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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.:
	)	
	)	
WATSON LABORATORIES, INC.,	)	
	)	
Defendant.	)	

COMPLAINT AND JURY DEMAND

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Watson Laboratories, Inc. ("Watson"), 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. 6,521,212 ("the '212 patent") (attached as Exhibit A hereto), 6,756,033 ("the '033 patent") (attached as Exhibit B hereto), and 8,497,393 (the '393 patent") (attached as Exhibit C hereto).

2. This action arises out of Watson's submission of Abbreviated New Drug Application ("ANDA") No. 208172 to the United States Food and Drug Administration (the "FDA") seeking approval, prior to the expiration of the '212, '393, and '033 patents, to manufacture, market, and sell a generic copy of UTC's TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml that 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, Watson is a corporation organized and existing under the laws of the State of California and has a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

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 Watson with respect to this Complaint because of, *inter alia*, its continuous and systematic contacts with this judicial district. The notice letter was sent from Watson at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey, NJ 07054. Upon information and belief, Watson 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 Watson's ANDA, Watson will sell its generic product throughout the United States, including in New Jersey. Upon information and belief, Watson is registered to conduct business in the State of New Jersey and employs people throughout New Jersey, including at least the following locations: Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054; 100 Enterprise Drive, Rockaway, New Jersey 07866; and 350 Mt. Kemble Avenue, Morristown, New Jersey 07960. In addition, Watson has previously availed itself of this Court as a forum in which to bring patent litigation against others.

BACKGROUND

8. UTC holds an approved New Drug Application (No. 22-387) for TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/ml, which UTC markets and sells under the registered trademark TYVASO®.

9. TYVASO® is a pharmaceutical product initially approved by FDA in the United States in July 2009, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature and results in high pressure in the pulmonary arteries, which increases strain on the right ventricle of the heart, thereby leading to heart failure and death.

10. TYVASO® is an inhalable product approved for sale in a 0.6 mg/mL concentration.

11. The ’212 patent, entitled “Method for treating peripheral vascular disease by administering benzindene prostaglandins by inhalation” was duly and legally issued by the United States Patent and Trademark Office on February 18, 2003, and is scheduled to expire on November 13, 2018. The named inventors are Gilles Cloutier, James Crow, Michael Wade, Richard E. Parker, and James E. Loyd.

12. UTC is the lawful owner of the ’212 patent by assignment of all right, title and interest in and to the ’212 patent, including the right to bring infringement suits thereon.

13. The ’393 patent, entitled “Process to Prepare Treprostinil, the Active Ingredient in Remodulin®,” was duly and legally issued by the United States Patent and Trademark Office on July 30, 2014, and is scheduled to expire December 15, 2028. The named inventors are Hitesh Batra, Sudersan M. Tuladhar, Raju Penmasta, and David A. Walsh.

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

15. The ’033 patent, entitled “Method for delivering benzindene prostaglandins by inhalation,” was duly and legally issued by the United States Patent and Trademark Office on June 29, 2004, and is scheduled to expire on November 13, 2018. The named inventors are Gilles Cloutier, James Crow, Michael Wade, Richard E. Parker, and James E. Loyd.

16. UTC is the lawful owner of the ’033 patent by assignment of all right, title and interest in and to the ’033 patent, including the right to bring infringement suits thereon.

17. TYVASO® and its FDA approved manufacture and uses are covered by one or more claims of the ’212 patent, the ’033 patent, and the ’393 patent, which have been listed in

connection with TYVASO® in the FDA's *Approved Drug Products with Therapeutic Equivalents* publication (also known as the "Orange Book").

ACTS GIVING RISE TO THIS ACTION

18. Watson notified UTC by letter dated June 12, 2015, which was delivered to UTC on or about, Saturday, June 13, 2015 ("Watson's Notice Letter"), that it had filed ANDA No. 208172 with the FDA seeking approval to commercially manufacture, market, use, and sell generic copies of TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/mL ("Watson's ANDA Product") prior to the expiration of the '212,'033, and '393 patents.

19. Watson's Notice Letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) purporting to recite Watson's "factual and legal basis" for its opinion that the '212, '033, and '393 patents are not valid, are unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of Watson's ANDA Product. Yet that statement did not include any explanation as to why claims 1-5 and 9-12 of the '212 patent, claims 4 and 6-10 of the '033 patent, and any claim of the '393 patent were invalid. The statement also did not include anything beyond conclusory statements as to why claims 6-8 of the '212 patent and claims 1-3 and 5 of the '033 patent were invalid. The statement also did not include anything beyond conclusory statements regarding alleged non-infringement. Watson provided no explanation as to the alleged unenforceability.

20. Upon information and belief, Watson submitted ANDA No. 208172 with the FDA seeking approval to commercially manufacture, market, use, and sell generic copies of TYVASO® (treprostinil) Inhalation Solution, 0.6 mg/mL ("Watson's ANDA Product") prior to the expiration of the '212, '033, and '393 patents.

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

22. Upon information and belief, Watson's ANDA Product contains the same active compound as UTC's approved TYVASO® product.

23. Upon information and belief, Watson's ANDA No. 208172 seeks approval from the FDA to market Watson's ANDA Product for the same indication as UTC's approved TYVASO® product.

24. Upon information and belief, Watson represented to the FDA in ANDA No. 208172 that Watson's ANDA Product is bioequivalent to UTC's approved TYVASO® product.

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

26. According to Watson's Notice Letter, Watson's ANDA No. 208172 contained a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) stating that in Watson's opinion the '212, '033, and '393 patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use or sale of Watson's ANDA Product.

27. Upon information and belief, as of the date of Watson's Notice Letter, Watson 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).

28. Upon information and belief, the acts of infringement by Watson have been intentional and willful.

29. In Watson's Notice Letter, Watson offered confidential access to portions of the Watson ANDA on terms and conditions set forth in paragraph VII of the Watson Notice Letter ("Watson Offer"). Watson requested that UTC accept the Watson Offer before receiving access

to any portion of the Watson ANDA. The Watson Offer contained sweeping, unreasonable restrictions that differ materially from restrictions found under protective orders, such as those protective orders in pending, related cases in the United States District Court for the District of New Jersey. For example, the Watson Offer required that UTC's outside counsel "do not engage, formally or informally, in any patent prosecution for United Therapeutics or any FDA counseling, litigation or other work before or involving the FDA."

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

31. UTC attempted to negotiate with Watson to obtain relevant information from the Watson ANDA under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful. For example, Watson continued to insist that attorneys representing UTC and in-house counsel and the staff of such counsel agree not to be engaged in the drafting of submissions related to compositions, treatment methods, or formulations containing treprostinil to the FDA or any FDA counseling related to such matters, though such a restrictions has not been present in any prior protective order relating to any other UTC treprostinil-containing product, such as REMODULIN® (treprostinil) Injection. *See United Therapeutics Corp. v. Sandoz, Inc.*, 3:12-cv-01617-PGS-LHG, Protective Order, Docket No. 32 (D.N.J. Sept. 12, 2012); *United Therapeutics Corp. v. Teva Pharmaceuticals USA, Inc.*, 3:14-cv-05498-PGS-LHG, Protective Order, Docket No. 24, Discovery Confidentiality Order (D.N.J. Nov. 25, 2014); *United Therapeutics Corp. v. Sandoz, Inc.*, 3:14-cv-05499-PGS-LHG, Stipulated

Protective Order and Cross Use Agreement (D.N.J. Jan. 15, 2015.). UTC objected to this provision of Watson's OCA as unreasonable and in violation of 21 U.S.C. 355(j)(5)(C)(i)(III).

32. UTC is not aware of any other means of obtaining information regarding Watson's ANDA Product within the 45-day statutory period. Without such information, UTC will use the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that Watson's ANDA Product fall within the scope of one or more claims of the '212 patent, the '393 patent, and the '033 patent.

COUNT 1 INFRINGEMENT OF THE '212 PATENT UNDER 35 U.S.C. § 271(e)

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

34. Upon information and belief, Watson's ANDA Product or an intermediate in its manufacture is covered by one or more claims of the '212 patent.

35. Watson had knowledge of the '212 patent when it submitted ANDA No. 208172.

36. Watson's submission of ANDA No. 208172 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Watson's ANDA Product was an act of infringement of the '212 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 Watson's ANDA Product would infringe one or more claims of the '212 patent.

38. Upon information and belief, Watson was and is aware of the existence of the '212 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '212 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

39. UTC will be substantially and irreparably damaged and harmed if Watson's infringement of the '212 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

40. Upon information and belief, the acts of infringement by Watson have been intentional and willful.

COUNT 2: INFRINGEMENT OF THE '212 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

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

42. Upon information and belief, upon FDA approval Watson will manufacture, market, sell, offer to sell, import, and distribute Watson's ANDA Products which will result in infringement of one or more claims of the '212 patent.

43. Watson's ANDA and Watson's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's ANDA Product upon receiving FDA approval prior to the expiration of the '212 patent creates an actual and justiciable controversy with respect to infringement of the '212 patent.

44. Upon information and belief, upon FDA approval of Watson's ANDA, Watson's commercial manufacture, use, sale offer for sale and/or importation into the United States of Watson's ANDA Product will directly infringe one or more claims of the '212 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).

45. Upon information and belief, Watson's ANDA Product or an intermediate in its manufacture as described in and/or directed by Watson's proposed labeling, ANDA, applicable

DMF, and/or other corporate documents for Watson's ANDA Product would infringe one or more claims of the '212 patent.

46. Upon information and belief, Watson will induce others to infringe one or more claims of the '212 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 Watson'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 '212 patent. Upon information and belief, Watson's aiding and abetting includes Watson's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Watson's ANDA.

47. Upon information and belief, Watson will also contributorily infringe one or more claims of the '212 patent under 35 U.S.C. § 271(c) in that Watson will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which Watson 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 '212 patent.

48. Upon information and belief, Watson will also infringe one or more claims of the '212 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Watson'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.

49. Upon information and belief, Watson was and is aware of the existence of the '212 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '212 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

50. UTC will be substantially and irreparably damaged and harmed if Watson's infringement of the '212 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

51. Upon information and belief, the acts of infringement by Watson will be intentional and willful.

COUNT 3: INFRINGEMENT OF THE '393 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, Watson's ANDA Product or an intermediate in its manufacture is covered by one or more claims of the '393 patent.

54. Watson had knowledge of the '393 patent when it submitted ANDA No. 208172.

55. Watson's submission of ANDA No. 208172 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Watson's ANDA Product was an act of infringement of the '393 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 Watson's ANDA Product would infringe one or more claims of the '393 patent.

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

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

59. Upon information and belief, the acts of infringement by Watson have been intentional and willful.

COUNT 4: INFRINGEMENT OF THE '393 PATENT UNDER 35 U.S.C. §§ 271(a)-(c) and (g)

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

61. Upon information and belief, upon FDA approval Watson will manufacture, market, sell, offer to sell, import, and distribute Watson's ANDA Product which will result in infringement of one or more claims of the '393 patent.

62. Watson's ANDA and Watson's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's ANDA Product upon receiving FDA approval prior to the expiration of the '393 patent creates an actual and justiciable controversy with respect to infringement of the '393 patent.

63. Upon information and belief, upon FDA approval of Watson's ANDA, Watson's commercial manufacture, use, sale offer for sale and/or importation into the United States of Watson's ANDA Product will directly infringe one or more claims of the '393 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).

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

65. Upon information and belief, Watson will induce others to infringe one or more claims of the '393 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 Watson'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 '393 patent. Upon information and belief, Watson's aiding and abetting includes Watson's engagement of, contracting of, and/or encouragement of others to engage in the manufacture, use, sale, or importation of infringing products pursuant to Watson's ANDA.

66. Upon information and belief, Watson will also contributorily infringe one or more claims of the '393 patent under 35 U.S.C. § 271(c) in that Watson will make, use, sell, offer to sell, and/or import its ANDA Product and/or the API thereof, which Watson 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 '393 patent.

67. Upon information and belief, Watson will also infringe one or more claims of the '393 patent under 35 U.S.C. § 271(g) by importing, selling, offering to sell or using Watson'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.

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

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

70. Upon information and belief, the acts of infringement by Watson will be intentional and willful.

COUNT 5: INFRINGEMENT OF THE '033 PATENT UNDER 35 U.S.C. § 271(e)

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

72. Upon information and belief, use of Watson's ANDA Product is covered by one or more claims of the '033 patent.

73. Watson had knowledge of the '033 patent when it submitted ANDA No. 208172.

74. Watson's submission of ANDA No. 208172 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Watson's ANDA Product was an act of infringement of the '033 patent under 35 U.S.C. § 271(e)(2).

75. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Watson's ANDA Product would directly or indirectly infringe one or more claims of the '033 patent.

76. Upon information and belief, Watson will induce others to infringe one or more claims of the '033 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 Watson's ANDA Product in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '033 patent. Upon information and belief, Watson's aiding and abetting includes Watson'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 Watson's ANDA.

77. Upon information and belief, Watson was and is aware of the existence of the '033 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '033 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

78. UTC will be substantially and irreparably damaged and harmed if Watson's infringement of the '033 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

79. Upon information and belief, the acts of infringement by Watson have been intentional and willful.

COUNT 6: INFRINGEMENT OF THE '033 PATENT UNDER 35 U.S.C. §§ 271(a) and (b)

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

81. Upon information and belief, upon FDA approval Watson will manufacture, market, sell, offer to sell, import, and distribute Watson's ANDA Product which will result in infringement of one or more claims of the '033 patent.

82. Watson's ANDA and Watson's intention to engage in the commercial manufacture, use, offer for sale, sale, or importation of Watson's ANDA Product upon receiving FDA approval prior to the expiration of the '033 patent creates an actual and justiciable controversy with respect to infringement of the '033 patent.

83. Upon information and belief, Watson will also induce others to infringe one or more claims of the '033 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 Watson's ANDA Product for the treatment of pulmonary arterial hypertension, which use constitutes direct infringement of one or more claims of the '033 patent.

Upon information and belief, Watson's aiding and abetting includes Watson'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 Watson's ANDA.

84. Upon information and belief, the use of Watson's ANDA Product as described in and/or directed by Watson's proposed labeling, ANDA, and/or other corporate documents for Watson's ANDA Product would directly infringe one or more claims of the '033 patent.

85. Upon information and belief, upon FDA approval of Watson's ANDA, Watson's commercial manufacture, use, sale offer for sale and/or importation into the United States of Watson's ANDA Product will infringe one or more claims of the '033 patent, and by actively inducing infringement by others, under 35 U.S.C. § 271(a) and/or 35 U.S.C. § 271(b).

86. Upon information and belief, Watson was and is aware of the existence of the '033 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '033 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

87. UTC will be substantially and irreparably damaged and harmed if Watson's infringement of the '033 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

88. Upon information and belief, the acts of infringement by Watson will be intentional and willful.

PRAYER FOR RELIEF

WHEREFORE, UTC requests the following relief:

1. A judgment that Watson:

A. has infringed the '212 patent, the '033 patent, and the '393 patent;

B. will induce infringement of the ’212 patent, the ’033 patent, and the ’393 patent, and

C. will contribute to the infringement by others of the ’212 patent, the ’033 patent, and the ’393 patent;

2. A judgment ordering that the effective date of any FDA approval for Watson to commercially manufacture, make, use, offer to sell, sell, market, or import into the United States Watson’s ANDA Product be not earlier than the latest of the expiration dates of the ’212 patent, the ’033 patent, and the ’393 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 Watson, 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 ’212 patent, the ’033 patent, and/or the ’393 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. 208172 and/or any applicable DMF until the expiration of the ’212 patent, the ’033 patent, and the ’393 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 Watson’s ANDA Product, or any product or compound that infringes one or more of the ’212 patent, the ’033 patent, and/or the ’393 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 ’212 patent, the ’033 patent, and the ’393 patent;

5. Temporary, preliminary, permanent, or other injunctive relief as necessary or appropriate should Watson seek to commercially manufacture, use, sell, offer to sell, or import Watson's ANDA Product prior to disposition of this action and/or the expiration of the '212 patent, the '033 patent, and the '393 patent;

6. A judgment awarding UTC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Watson commercially manufactures, uses, sells, offers to sell and/or imports any product that is the subject of ANDA No. 208172 that infringes one or more of the '212 patent, the '033 patent, and/or the '393 patent;

7. A judgment declaring that Watson's infringement has been willful;

8. A judgement awarding UTC its actual damages for willful infringement;

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

10. Costs and expenses in this action; and

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

JURY DEMAND

UTC requests trial by jury for any issues so triable.

Dated: July 22, 2015

Respectfully,

s/William J. O'Shaughnessy
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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 other than the following identified proceedings:

- *United Therapeutics Corporation v. Sandoz Inc.* (3:14-cv-05499-PGS-LHG) (D.N.J.); and
- *United Therapeutics Corporation v. Teva Pharms. USA, Inc.* (3:14-cv-05498-PGS-LHG) (D.N.J.).

Plaintiff believes that this case is related to the foregoing cases in that it involves products that contain Treprostinil as the active ingredient of the formulation. Also, the '393 patent, which is asserted in each of the above cases, is asserted in this Complaint. All of these cases have been assigned to Hon. Peter G. Sheridan, U.S.D.J. and the Hon. Lois H. Goodman, U.S.M.J.

Dated: July 22, 2015

Respectfully,

s/William J. O'Shaughnessy
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