IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ANTARES PHARMA, INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No. _____
	)	
MEDAC PHARMA, INC. and MEDAC GmbH,	)	
	)	
	)	
Defendants.	)	

COMPLAINT

Plaintiff Antares Pharma, Inc. ("Antares"), by and through its attorneys brings this Complaint for patent infringement against Defendants Medac Pharma, Inc. and medac GmbH (collectively, "Medac") and alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §100, *et seq*., arising from:

(a) Medac's infringement of Antares' United States Patent Nos. 8,480,631 ("the '631 patent") and 6,565,553 ("the '553 patent"), by filing with the United States Food and Drug Administration ("FDA") a New Drug Application pursuant to 21 U.S.C. § 355(b)(2) (the "Medac NDA") seeking approval to commercially make, use, offer for sale, sell and import into the United States an infringing, subcutaneous, injectable methotrexate pen drug product (the "Medac MTX product"), and

(b) Medac's imminent infringement of the '631 and '553 patents through the use, manufacture, offer for sale, sale and importation into the United States of the Medac MTX product prior to the expiration of the '631 and '553 patents.

THE PARTIES AND JURISDICTION

2. Plaintiff Antares is a company organized and existing under the laws of the State of Delaware, having a place of business at 100 Princeton South, Suite 300, Ewing, New Jersey 08628. Antares is a small company in the business of developing and commercializing injectable therapeutic products using advanced, novel drug delivery systems for improved patient safety and efficacy, reduced side effects, and enhanced patient comfort and adherence.

3. On information and belief, Medac Pharma, Inc. is a company organized and existing under the laws of the State of Delaware, having a principal place of business at 29 North Wacker Drive, Suite 704, Chicago, IL 60606.

4. On information and belief, Medac Pharma, Inc. is a wholly-owned subsidiary of medac GmbH, and Medac Pharma, Inc. acts as an agent for medac GmbH in connection with the preparation and submission of the Medac NDA by Medac Pharma, Inc. seeking FDA approval to commercially market a subcutaneous injectable formulation of methotrexate administered by an "auto-pen," i.e., the Medac MTX product.

5. On information and belief, because of its incorporation in this State, Medac Pharma, Inc. has established continuous and systematic contacts within this State and this District, and purposefully availed itself of the benefits of jurisdiction in this State.

6. Medac Pharma, Inc. is subject to personal jurisdiction in this judicial District.

7. On information and belief, medac GmbH is a company organized and existing under the laws of the country of Germany, having a principal place of business at Theaterstrasse 6, 22880 Wedel, Germany.

8. On information and belief, medac GmbH controls Medac Pharma, Inc., which is a wholly-owned subsidiary of medac GmbH.

9. On information and belief, medac GmbH is a pharmaceutical company that conducts its North American operations, in part, through Medac Pharma, Inc. and together they collaborate in developing pharmaceutical drug products for commercial sale, including distribution in the District of Delaware and throughout the United States.

10. On information and belief, Medac Pharma, Inc. "evaluates U.S. marketing opportunities for medac GmbH products that have been approved in Europe." *See* http://www.medacpharma.com/heritage. Further, Medac Pharma, Inc. draws "on the extensive resources of our parent company [medac GmbH] to offer comprehensive support to patients and providers in a market with a strong need for more effective treatments." *Id.*

11. According to a January 27, 2014 press release and the Medac Pharma, Inc. website, Medac Pharma, Inc. filed the Medac NDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act seeking FDA approval to commercially market a subcutaneous injectable formulation of methotrexate administered by an "auto-pen," the Medac MTX product, which the FDA accepted on or about January 27, 2014.

12. On information and belief, medac GmbH was involved in and directed the decision to file the Medac NDA by Medac Pharma, Inc.

13. On information and belief, and according to Medac Pharma Inc.'s January 27, 2014 press release, medac GmbH will supply Medac Pharma with methotrexate for use in the Medac MTX product.

14. On information and belief, medac GmbH, as the owner of a Delaware corporation, has established continuous and systematic contacts with this State and this District, and has purposefully availed itself of the benefits of jurisdiction in this State and this judicial District.

medac GmbH has a presence in this State and District because it has purposefully created a subsidiary—Medac Pharma, Inc.—that is incorporated in this District.

15. medac GmbH is subject to personal jurisdiction in this judicial district.

16. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02, and under the patent laws of the United States, Title 35 of the United States Code, specifically 35 U.S.C. § 271(a), (b), (c) and (e)(2).

17. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

18. Venue is proper in this District under 28 U.S.C. §§ 1391(b), 1391(c), 1391(d), and 1400(b).

THE PATENTS-IN-SUIT

19. The United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 8,480,631 on July 9, 2013. A copy of the '631 patent is attached as Exhibit A. The '631 Patent is titled "Hazardous Agent Injection System," and names as inventors Paul Wotton, Peter L. Sadowski and John William Hayes.

20. Antares is the assignee of the '631 patent and lawfully owns all right, title, and interest in the '631 Patent, including the right to sue, enforce, and to recover any remedy for infringement.

21. The PTO issued U.S. Patent No. 6,565,553 on May 20, 2003. A copy of the '553 patent is attached as Exhibit B. The '553 Patent is titled "Needle Assisted Jet Injector," and names as inventors Peter L. Sadowski, David M. DeBoer, Claude L. Berman and Paul R. Lesch, Jr.

22. Antares is the assignee of the '553 patent and lawfully owns all right, title, and interest in the '553 Patent, including the right to sue, enforce, and to recover any remedy for infringement.

BACKGROUND AND THE OTREXUP™ DRUG PRODUCT

23. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 et seq., sets forth the rules that the U.S. Food and Drug Administration must follow when considering whether to approve the marketing of certain drug products.

24. Upon approval of a drug product on the basis of safety and efficacy under the FFDCA, including an NDA under 21 U.S.C. § 355(b)(2), the FDA publishes the patent information associated with an FDA approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book."

25. By filing an application under 21 U.S.C. § 355(b)(2) and submitting a patent for listing in the Orange Book, the NDA applicant/holder puts all prospective manufacturers of that drug product, including those filing pursuant to 355(b)(2) of the FFDCA, on notice that the listed patent may be applicable.

26. On October 11, 2013, the FDA approved Antares' NDA for Otrexup™ (methotrexate) Injection, 10 mg/0.4 mL, 15 mg/0.4 mL, 20 mg/0.4 mL and 25 mg/0.4 mL (NDA 204-824), filed pursuant to 21 U.S.C. § 355(b)(2). Antares markets the drug in each of those concentrations in the United States. Otrexup™ is approved for the management of patients with severe, active rheumatoid arthritis (RA) and polyarticular juvenile idiopathic arthritis (pJIA), and also for the control of severe, recalcitrant, disabling psoriasis.

27. Otrexup™ is the first and only FDA-approved product for the subcutaneous injection of methotrexate. Otrexup™ can be self-administered by patients subcutaneously through the use of a needle-assisted jet injector, also known as an "auto-pen."

28. Otrexup™ is the focus of Antares' commercial efforts concerning injectable therapeutic products, as it is the only actively marketed pharmaceutical product that Antares currently sells.

29. Antares' Otrexup™ (methotrexate) injection product is the result of years of costly, innovative research and development that resulted in the issuance of several patents by the United States Patent and Trademark Office ("USPTO").

30. Antares sought patent protection in part because, in order to maintain its incentive to undertake costly pharmaceutical research and development projects that result in therapeutically valuable products like Otrexup™ (methotrexate) injection, the grant of United States patents such as those asserted in this case can be used to prevent infringers like Medac from copying Antares' technology and profiting from that copying.

31. In accordance with the FFDCA, Antares listed seven patents associated with the Otrexup™ product in the FDA's Orange Book, including the '631 patent.

32. On information and belief, the Medac NDA was submitted by Medac Pharma, Inc., at the direction of medac GmbH, pursuant to 21 U.S.C. § 355(b)(2).

ACTS GIVING RISE TO THIS ACTION

33. Upon information and belief, Medac Pharma, Inc. filed the Medac NDA at the direction of medac GmbH pursuant to § 505(b)(2) of the FFDCA for its lead product candidate, the Medac MTX product, also referred to by Medac as MPI-2505.

34. The Medac MTX product is a purportedly subcutaneous injectable methotrexate product in a ready-to-use injection device, for which the proposed indications are rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis.

35. On information and belief, Medac Pharma, Inc. is the owner of the Medac NDA.

36. Upon information and belief, the proposed Medac MTX product indications for which Medac is seeking FDA approval are the same as those approved for Otrexup™.

37. Upon information and belief, the Medac MTX product has the same structure and functionality as the Medac subcutaneous injectable methotrexate product that medac GmbH is currently marketing in certain European countries under the name "metex PEN."

38. On information and belief, if the Medac NDA is approved by the FDA before the expiration of the '631 or '553 patents, Medac will begin manufacturing, using, importing, offering for sale, and/or selling the Medac MTX product, including for the same indications as Otrexup's™ currently approved indications.

39. In a press release dated January 27, 2014, attached as Exhibit C, Medac Pharma stated:

> Medac Pharma, Inc., a privately held pharmaceutical company focused on the development of new molecules and improving the effectiveness of existing medicines, announced the FDA acceptance of its New Drug Application (NDA) for its lead product candidate, MPI-2505, a subcutaneous injectable methotrexate (MTX) in a ready-to-use injection device, for which the proposed indications are rheumatoid arthritis (RA), poly-articular-course juvenile RA and psoriasis....

40. In the same January 27, 2014 press release, Medac Pharma also stated:

> The subcutaneous mode of delivery of MPI-2505, with a wide range of dosing options, has been designed to improve bioavailability and overcome tolerability issues associated with today's oral MTX therapies. Additionally, by providing patients with a ready-to-use autopen and concentrated formulations that allow for reduced drug volume, the MTX subcutaneous autopen addresses the stigmas associated with injectable medicines.
>
> 'The FDA's acceptance of Medac Pharma Inc.'s NDA marks a significant milestone not only for our company, but also patients seeking a more personalized method for managing their disease,' said Terri Shoemaker, President and CEO of Medac Pharma, Inc. 'While methotrexate has proven itself as a highly effective medicine for treating several forms of arthritis, there remains a substantial need to make treatment for this patient demographic more manageable. As a newly-founded company, we believe this inflection point, combined with our patent allowance for a broad dosing range of methotrexate, serve as stepping stones for our commitment to providing valuable resources for the immunology market.'....
>
> Medac Pharma, Inc. expects to self commercialize its subcutaneous MTX autopen device in the U.S. later this year upon FDA approval. As a wholly owned subsidiary of medac GmbH, a global pharmaceutical company that has been developing, manufacturing and marketing pharmaceuticals for more than 40 years in 70 countries, Medac Pharma, Inc. will receive a continuous supply of MTX for its product.

41. In the same January 27, 2014 press release, Medac Pharma, Inc. also stated:

> Among the multiple indications for which MPI-2505 is expected include RA, an incurable, progressive, inflammatory, autoimmune disease affecting the lining of joints resulting in pain, swelling, reduced mobility and requires lifelong treatment with potent drugs, with MTX remaining the first-in-line therapy. Medac Pharma Inc.'s fully integrated infrastructure with experienced management team and significant resources make it well positioned to develop, in-license and commercialize personalized therapies in autoimmune and oncology therapeutics.

42. Upon information and belief, Medac intends to make, use, sell, and/or offer for sale in the United States the Medac MTX product.

43. Upon information and belief, Medac expects to launch the Medac MTX product in the United States before the end of this year (2014).

44. Upon information and belief, Medac Pharma, Inc. has imported Medac MTX products and/or components of Medac MTX products into the United States.

45. Upon information and belief, Medac Pharma, Inc. has imported Medac MTX products and/or components of Medac MTX products into the United States, directly or indirectly from medac GmbH.

46. Upon information and belief, Medac Pharma, Inc. intends to import and, unless enjoined, will import Medac MTX products and/or components of Medac MTX products into the United States, including upon approval of the Medac NDA.

47. Upon information and belief, Medac Pharma, Inc. intends to import and, unless enjoined, will import Medac MTX products and/or components of Medac MTX products into the United States, directly or indirectly from medac GmbH, including upon approval of the Medac NDA.

48. Upon information and belief, medac GmbH intends to supply, and Medac Pharma, Inc. intends to import the Medac MTX product for sale in the United States.

49. Upon information and belief, Medac Pharma, Inc. and/or medac GmbH has approached physicians in the United States to join Medac Pharma, Inc. and/or medac GmbH's advisory board in preparation for Medac's sales and marketing efforts with respect to the Medac MTX product.

50. Upon information and belief, Medac Pharma, Inc. and/or medac GmbH has approached marketing partners to help market the Medac MTX product in the United States.

51. Upon information and belief, Medac Pharma, Inc. and/or medac GmbH has presented at trade shows in the United States regarding the forthcoming Medac MTX product, and demonstrated the product at one or more shows.

52. Upon information and belief, Medac Pharma, Inc. and/or medac GmbH has presented and/or demonstrated the Medac MTX product for physicians in the United States.

53. Antares identified the '631 patent in connection with its NDA 204-824 application. The FDA published the approved NDA 204-824 application with the listing of the '631 patent in the Orange Book.

54. Antares also marks all of its Prescribing Information materials, available with the commercial Otrexup™ product, including with the '631 patent.

55. Thus, for these reasons, Medac knew or should have known of Antares' claim that at least the '631 patent was directed to subcutaneous methotrexate injections and methods for use of the same.

56. On information and belief, Medac was aware of at least the '631 patent when the Medac NDA was submitted to the FDA.

COUNT I – INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(e)(2)

57. Antares re-alleges and incorporates herein the allegations of paragraphs 1-56.

58. On information and belief, Medac submitted the Medac NDA under section 355(b)(2) of Title 21 for a drug and its use that is claimed in Antares' '631 patent.

59. That submission, which seeks approval to engage in commercial use, manufacture, sale, offer for sale and/or importation of the Medac MTX product prior to the expiration of the '631 patent, constitutes infringement of one or more claims of the '631 patent under 35 U.S.C. § 271(e)(2)(A).

60. Under 35 U.S.C. § 271(e)(2)(A), Medac infringed one or more claims of the '631 patent, in violation of Antares' patent rights, by submitting to the FDA the Medac NDA that seeks approval to commercially market—before the expiration date of the '631 patent—Medac's MTX product, and the manufacture and sale of which would contribute to and/or induce the direct infringement of one or more claims of the '631 patent by users of Medac's MTX product.

61. On information and belief, Medac has knowledge of the '631 patent and has filed the Medac NDA seeking authorization to commercially manufacture, use, offer for sale, and sell Medac's MTX product in the United States. On information and belief, if the FDA approves the Medac NDA, Medac's using, making, selling, offering for sale and/or importation of the Medac MTX product in the United States will directly infringe one or more claims of the '631 patent.

62. On information and belief, Medac knows and intends that physicians, health care providers, and/or patients will use Medac's MTX product in accordance with the instructions and/or label provided by Medac, and will therefore induce infringement of one or more of the claims of the '631 patent with the requisite intent.

63. On information and belief, if the FDA approves the Medac NDA, Medac will sell or offer to sell its Medac's MTX product specifically labeled for use in practicing one or more of the claims of the '631 patent, wherein Medac's MTX product is a material part of the claimed invention, wherein Medac knows that physicians will prescribe and patients will use Medac's MTX product in practicing one or more of the claims of the '631 patent, and wherein the Medac MTX product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Medac will thus contribute to the infringement of the '631 patent.

64. Such act of infringement, upon information and belief, was carried out by Medac in deliberate and willful disregard of Antares' patent rights.

65. The act of infringement by Medac will cause Plaintiff Antares irreparable harm for which it has no adequate remedy at law, which acts will continue unless enjoined by this Court.

COUNT II – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(a)

66. Antares re-alleges and incorporates herein the allegations of paragraphs 1-65.

67. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

68. There is an actual, substantial, continuing, and justiciable controversy between Antares and Medac regarding whether Medac's importation, use, and plans to commercially launch the Medac MTX product will infringe the '631 patent and whether that infringement will be willful.

69. Unless enjoined by this Court, upon FDA approval of Medac's NDA, Medac will infringe one or more claims of the '631 patent under 35 U.S.C. § 271(a) by using, making, selling, offering for sale and/or importation of the Medac MTX product in the United States, and Medac will continue to so infringe unless enjoined by this Court.

70. Such acts of infringement, upon information and belief, will be carried out by Medac in deliberate and willful disregard of Antares' patent rights.

71. Medac's infringing activities will substantially and irreparably harm Antares unless enjoined by this Court.

72. Antares does not have an adequate remedy at law.

COUNT III – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(b)

73. Antares re-alleges and incorporates herein the allegations of paragraphs 1-72.

74. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(b), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

75. There is an actual, substantial, continuing, and justiciable controversy between Antares and Medac regarding whether Medac's importation, use, and plans to commercially launch the Medac MTX product will induce infringement of the '631 patent and whether that infringement will be willful.

76. The manufacture, sale, offer for sale, and/or importation of Medac's MTX product, if approved by the FDA, will induce the infringement of one or more claims of the '631 patent under 35 U.S.C. § 271(b) in violation of Antares' patent rights.

77. On information and belief, Medac has knowledge of the '631 patent and has filed the Medac NDA seeking authorization to commercially manufacture, use, offer for sale, sell and or import Medac's MTX product in the United States. On information and belief, if the FDA approves Medac's MTX product, physicians, health care providers, and/or patients will use Medac's MTX product in accordance with the instructions and/or label provided by Medac and will directly infringe one or more claims of the '631 patent.

78. On information and belief, Medac knows and intends that physicians, health care providers, and/or patients will use Medac's MTX product in accordance with the instructions and/or label provided by Medac, and will therefore induce infringement of one or more of the claims of the '631 patent with the requisite intent under 35 U.S.C. § 271(b).

79. Medac will continue to so induce infringement unless enjoined by this Court.

80. Such acts of infringement, upon information and belief, will be carried out by Medac in deliberate and willful disregard of Antares' patent rights.

81. Medac's infringing activities will substantially and irreparably harm Antares unless enjoined by this Court.

82. Antares does not have an adequate remedy at law.

COUNT IV – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '631 PATENT UNDER 35 U.S.C. § 271(c)

83. Antares re-alleges and incorporates herein the allegations of paragraphs 1-82.

84. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

85. There is an actual, substantial, continuing, and justiciable controversy between Antares and Medac regarding whether Medac's importation, use, and plans to commercially launch its MTX product will contribute to infringement of the '631 patent and whether that infringement will be willful.

86. On information and belief, if the FDA approves the Medac NDA, Medac will sell or offer to sell its MTX product, specifically labeled for use in practicing one or more claims of the '631 patent, wherein Medac's MTX product is a material part of the invention claimed in the '631 patent, wherein Medac knows that physicians will prescribe and patients will use Medac's MTX product in accordance with the claims in the '631 patent, and wherein the Medac MTX product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Medac will thus contribute to the infringement of the '631 patent under 35 U.S.C. § 271(c).

87. Medac will continue to so contribute to infringement unless enjoined by this Court.

88. Such acts of infringement, upon information and belief, will be carried out by Medac in deliberate and willful disregard of Antares' patent rights.

89. Medac's infringing activities will substantially and irreparably harm Antares unless enjoined by this Court.

90. Antares does not have an adequate remedy at law.

COUNT V – INFRINGEMENT OF THE '553 PATENT UNDER 35 U.S.C. § 271(e)(2)

91. Antares re-alleges and incorporates herein the allegations of paragraphs 1-90.

92. On information and belief, Medac submitted the Medac NDA under section 355(b)(2) of Title 21 for a drug and its use that is claimed in Antares' '553 patent.

93. That submission, which seeks approval to engage in commercial use, manufacture, sale, offer for sale and/or importation of the Medac MTX product prior to the expiration of the '553 patent, constitutes infringement of one or more claims of the '553 patent under 35 U.S.C. § 271(e)(2)(A).

94. Under 35 U.S.C. § 271(e)(2)(A), Medac infringed one or more claims of the '553 patent, in violation of Antares' patent rights, by submitting to the FDA the Medac NDA that seeks approval to commercially market—before the expiration date of the '553 patent—Medac's MTX product, and the manufacture and sale of which would contribute to or induce the direct infringement of one or more claims of the '553 patent by users of Medac's MTX product.

95. On information and belief, if the FDA approves the Medac NDA, Medac's using, making, selling, offering for sale and/or importation of the Medac MTX product in the United States will directly infringe one or more claims of the '553 patent.

96. On information and belief, Medac knows and intends that physicians, health care providers, and/or patients will use Medac's MTX product in accordance with the instructions

and/or label provided by Medac, and will therefore induce infringement of one or more of the claims of the '553 patent with the requisite intent.

97. On information and belief, if the FDA approves the Medac NDA, Medac will sell or offer to sell its Medac's MTX product specifically labeled for use in practicing one or more of the claims of the '553 patent, wherein Medac's MTX product is a material part of the claimed invention, wherein Medac knows that physicians will prescribe and patients will use Medac's MTX product in practicing one or more of the claims of the '553 patent, and wherein the Medac MTX product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Medac will thus contribute to the infringement of the '631 patent.

98. Such act of infringement, upon information and belief, was carried out by Medac in deliberate and willful disregard of Antares' patent rights.

99. The act of infringement by Medac will cause Plaintiff Antares irreparable harm for which it has no adequate remedy at law, which acts will continue unless enjoined by this Court.

COUNT VI – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '553 PATENT UNDER 35 U.S.C. § 271(a)

100. Antares re-alleges and incorporates herein the allegations of paragraphs 1-99.

101. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(a), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

102. There is an actual, substantial, continuing, and justiciable controversy between Antares and Medac regarding whether Medac's importation, use, and plans to commercially launch the Medac MTX product will infringe the '553 patent and whether that infringement will be willful.

103. Unless enjoined by this Court, upon FDA approval of Medac's NDA, Medac will infringe one or more claims of the '553 patent under 35 U.S.C. § 271(a) by using, making, selling, offering for sale and/or importation of the Medac MTX product in the United States, and Medac will continue to so infringe unless enjoined by this Court.

104. Such acts of infringement, upon information and belief, will be carried out by Medac in deliberate and willful disregard of Antares' patent rights.

105. Medac's infringing activities will substantially and irreparably harm Antares unless enjoined by this Court.

106. Antares does not have an adequate remedy at law.

COUNT VII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '553 PATENT UNDER 35 U.S.C. § 271(b)

107. Antares re-alleges and incorporates herein the allegations of paragraphs 1-106.

108. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(b), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

109. There is an actual, substantial, continuing, and justiciable controversy between Antares and Medac regarding whether the Medac's importation, use, and plans to commercially launch the Medac MTX product will induce infringement of the '553 patent and whether that infringement will be willful.

110. The manufacture, sale, offer for sale, and/or importation of Medac's MTX product, if approved by the FDA, will induce the infringement of one or more claims of the '553 patent under 35 U.S.C. § 271(b) in violation of Antares' patent rights.

111. On information and belief, Medac has filed the Medac NDA seeking authorization to commercially manufacture, use, offer for sale, and sell Medac's MTX product in the United

States. On information and belief, if the FDA approves Medac's MTX product, physicians, health care providers, and/or patients will use Medac's MTX product in accordance with the instructions and/or label provided by Medac and will directly infringe one or more claims of the '553 patent.

112. On information and belief, Medac knows and intends that physicians, health care providers, and/or patients will use Medac's MTX product in accordance with the instructions and/or label provided by Medac, and will therefore induce infringement of one or more of the claims of the '553 patent with the requisite intent under 35 U.S.C. § 271(b).

113. Medac will continue to so induce infringement unless enjoined by this Court.

114. Such acts of infringement, upon information and belief, will be carried out by Medac in deliberate and willful disregard of Antares' patent rights.

115. Medac's infringing activities will substantially and irreparably harm Antares unless enjoined by this Court.

116. Antares does not have an adequate remedy at law.

COUNT VIII – DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '553 PATENT UNDER 35 U.S.C. § 271(c)

117. Antares re-alleges and incorporates herein the allegations of paragraphs 1-116.

118. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 et seq., including 35 U.S.C. § 271(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

119. There is an actual, substantial, continuing, and justiciable controversy between Antares and Medac regarding whether Medac's importation, use, and plans to commercially launch the Medac MTX product will contribute to infringement of the '553 patent and whether that infringement will be willful.

120. On information and belief, if the FDA approves the Medac NDA, Medac will sell or offer to sell its MTX product, specifically labeled for use in practicing one or more claims of the '553 patent, wherein Medac's MTX product is a material part of the invention claimed in the '553 patent, wherein Medac knows that physicians will prescribe and patients will use Medac's MTX product in accordance with the claims in the '553 patent, and wherein the Medac MTX product is not a staple article or commodity of commerce suitable for substantial noninfringing use. Medac will thus contribute to the infringement of the '553 patent under 35 U.S.C. § 271(c).

121. Medac will continue to so contribute to infringement unless enjoined by this Court.

122. Such acts of infringement, upon information and belief, will be carried out by Medac in deliberate and willful disregard of Antares' patent rights.

123. Medac's infringing activities will substantially and irreparably harm Antares unless enjoined by this Court.

124. Antares does not have an adequate remedy at law.

PRAYER FOR RELIEF

Wherefore, Antares respectfully requests that this Court:

A. Enter Judgment pursuant to 35 U.S.C. § 271(e)(2) that Medac has infringed the '631 and '553 patents, either literally or by the doctrine of equivalents, and that these patents have not been proven invalid or unenforceable;

B. Enter Judgment pursuant to 35 U.S.C. § 271(a), (b), and (c) that the commercial use, sale, offer for sale, manufacture and importation into the United States of the Medac MTX product will infringe the '631 and '553 patents;

C. Declare that Medac's importation, use, and plans to launch a subcutaneous methotrexate injector described above will infringe, pursuant to 35 U.S.C. § 271(a), (b), and (c), the '631 and '553 patents by acts constituting direct, induced, and/or contributory infringement;

D. Enter a preliminary and permanent injunction to enjoin Medac (including all officers, partners, agents, employees, parents, subsidiaries, divisions, and affiliates) and those in privity with, or acting in concert with, Medac from engaging in the importation, use, and plans to launch a subcutaneous methotrexate injector and from other activities that would further infringe Antares' '631 and '553 patents during the remainder of the terms for which the '631 and '553 patents have been granted, and to preclude any product that is similar or only marginally different from those products;

E. Enjoin Medac, and all persons acting in concert with Medac, from seeking, obtaining, or maintaining final approval of its § 505(b)(2) NDA until the expiration of the '631 and '553 patents, including any exclusivities or extensions to which Plaintiffs are or become entitled;

F. Enter an Order, in accordance with 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of Medac's NDA under 21 U.S.C. § 355(b)(2), be a date which is not earlier than the expiration date of the '631 and '553 patents, including any extensions or added periods of exclusivity;

G. Award damages or other monetary relief, including prejudgment interest, if Medac engages in the commercial manufacture, use, offering to sell, sale, marketing, distribution, or importation of a automated injector with methotrexate for subcutaneous use, or any other products that would infringe the '631 or '553 patents, or the inducement or contribution to the foregoing, prior to the expiration of such patents;

H. Award Antares its attorneys' fees, costs, and/or expenses because this is an exceptional case under 35 U.S.C. § 285; and

I. Award such other relief as the Court determines to be just and proper.

Dated: February 28, 2014

PHILLIPS, GOLDMAN & SPENCE, P.A.

/s/ John C. Phillips, Jr.

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