IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

UNITED THERAPEUTICS CORPORATION,	)	
Plaintiff,	)	
v.	)	C.A. No. _____
PAR STERILE PRODUCTS, LLC, PAR PHARMACEUTICAL, INC. and PAR PHARMACEUTICAL COMPANIES, INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiff United Therapeutics Corporation ("UTC"), by its undersigned attorneys, for its Complaint against Defendants Par Sterile Products, LLC, Par Pharmaceutical, Inc., and Par Pharmaceutical Companies, Inc. (collectively, "Par" or Defendants), 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. 8,497,393 ("the '393 patent") (attached as Exhibit A hereto), 9,199,908 ("the '908 patent") (attached as Exhibit B hereto), 7,999,007 (the '007 patent") (attached as Exhibit C hereto), 8,653,137 ("the '137 patent") (attached as Exhibit D hereto), and 8,658,694 ("the '694 patent") (attached as Exhibit E hereto).

2. This action arises out of Par's submission of Abbreviated New Drug Application ("ANDA") No. 209382 to the United States Food and Drug Administration (the "FDA") seeking approval, prior to the expiration of the '393, '908, '007, '137, and/or '694 patents, to manufacture, market, and sell a generic copy of UTC's REMODULIN® (Treprostinil Sodium) Injection product, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5

mg/mL), and 200 mg/20 mL (10 mg/mL), 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, having a place of business at 1040 Spring Street, Silver Spring, Maryland 20910. UTC is a biotechnology company focused on the development and commercialization of products designed to address the needs of patients with chronic and life-threatening conditions.

4. Defendant Par Sterile Products, LLC ("Par Sterile Products"), is a limited liability company organized and existing under the laws of the State of Delaware, having a principal place of business in Chestnut Ridge, NY. Par Sterile Products is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. Par Sterile Products develops, manufactures and markets branded and generic aseptic injectable products, and provides contract manufacturing services to the biopharmaceutical and pharmaceutical industry.

5. Defendant Par Pharmaceutical, Inc. ("Par Pharmaceutical") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Chestnut Ridge, NY. Par Pharmaceutical is a wholly-owned subsidiary of Par Pharmaceutical Companies, Inc. Par Pharmaceutical develops, manufactures, markets and distributes generic pharmaceuticals in the United States.

6. Defendant Par Pharmaceutical Companies, Inc. ("Par Pharmaceutical Companies") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in Chestnut Ridge, NY. Par Pharmaceutical Companies develops, licenses, manufactures, markets, and distributes generic drugs in the United States.

JURISDICTION AND VENUE

7. 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.

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

9. This Court has personal jurisdiction over each of the Defendants because Delaware is their state of incorporation or organization.

10. Upon information and belief, this Court also has personal jurisdiction over Defendants because, *inter alia*, Defendants have purposefully availed themselves of the rights and benefits of Delaware law by engaging in continuous and systematic contacts with this judicial district.

11. For example, Defendants have purposefully availed themselves of the privilege of selling their pharmaceutical products in Delaware. Among other things, Par conducts marketing and sales activities in Delaware, including but not limited to the distribution, marketing and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

12. Upon information and belief, Defendants derive 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 Par's ANDA, Defendants will sell their generic ANDA Products throughout the United States, including in Delaware.

13. Defendants collectively share common directors, officers, and/or facilities, operate as agents of each other and act in concert in the design, development, manufacture, distribution and sale of pharmaceutical products throughout the United States, including Delaware.

14. Defendants acted in concert to develop the generic version of REMODULIN® and to seek approval from the FDA to sell their generic product described ANDA 209382 throughout the United States, including within this District.

15. In addition, Defendants have previously availed themselves of this Court as a forum in which to bring patent litigation against others. *See, e.g., Par Pharmaceutical, Inc. et al. v. Breckenridge Pharmaceutical Inc. et al.*, 15-486-SLR (D. Del.).

BACKGROUND

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

17. REMODULIN® is a pharmaceutical product initially approved by the FDA in the United States in May 2002, and is indicated for the treatment of pulmonary arterial hypertension. Pulmonary arterial hypertension is a rare disease affecting the pulmonary vasculature 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.

18. REMODULIN® is an injectable product approved for sale in 1 mg/mL, 2.5 mg/mL, 5 mg/mL, and 10 mg/mL concentrations.

19. 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.

20. 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 suits for infringement thereof.

21. The ’908 patent, entitled “Compounds and Methods for Delivery of Prostacyclin Analogs,” was duly and legally issued by the United States Patent and Trademark Office on December 1, 2015, and is scheduled to expire on March 24, 2024. The named inventors are Ken Phares, David Mottola, Roger Jeffs, and Michael Wade.

22. UTC is the lawful owner of the ’908 patent by assignment of all right, title and interest in and to the ’908 patent, including the right to bring suits for infringement thereof.

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

24. 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 suits for infringement thereof.

25. The ’137 patent, entitled “Buffer solutions having selective bactericidal activity against gram negative bacteria and methods of using same,” was duly and legally issued by the United States Patent and Trademark Office on February 18, 2014, and is scheduled to expire on September 5, 2028. The named inventors are Roger Jeffs and David Zaccardelli.

26. UTC is the lawful owner of the ’137 patent by assignment of all right, title and interest in and to the ’137 patent, including the right to bring suits for infringement thereof.

27. The ’694 patent, entitled “Buffer solutions having selective bactericidal activity against gram negative bacteria and methods of using same,” was duly and legally issued by the United States Patent and Trademark Office on February 25, 2014, and is scheduled to expire on September 5, 2028. The named inventors are Roger Jeffs and David Zaccardelli.

28. UTC is the lawful owner of the ’694 patent by assignment of all right, title and interest in and to the ’694 patent, including the right to bring suits for infringement thereof.

29. REMODULIN®, its manufacture, and FDA approved uses thereof are covered by one or more claims of the ’393 patent, the ’908 patent, the ’007 patent, the ’137 patent, and the ’694 patent, which have 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

30. Par notified UTC by letter dated October 3, 2016, which was received by UTC on October 4, 2016, (“Par’s Notice Letter”) that it had submitted ANDA No. 209382 to the FDA seeking approval to commercially manufacture, market, use, and sell generic versions of REMODULIN® (Treprostinil Sodium) Injection, 20 mg/20 mL (1 mg/mL), 50 mg/20 mL (2.5 mg/mL), 100 mg/20 mL (5 mg/mL), and 200mg/20mL (10mg/mL) (“Par’s ANDA Products”) prior to the expiration of the ’393 patent and the ’908 patent. Because the ’007 patent, the ’137 patent, and the ’694 patent expire no earlier than one or more of the ’393 patent and the ’908 patent, Par also submitted ANDA No. 209382 with the FDA seeking approval to commercially manufacture, market, use, and sell generic versions of Par’s ANDA Products prior to the expiration of the ’007 patent, the ’137 patent, and the ’694 patent.

31. UTC is commencing this action before the expiration of forty-five days from the date UTC received Par’s Notice Letter.

32. Par’s Notice Letter was accompanied by an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) (“Offer”). The Offer proposed confidential access to “certain information from its proprietary and confidential ANDA” on terms and conditions set forth in the enclosure accompanying the Par Notice Letter. Par requested that UTC accept the Offer before

receiving access to any portion of the Par ANDA. The Par Offer contained unreasonable restrictions that differ materially from restrictions found under protective orders, including protective orders in other litigation over the same or related patents.

33. 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."

34. UTC attempted to negotiate with Par to obtain relevant information from the Par ANDA under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful because Par insisted on including unduly restrictive provisions.

35. Par also has declined to provide a copy of its proposed product labelling.

36. Plaintiff is not aware of any other means of obtaining information regarding Par's ANDA Products within the 45-day statutory period. Without such information, Plaintiff 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 the Court evidence that Par's ANDA Products fall within the scope of one or more claims of the'393, '908, '007, '137, and '694 patents.

37. Upon information and belief, Par's ANDA Products contains the same active pharmaceutical ingredient ("API") as UTC's approved REMODULIN® product, i.e., treprostinil sodium.

38. Upon information and belief, Par's ANDA No. 209382 seeks approval from the FDA to market Par's ANDA Products for the same indication as UTC's approved REMODULIN® product, the treatment of pulmonary arterial hypertension (PAH).

39. Upon information and belief, Par represented to the FDA in ANDA No. 209382 that Par's ANDA Products is bioequivalent to UTC's approved REMODULIN® product.

40. Upon information and belief, Par represented to the FDA in ANDA No. 209382 that Par's proposed labeling "is the same as the labeling approved for [Remodulin] (i) except for changes required because of differences approved under a petition filed under subparagraph (C) or because the new drug and the listed drug are produced or distributed by different manufacturers" pursuant to 21 U.S.C. § 355(j)(2)(A)(v).

41. Par's Notice letter did not assert that its proposed labeling for its ANDA Products included any "changes required because of differences approved under a petition." And, Par has not provided documentary evidence indicating changes to its proposed labeling. Upon information and belief, Par's proposed labeling is substantially the same as that of REMODULIN® (attached hereto as Exhibit F).

42. Upon information and belief, Par intends to commercially manufacture, sell, offer for sale, and/or import Par's ANDA Products upon FDA approval.

43. Par's Notice Letter included a statement pursuant to 21 U.S.C. § 355(j)(2)(vii)(IV) ("Detailed Statement") purporting to recite Par's "factual and legal bases" for its opinion that the '393 and '908 patents are "invalid, unenforceable and/or will not be infringed" by the commercial manufacture, use, or sale of Par's ANDA Products. But the Detailed Statement did not include any explanation as to why any claim of the '393 patent was invalid or why the '908 patent was not infringed. Moreover, the Detailed Statement did not include anything beyond conclusory statements regarding alleged non-infringement of the '393 patent. The statement of invalidity for the '908 patent was similarly based on conclusory statements and faulty analysis.

44. Par's Notice Letter did not address the '007 patent, the '137 patent, or the '694 patent.

45. Par has not explained why it did not address the '007 patent, the '137 patent, and the '694 patent. For example, Par has not stated whether or not it has submitted a statement under 21 U.S.C. § 355(j)(2)(A)(viii) for the '007, '137, and '694 patents ("Section viii carve out"). A Section viii carve out is essentially a representation to the FDA that approval is sought for a use other than a patented use. *See* 21 U.S.C. § 355(j)(2)(A)(viii).

46. A Section viii carve out cannot be used to address an Orange Book-listed patent containing composition claims. An ANDA applicant must submit either a Paragraph IV or Paragraph III certification for a patent with composition claims.

47. The '007 patent includes composition claims.

48. A Section viii carve out is not valid if the ANDA applicant actually seeks approval for a patented use of one of the Orange Book listed patents.

49. On information and belief, and without having proof of the contents of Par's ANDA or its proposed label for its ANDA Products, no valid Section viii carve outs are substantiated.

50. Upon information and belief, Par was aware of the '908, '393,'007, '137, and '694 patents when Par filed ANDA No. 209382 containing the Paragraph IV certification.

51. Upon information and belief, as of the date of Par's Notice Letter, Par 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 '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, Par's ANDA Products or an intermediate in their manufacture is covered by one or more claims of the '393 patent.

54. Par's submission of ANDA No. 209382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Par's ANDA Products was an act of infringement of the '393 patent under 35 U.S.C. § 271(e)(2).

55. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Products would infringe one or more claims of the '393 patent.

56. Upon information and belief, Par's ANDA Products do and/or will infringe at least claims 1 and 9 of the '393 patent literally or under the doctrine of equivalents.

57. Par had knowledge of the '393 patent when it submitted ANDA No. 209382.

58. Upon information and belief, Par 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.

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

COUNT 2 INFRINGEMENT OF THE '908 PATENT UNDER 35 U.S.C. § 271(e)

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

61. Par's submission of ANDA No. 209382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Par's ANDA Products was an act of infringement of the '908 patent under 35 U.S.C. § 271(e)(2).

62. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Products would directly or indirectly infringe one or more claims of the '908 patent.

63. Par has not offered any basis in its Notice Letter for non-infringement of the '908 patent.

64. Upon information and belief, use of Par's ANDA Products meets one or more claims of the '908 patent. Upon information and belief, use of Par's ANDA products meets all limitations of claim 1 of the '908 patent.

65. Upon information and belief, Par will induce others to infringe one or more claims of the '908 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 Par's ANDA Products in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '908 patent. Upon information and belief, Par's aiding and abetting includes Par's active steps to promote its ANDA Products for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Par's ANDA.

66. Upon information and belief, Par will also contributorily infringe one or more claims of the '908 patent because Par will make, use, sell, offer to sell, and/or import its ANDA Products and/or the API thereof, which Par knows has no substantial non-infringing uses and is

not a staple article of commerce. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '908 patent.

67. Par had knowledge of the '908 patent when it submitted ANDA No. 209382.

68. Upon information and belief, Par was and is aware of the existence of the '908 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '908 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

69. UTC will be substantially and irreparably damaged and harmed if Par's infringement of the '908 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 3: INFRINGEMENT OF THE '007 PATENT UNDER 35 U.S.C. § 271(e)

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

71. Par's submission of ANDA No. 209382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Par's ANDA Products was an act of infringement of the '007 patent under 35 U.S.C. § 271(e)(2).

72. Pursuant to 21 U.S.C. § 355(j)(2)(A), an ANDA filer must include the same labeling as the reference listed drug ("RLD"), absent an appropriate Section viii carve out.

73. Par has not provided any documentary evidence of any appropriate carve out. Therefore, on information and belief, Par's proposed labeling is substantially the same as that of REMODULIN®.

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

75. Upon information and belief, Par's ANDA Products are covered by one or more claims of the '007 patent. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Products would directly or indirectly infringe at least claim 22 of the '007 patent.

76. Upon information and belief, Par 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 Par's ANDA Products in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '007 patent. Upon information and belief, Par's aiding and abetting includes Par's active steps to promote its ANDA Products for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Par's ANDA.

77. Upon information and belief, Par will also contributorily infringe one or more claims of the '007 patent because Par will make, use, sell, offer to sell, and/or import its ANDA Products and/or the API thereof, which Par knows has no substantial non-infringing uses and is not a staple article of commerce. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '007 patent.

78. Par had knowledge of the '007 patent when it submitted ANDA No. 209382.

79. Upon information and belief, Par 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.

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

COUNT 4: INFRINGEMENT OF THE '137 PATENT UNDER 35 U.S.C. § 271(e)

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

82. Par's submission of ANDA No. 209382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Par's ANDA Products was an act of infringement of the '137 patent under 35 U.S.C. § 271(e)(2).

83. Pursuant to 21 U.S.C. § 355(j)(2)(A), an ANDA filer must include the same labeling as the RLD, absent an appropriate Section viii carve out.

84. Par has not provided any documentary evidence of any appropriate carve out. Therefore, on information and belief, Par's proposed labeling is substantially the same as that of REMODULIN®.

85. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Products would directly or indirectly infringe one or more claims of the '137 patent.

86. Upon information and belief, use of Par's ANDA Products is covered by one or more claims of the '137 patent. Upon information and belief, the use of Par's ANDA Products according to a label that is the same or substantially similar to that of REMODULIN® would literally meet claim 1 of the '137 patent.

87. Upon information and belief, Par will induce others to infringe one or more claims of the '137 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 Par's ANDA Products in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '137 patent. Upon information and belief, Par's aiding and abetting includes Par's active steps to promote its ANDA Products for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Par's ANDA.

88. Upon information and belief, Par will also contributorily infringe one or more claims of the '137 patent because Par will make, use, sell, offer to sell, and/or import its ANDA Products and/or the API thereof, which Par knows has no substantial non-infringing uses and is not a staple article of commerce. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the '137 patent.

89. Par had knowledge of the '137 patent when it submitted ANDA No. 209382.

90. Upon information and belief, Par was and is aware of the existence of the '137 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '137 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

91. UTC will be substantially and irreparably damaged and harmed if Par's infringement of the '137 patent is not enjoined by this Court. UTC does not have an adequate remedy at law.

COUNT 5: INFRINGEMENT OF THE '694 PATENT UNDER 35 U.S.C. § 271(e)

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

93. Par's submission of ANDA No. 209382 for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, and/or offer for sale of Par's ANDA Products was an act of infringement of the '694 patent under 35 U.S.C. § 271(e)(2).

94. Pursuant to 21 U.S.C. § 355(j)(2)(A), an ANDA filer must include the same labeling as the RLD, absent an appropriate Section viii carve out.

95. Par has not provided any documentary evidence of any appropriate carve out. Therefore, on information and belief, Par's proposed labeling is substantially the same as that of REMODULIN®.

96. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Par's ANDA Products would directly or indirectly infringe one or more claims of the '694 patent.

97. Upon information and belief, use of Par's ANDA Products is covered by one or more claims of the '694 patent. Upon information and belief, the use of Par's ANDA Products according to a label that is the same or substantially similar to that of REMODULIN® would literally meet claim 1 of the '634 patent.

98. Upon information and belief, Par will induce others to infringe one or more claims of the '694 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 Par's ANDA Products in diluted form for intravenous administration, which use constitutes direct infringement of one or more claims of the '694 patent. Upon information and belief, Par's aiding and abetting includes Par's active steps to promote its ANDA Products for infringing uses, and encourage and instruct such use as stated in, for example and without limitation, proposed product package insert labeling pursuant to Par's ANDA.

99. Upon information and belief, Par will also contributorily infringe one or more claims of the ’694 patent because Par will make, use, sell, offer to sell, and/or import its ANDA Products and/or the API thereof, which Par knows has no substantial non-infringing uses and is not a staple article of commerce. Upon information and belief, subsequent purchasers, distributors, or users thereof will also directly infringe one or more claims of the ’694 patent.

100. Par had knowledge of the ’694 patent when it submitted ANDA No. 209382.

101. Upon information and belief, Par was and is aware of the existence of the ’694 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the ’694 patent, thus rendering this case “exceptional” under 35 U.S.C. § 285.

102. UTC will be substantially and irreparably damaged and harmed if Par’s infringement of the ’694 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:

   A. Par has infringed the ’908 patent, the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent;

   B. Par will induce infringement of the ’908 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent, and

   C. Par will contribute to the infringement by others of the ’908 patent, the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent;

2. A judgment ordering that the effective date of any FDA approval for Par to commercially manufacture, make, use, offer to sell, sell, market, or import into the United States Par’s ANDA Products be not earlier than the latest of the expiration of the ’908 patent the ’393

patent, the ’007 patent, the ’137 patent, and/or the ’694 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 Par, 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 ’908 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 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. 209382 and/or any applicable DMF until the expiration of the ’908 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 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 Par’s ANDA Products, or any product or compound that infringes one or more of the ’393 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 ’908 patent the ’393 patent,’007 patent, the ’137 patent, and/or the ’694 patent;

5. Preliminary and permanent injunctive relief as necessary or appropriate should Par seek to commercially manufacture, use, sell, offer to sell, or import Par’s ANDA Products prior to disposition of this action and/or the expiration of the ’908 patent the ’393 patent, the ’007 patent, the ’137 patent, and/or the ’694 patent;

6. A judgment awarding UTC damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(c) and 284, if Par commercially manufactures, uses, sells, offers to sell

and/or imports any product that is the subject of ANDA No. 209382 that infringes one or more of the '908 patent the '393 patent,'007 patent, the '137 patent, and/or the '694 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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