ’007 patent by, among other things, actively and knowingly aiding and abetting others to infringe, including, but not limited to patients or health care providers that administer Sandoz’s ANDA Product in diluted form, which use constitutes direct infringement of one or more claims of the ’007 patent. Upon information and belief, Sandoz’s aiding and abetting includes Sandoz’s active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Sandoz’s ANDA.

75. Upon information and belief, Sandoz was and is aware of the existence of the ’007 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’007 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

76. UTC will be substantially and irreparably damaged and harmed if Sandoz’s infringement of the ‘007 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 6: INFRINGEMENT OF THE ’007 PATENT UNDER 35 U.S.C. §§ 271(a) and (b)

77. UTC repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

78. Upon information and belief, upon FDA approval Sandoz will manufacture, market, sell, offer to sell, import, and distribute Sandoz’s ANDA Product which will result in direct or indirect infringement of one or more claims of the ’007 patent.

79. Sandoz’s ANDA and Sandoz’s intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Sandoz’s ANDA Product upon receiving FDA approval

prior to the expiration of the ’007 patent creates an actual and justiciable controversy with respect to infringement of the ’007 patent.

80. Upon information and belief, Sandoz will also induce others to infringe one or more claims of the ’007 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 patients or health care providers that administer Sandoz’s ANDA product for the treatment of pulmonary hypertension, which use constitutes direct infringement of one or more claims of the ’007 patent. Upon information and belief, Sandoz’s aiding and abetting includes Sandoz’s active steps to promote its ANDA Product for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, its proposed product package insert labeling pursuant to Sandoz’s ANDA.

81. Upon information and belief, the use of Sandoz’s ANDA Product as described in and/or directed by Sandoz’s proposed labeling, ANDA, and/or other corporate documents for Sandoz’s ANDA Product would directly infringe one or more claims of the ’007 patent.

82. Upon information and belief, upon FDA approval of Sandoz’s ANDA, Sandoz’s commercial manufacture, use, sale offer for sale and/or importation into the United States of Sandoz’s ANDA Product will infringe one or more claims of the ’007 patent, and by actively inducing infringement by others, under 35 U.S.C. § 271(a) and/or 35 U.S.C. § 271(b).

83. Upon information and belief, Sandoz is aware of the existence of the ’007 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’007 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

84. UTC will be substantially and irreparably damaged and harmed if Sandoz’s infringement of the ‘007 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, UTC requests the following relief:

1. A judgment that Sandoz:

   A. has infringed the'222 patent, the '117 patent, and/or the '007 patent,

   B. will actively induce infringement of the '222 patent, the '117 patent, and/or the '007 patent, and

   C. will contribute to the infringement by others of the '222 patent, and/or the '117 patent;

2. A judgment ordering that the effective date of any FDA approval for Sandoz to commercially manufacture, make, use, offer to sell, sell, market, or import into the United States Sandoz's ANDA product be not earlier than the latest of the expiration dates of the '222 patent, the '117 patent, and/or the '007 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

3. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Sandoz, its officer, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation, or privity with them, their successors, and assigns, from infringing, contributorily infringing, or inducing others to infringe the '222 patent, the '117 patent, and/or the '007 patent, including engaging in the commercial manufacture, use, sale, offer to sale and/or importation in the United States of the product that is the subject of ANDA No. 203649 and/or any applicable DMF until the expiration of the '222 patent, '117 patent, and/or '007 patent inclusive of any extension(s) and additional period(s) of exclusivity to which UTC is or may become entitled;

4. A judgment declaring that making, using, selling, offering for sale, or importing into the United States of Sandoz's ANDA Product, or any product or compound that infringes one or more of the '222 patent, the '117 patent, and the '007 patent, prior to the expiration dates of the respective patents, will infringe, actively induce infringement of, and will contribute to the infringement by others of the '222 patent, the '117 patent, and/or the '007 patent;

5. Temporary, preliminary, permanent, or other injunctive relief as necessary or appropriate should Sandoz seek to commercially manufacture, use, sell, offer to sell, or import Sandoz's ANDA Product prior to disposition of this action and/or the expiration of the '222 patent, the '117 patent, and/or the '007 patent;

6. A judgment awarding UTC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Sandoz commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 203649 that infringes one or more of the '222 patent, the '117 patent, and the '007 patent;

7. A judgment declaring that, pursuant to 35 U.S.C. § 285, this is an exceptional case and awarding UTC its attorney's fees;

8. Costs and expenses in this action; and

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

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Dated: March 14, 2012

Attorneys for Plaintiff
United Therapeutics Corporation

JURY DEMAND

UTC requests trial by jury for any issues so triable.

Respectfully submitted,

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Dated: March 14, 2012

Attorneys for Plaintiff
United Therapeutics Corporation

LOCAL CIVIL RULE 11.2 CERTIFICATION

UTC hereby certifies that, to its knowledge, the matter in controversy in this action is not the subject of any other pending lawsuit, arbitration, or administrative proceeding.

Respectfully submitted,

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