IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, AVENTISUB LLC, SANOFI, and GENZYME CORPORATION, Plaintiffs, v. WATSON LABORATORIES, INC. and TEVA PHARMACEUTICALS USA, INC. Defendants.	Civil Action No.

COMPLAINT

Plaintiffs sanofi-aventis U.S. LLC ("sanofi-aventis U.S."), Aventisub LLC ("Aventisub"), Sanofi, and Genzyme Corporation ("Genzyme") (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Watson Laboratories, Inc. and Teva Pharmaceuticals USA, Inc. (collectively, "Defendants"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent Nos. 6,794,410 ("the '410 patent," a true and accurate copy of which is attached hereto as Exhibit A) and 9,186,346 ("the '346 patent," a true and accurate copy of which is attached hereto as Exhibit B) arising under the Patent Laws of the United States, Title 35, United States Code, Sections 100 *et seq*. This action relates to Abbreviated New Drug Application ("ANDA") No. 209549, filed by Watson Laboratories, Inc. with the United States Food and Drug Administration ("FDA") for approval to market a proposed generic version of the Aubagio® (teriflunomide) drug product.

THE PARTIES

2. Plaintiff sanofi-aventis U.S., a wholly-owned U.S. subsidiary of Sanofi, is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807.

3. Plaintiff Aventisub LLC is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 3711 Kennett Pike, Suite 200, Greenville, Delaware 19807.

4. Plaintiff Sanofi is a corporation organized and existing under the laws of France, having its principal place of business at 54 rue la Boétie, 75008 Paris, France.

5. Plaintiff Genzyme is a corporation organized and existing under the laws of the State of Massachusetts, having its principal place of business at 500 Kendall Street, Cambridge, Massachusetts 02142.

6. On information and belief, Defendant Watson Laboratories, Inc. ("Watson Labs") is a company organized and existing under the laws of Nevada with its principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, New Jersey 07054.

7. On information and belief, Watson Labs is in the business of, among other things, marketing and selling generic versions of branded pharmaceutical products for the United States market, alone and/or through its wholly-owned subsidiaries and agents.

8. On information and belief, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") is a company organized and existing under the laws of Delaware, with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva is in the business of manufacturing and selling generic versions of pharmaceutical products for the United States market.

9. On information and belief, Watson Labs is a wholly-owned subsidiary of Teva, is controlled by Teva, and is an agent or affiliate of Teva.

10. On information and belief, the acts of Watson Labs complained of herein were done at the direction or, with the authorization of, and/or with the cooperation, participation, and assistance of Teva. On information and belief, the acts of Watson Labs complained of herein were done at least in part for the benefit of Teva.

WATSON LABS' ANDA

11. On information and belief and as stated in the letter dated November 10, 2016, and received by Plaintiffs on or about November 11, 2016, purporting to be a notice pursuant to Section 505(j)(2)(B)(iv) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) and 21 C.F.R. § 314.95(c) (the "Notice Letter"), Watson Labs submitted ANDA No. 209549 to the FDA under Section 505(j) of the Federal Food Drug and Cosmetic Act (21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale and/or importation of teriflunomide tablets, 7 mg and 14 mg ("Teriflunomide ANDA Products"), as a generic version of the Aubagio® (teriflunomide) drug product throughout the United States, including within the State of Delaware, prior to the expiration of the '410 and '346 patents.

JURISDICTION AND VENUE

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

13. On information and belief, Watson Labs, with the assistance and/or direction of Teva, develops, formulates, manufactures, imports, offers for sale, sells, commercializes, markets, and/or distributes generic versions of branded pharmaceutical products in/into the United States, including in the State of Delaware.

14. On information and belief, Watson Labs prepared and filed ANDA No. 209549, seeking approval from the FDA to sell Teriflunomide ANDA Products throughout the United States, including within the State of Delaware.

15. On information and belief, Teva participated in the preparation and/or filing of ANDA No. 209549, seeking approval from the FDA to sell Teriflunomide ANDA Products throughout the United States, including within the State of Delaware.

16. This Court has personal jurisdiction over Defendants because, *inter alia*, they have committed an act of patent infringement under 35 U.S.C. § 271 (e)(2), and intend a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. For example, on information and belief, following approval of ANDA No. 209549, Defendants will work in concert to make, use, import, sell, and/or offer for sale Teriflunomide ANDA Products in/into the United States, including in this State, prior to the expiration of the '410 and '346 patents.

17. This Court has personal jurisdiction over Watson Labs because, *inter alia*, Watson Labs, on information and belief: (1) maintains substantial, systematic, and continuous contacts with the State of Delaware; (2) intends to manufacture, market, sell, or distribute the Teriflunomide ANDA Products to residents of this State, which is confirmed by the filing of ANDA No. 209549; (3) maintains a broad distributorship network within this State; (4) regularly transacts and/or solicits business in the State of Delaware; (5) continuously and systematically places goods into the stream of commerce for distribution in the United States, including in the State of Delaware; and (6) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of Delaware.

18. Additionally, on information and belief, Watson Labs has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Reckitt Benckiser Pharmaceuticals, Inc. et al. v. Watson Laboratories, Inc.*, Civil Action No. 13-1674-RGA (D. Del.); *Fresenius Kabi USA, LLC v. Watson Laboratories, Inc. et al.*, Civil Action No. 14-161-SLR (D. Del.); *Sanofi and Sanofi-Aventis U.S. LLC v. Watson Laboratories, Inc.*, Civil Action No. 14-cv-00265-RGA (D. Del.); *Alcon Research, Ltd. v. Actavis Pharma, Inc., Watson Laboratories, Inc., and Actavis, Inc.*, Civil Action No. 15-1159-SLR (D. Del.).

19. This Court has personal jurisdiction over Teva because, *inter alia*, Teva, on information and belief: (1) maintains substantial, systematic, and continuous contacts with the State of Delaware; (2) avails itself of the laws of the State of Delaware by being incorporated in Delaware under File No. 2053734; (3) holds Pharmacy Wholesale Licenses from the State of Delaware under License Nos. A4-0001468 and A4-0001447 and Distributor/Manufacturer Licenses from the State of Delaware under License Nos. DM-0007115 and DM-0006546; (4) maintains a broad distributorship network within this State; (5) regularly transacts and/or solicits business in the State of Delaware; (6) continuously and systematically places goods into the stream of commerce for distribution in the United States, including in the State of Delaware; (7) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of Delaware.

20. Additionally, on information and belief, Teva has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by filing suit and asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories, Ltd., et al.*, Civil Action No.

16-01267 (D. Del.); *Merck Sharp & Dohme B.V. v. Teva Pharmaceuticals USA, Inc., et al.*, Civil Action No. 15-806-GMS (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 15-00124 (D. Del.).

21. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

THE PATENTS

22. The '410 patent, titled "Use of (Z)-2-cyano-3-hydroxy-but-2-enoic Acid-(4'-trifluoromethylphenyl)-amide for Treating Multiple Sclerosis," was duly and legally issued on September 21, 2004 to inventor Joseph Wettstein. The '410 patent was assigned to Aventis Pharmaceuticals Inc. On July 31, 2013, the United States Patent and Trademark Office granted reexamination certificate C1 6,794,410 for the '410 patent, allowing new claims 2-22. On June 16, 2014, the '410 patent was assigned to Aventisub LLC. Since June 16, 2014, Aventisub has been the owner of the '410 patent. The '410 patent will expire on April 15, 2022.

23. The '346 patent, titled "Methods for Reducing the Risk of an Adverse Teriflunomide and Rosuvastatin Interaction in Multiple Sclerosis Patients," was duly and legally issued on November 17, 2015 to inventors Dietmar Weitz, Francoise Menguy-Vacheron, Pierre-Francois Clot, and Sandrine Turpault. The '346 patent was assigned to Sanofi. The '346 patent will expire on February 4, 2034. At all times from the issuance of the '346 patent, Sanofi has been the owner of the '346 patent.

ACTS GIVING RISE TO THIS ACTION

24. Sanofi-Aventis U.S. LLC is the holder of the approved New Drug Application ("NDA") No. 202992 for the Aubagio® (teriflunomide), 7 mg and 14 mg, drug product

("Aubagio® NDA"). Sanofi-Aventis U.S. LLC, Aventisub LLC, Sanofi, and Genzyme all share in the revenue generated from the sale of Aubagio®.

25. Aubagio® is indicated for the treatment of patients with relapsing forms of multiple sclerosis ("MS") ("Approved Indication") and acts to alleviate and/or slow the appearance of symptoms of an acute episode of MS, and slow the progression of an acute episode of MS. Usage of Aubagio® and the Approved Indication are described in the Aubagio® Prescribing Information, which also instructs that when Aubagio is coadministered with rosuvastatin, the dose of rosuvastatin should not exceed 10 mg once daily in patients.

26. The '410 and '346 patents are listed in the FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluation" (the Orange Book) as being applicable to Aubagio®.

27. The '410 patent covers the use of Aubagio® according to its Approved Indication, which includes treatment of patients with relapsing forms of MS, which includes alleviating and/or slowing the appearance of symptoms of and the progression of an acute episode of MS. The '346 patent covers the use of Aubagio® when coadministered with rosuvastatin to manage the risk of drug interactions as described in the Aubagio® Prescribing Information.

28. Defendants have knowledge of the '410 and '346 patents.

29. By the Notice Letter, Watson Labs notified Plaintiffs that it had submitted ANDA No. 209549 to the FDA seeking approval to engage in the commercial manufacture, importation, use, and/or sale of Teriflunomide ANDA Products prior to the expiration of the '410 and '346 patents.

30. Watson Labs submitted ANDA No. 209549 to obtain FDA approval to engage in the commercial manufacture, importation, use, and/or sale of Teriflunomide ANDA Products prior to the expiration of the '410 and '346 patents.

31. On information and belief, Defendants intend to engage in the commercial manufacture, importation, use, and/or sale of Teriflunomide ANDA Products in/into the United States and/or induce or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the '410 and '346 patents.

32. In the Notice Letter, Watson Labs notified Plaintiffs that ANDA No. 209549 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Watson Labs' opinion, the '410 and '346 patents are invalid, unenforceable, and/or will not be infringed by the manufacture, use, sale, offer for sale, and/or importation of Teriflunomide ANDA Products in/into the United States ("Paragraph IV Certification").

33. In addition to the information provided to Plaintiffs in the Notice Letter, counsel for Plaintiffs reviewed the portions of ANDA No. 209549 that were voluntarily provided by Watson Labs under the terms of a confidentiality agreement.

34. On information and belief, the active ingredient of Teriflunomide ANDA Products is teriflunomide, which is the same active ingredient in Aubagio® and the same active ingredient used in the methods of one or more claims of the '410 and '346.

35. On information and belief, Watson Labs asserted in ANDA No. 209549 that Teriflunomide ANDA Products are bioequivalent to Aubagio®.

36. On information and belief, ANDA No. 209549 refers to and relies upon the Aubagio® NDA and contains data that, according to Watson Labs, demonstrate the bioequivalence of Teriflunomide ANDA Products and Aubagio®.

37. On information and belief, Watson Labs is seeking approval to market Teriflunomide ANDA Products for the same Approved Indication as Aubagio®.

38. On information and belief, Watson Labs is seeking approval to market Teriflunomide ANDA Products for the treatment of patients with relapsing forms of multiple sclerosis, which includes alleviating and/or slowing the appearance of symptoms of an acute episode of MS, and slowing the progression of an acute episode of MS.

39. On information and belief, Watson Labs is seeking approval to market Teriflunomide ANDA Products that, when coadministered with rosuvastatin, will be used such that the dose of rosuvastatin will not exceed 10 mg once daily in patients.

40. On information and belief, Teva was actively involved in the preparation and/or submission of ANDA No. 209549 including the Paragraph IV certification against the ‘410 and ‘346 patents.

41. On information and belief, Teva actively and knowingly provided Watson Labs with material information and support in preparing and submitting ANDA No. 209549 and has therefore aided and/or abetted in the filing of ANDA No. 209549.

42. On information and belief, Defendants will work in concert with one another to commercially manufacture, use, offer for sale, and/or sell Teriflunomide ANDA Products throughout the United States, import Teriflunomide ANDA Products into the United States, and/or induce and/or contribute to such acts promptly upon receiving FDA approval to do so and during the term of the ‘410 and ‘346 patents.

43. On information and belief, Defendants will knowingly accompany their Teriflunomide ANDA Products with prescribing information that will contain instructions for use that substantially copy the instructions for Aubagio®, including instructions for administering

Teriflunomide ANDA Products as claimed in at least one of the claims, including but not limited to claim 10, of the ‘410 patent and at least one of the claims, including but not limited to claim 5, of the ‘346 patent.

44. On information and belief, Defendants’ prescribing information for Teriflunomide ANDA Products will instruct users to administer Teriflunomide ANDA Products to treat patients with relapsing forms of multiple sclerosis, which includes alleviating and/or slowing the appearance of symptoms of an acute episode of MS, or slowing the progression of an acute episode of MS.

45. On information and belief, Defendants’ prescribing information for Teriflunomide ANDA Products will instruct users to administer Teriflunomide ANDA Products to treat multiple sclerosis while managing the risk of teriflunomide and rosuvastatin drug interaction when coadministered.

46. On information and belief, Defendants have knowledge and/or an expectation that Teriflunomide ANDA Products will be used in accordance with its prescribing information.

47. On information and belief, Defendants know that the prescribing information that will accompany Teriflunomide ANDA Products will induce and/or contribute to others using Teriflunomide ANDA Products in the manner set forth in the prescribing information.

48. On information and belief, physicians, health care providers, and/or patients will directly infringe one or more claims of the ‘410 and ‘346 patents by using Teriflunomide ANDA Products in accordance with the prescribing information provided by Defendants after the FDA approves ANDA No. 209549.

49. On information and belief, Defendants specifically intend that physicians, health care providers, and/or patients will use Teriflunomide ANDA Products in accordance with the

prescribing information provided by Defendants to directly infringe one or more claims of the '410 and '346 patents.

50. On information and belief, Defendants designed Teriflunomide ANDA Products for use in a way that would infringe the '410 and '346 patents and will instruct users of Teriflunomide ANDA Products to use Teriflunomide ANDA Products in a way that would infringe one or more claims of the '410 and '346 patents.

51. On information and belief, Teriflunomide ANDA Products are not staple articles or commodities of commerce suitable for substantial non-infringing use.

52. On information and belief, Defendants knowingly have taken and intend to take active steps to induce and/or contribute to physicians, health care providers, and/or patients using Teriflunomide ANDA Products in a manner that directly infringes one or more claims of the '410 and '346 patents including, but not limited to, providing prescribing information with instructions for administering Teriflunomide ANDA Products as claimed in one or more claims of the '410 and '346 patents.

53. Plaintiffs commenced this action within 45 days of receiving the Notice Letter.

COUNT I
INFRINGEMENT OF U.S. PATENT NO. 6,794,410

54. Plaintiffs repeat and reallege the allegations of paragraphs 1-53 as if fully set forth herein.

55. Watson Labs' submission of ANDA No. 209549 containing the Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of Teriflunomide ANDA Products in/into the United States prior to the expiration of the '410 patent constitutes infringement of at least one of the claims, including but not limited to claim 10, of the '410 patent under 35 U.S.C. § 271 (e)(2)(A).

56. Teva actively and knowingly aided, abetted, and induced Watson Labs to submit ANDA No. 209549 containing the Paragraph IV Certification before the expiration of the '410 patent.

57. Defendants had notice of the '410 patent at the time of their infringement. Defendants' infringement has been, and continues to be, deliberate.

58. Plaintiffs will be substantially and irreparably harmed if Defendants' infringement of the '410 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

59. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 6,794,410

60. Plaintiffs repeat and reallege the allegations of paragraphs 1-59 as if fully set forth herein.

61. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps, through the submission of ANDA No. 209549, to obtain approval from the FDA to commercially manufacture, import, use, or sell Teriflunomide ANDA Products prior to the expiration of the '410 patent.

62. After obtaining FDA approval, Defendants plan to act in concert with each other to commercially manufacture, use, offer for sale, and/or sell Teriflunomide ANDA Products in the United States, import Teriflunomide ANDA Products into the United States, and/or induce or contribute to such acts prior to the expiration of the '410 patent.

63. Upon FDA approval of ANDA No. 209549, Defendants will infringe one or more of the claims, including but not limited to claim 10, of the ‘410 patent under §§ 271 (a), (b), or (c) by making, using, selling, offering for sale, or importing Teriflunomide ANDA Products in/into the United States and/or inducing or contributing to such acts prior to the expiration of ‘410 patent, unless enjoined by this Court. Accordingly, an actual and immediate controversy exists between the parties regarding infringement of the ‘410 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

64. Upon FDA approval of ANDA No. 209549, use of Teriflunomide ANDA Products as directed by the instructions to be included with Teriflunomide ANDA Products will directly infringe at least one of the claims, including but not limited to claim 10, of the ‘410 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (a), unless enjoined by this Court.

65. Defendants have taken and intend to take active steps to induce or contribute to the direct infringement of one or more claims, including but not limited to claim 10, of the ‘410 patent under 35 U.S.C. § 271 (b) and/or § 271 (c) after ANDA No. 209549 is approved, unless enjoined by this Court.

66. Defendants have knowledge of the ‘410 patent and, by the prescribing information that will be included with Teriflunomide ANDA Products, know or should know that they will aid and abet another’s direct infringement of at least one of the claims, including but not limited to claim 10, of the ‘410 patent either literally or under the doctrine of equivalents.

67. Defendants’ offering for sale, sale, and/or importation of Teriflunomide ANDA Products in/into the United States with the prescribing information for Teriflunomide ANDA Products will actively induce infringement of at least one of the claims, including but not limited

to claim 10, of the '410 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b).

68. The use of Teriflunomide ANDA Products constitutes a material part of at least one of the claims, including but not limited to claim 10, of the '410 patent; Defendants know that Teriflunomide ANDA Products are especially made or adapted for use in infringing at least one of the claims, including but not limited to claim 10, of the '410 patent either literally or under the doctrine of equivalents; and Defendants know that Teriflunomide ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

69. Defendants' manufacture, use, offering for sale, sale, and/or importation of Teriflunomide ANDA Products in/into the United States will contributorily infringe at least one of the claims, including but not limited to claim 10, of the '410 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (c).

70. Defendants will have notice of the '410 patent at the time of their infringement. Defendants' infringement of the '410 patent will be deliberate.

71. Plaintiffs will be substantially and irreparably harmed if Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

72. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT III
INFRINGEMENT OF U.S. PATENT NO. 9,186,346

73. Plaintiffs repeat and reallege the allegations of paragraphs 1-72 as if fully set forth herein.

74. Watson Labs' submission of ANDA No. 209549 containing the Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture,

importation, use, or sale of Teriflunomide ANDA Products in/into the United States prior to the expiration of the '346 patent constitutes infringement of at least one of the claims, including but not limited to claim 5, of the of the '346 patent under 35 U.S.C. § 271 (e)(2)(A).

75. Teva actively and knowingly aided, abetted, and induced Watson Labs to submit ANDA No. 209549 containing the Paragraph IV Certification before the expiration of the '346 patent.

76. Defendants had notice of the '346 patent at the time of their infringement. Defendants' infringement has been, and continues to be, deliberate.

77. Plaintiffs will be substantially and irreparably harmed if Defendants' infringement of the '346 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

78. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT
OF U.S. PATENT NO. 9,186,346

79. Plaintiffs repeat and reallege the allegations of paragraphs 1-78 as if fully set forth herein.

80. This claim arises under the Patent Laws, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, based upon an actual controversy between the parties. Defendants have taken immediate and active steps, through the submission of ANDA No. 209549, to obtain approval from the FDA to commercially manufacture, import, use, or sell Teriflunomide ANDA Products prior to the expiration of the '346 patent.

81. After obtaining FDA approval, Defendants plan to act in concert with each other to commercially manufacture, use, offer for sale, and/or sell Teriflunomide ANDA Products in

the United States, import Teriflunomide ANDA Products into the United States, and/or induce or contribute to such acts prior to the expiration of the '346 patent.

82. Upon FDA approval of ANDA No. 209549, Defendants will infringe one or more of the claims of the '346 patent under §§ 271 (a), (b), or (c) by making, using, selling, offering for sale, or importing Teriflunomide ANDA Products in/into the United States and/or inducing or contributing to such acts prior to the expiration of '346 patent, unless enjoined by this Court. Accordingly, an actual and immediate controversy exists between the parties regarding infringement of the '346 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

83. Upon FDA approval of ANDA No. 209549, use of Teriflunomide ANDA Products as directed by the instructions to be included with Teriflunomide ANDA Products will directly infringe at least one of the claims, including but not limited to claim 5, of the '346 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (a), unless enjoined by this Court.

84. Defendants have taken and intend to take active steps to induce or contribute to the direct infringement of one or more claims, including but not limited to claim 5, of the '346 patent under 35 U.S.C. § 271 (b) and/or § 271 (c) after ANDA No. 209549 is approved, unless enjoined by this Court.

85. Defendants have knowledge of the '346 patent and, by the prescribing information that will be included with Teriflunomide ANDA Products, know or should know that they will aid and abet another's direct infringement of at least one of the claims, including but not limited to claim 5, of the '346 patent either literally or under the doctrine of equivalents.

86. Defendants' offering for sale, sale, and/or importation of Teriflunomide ANDA Products in/into the United States with the prescribing information for Teriflunomide ANDA

Products will actively induce infringement of at least one of the claims, including but not limited to claim 5, of the '346 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (b).

87. The use of Teriflunomide ANDA Products constitutes a material part of at least one of the claims, including but not limited to claim 5, of the '346 patent; Defendants know that Teriflunomide ANDA Products are especially made or adapted for use in infringing at least one of the claims, including but not limited to claim 5, of the '346 patent either literally or under the doctrine of equivalents; and Defendants know that Teriflunomide ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

88. Defendants' manufacture, use, offering for sale, sale, and/or importation of Teriflunomide ANDA Products in/into the United States will contributorily infringe at least one of the claims, including but not limited to claim 5, of the '346 patent either literally or under the doctrine of equivalents, under 35 U.S.C. § 271 (c).

89. Defendants will have notice of the '346 patent at the time of their infringement. Defendants' infringement of the '346 patent will be deliberate.

90. Plaintiffs will be substantially and irreparably harmed if Defendants' infringement is not enjoined. Plaintiffs do not have an adequate remedy at law.

91. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A judgment declaring that Defendants have infringed one or more claims of the ‘410 and ‘346 patents by the filing of ANDA No. 209549;

(b) A judgment declaring that Defendants’ manufacturing, using, selling, offering for sale, or importing Teriflunomide ANDA Products in/into the United States will infringe one or more claims of the ‘410 and ‘346 patents;

(c) A judgment under 35 U.S.C. § 271 (e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 209549 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) be a date no earlier February 4, 2034, the expiration date of the ‘346 patent, which is the latest expiring of the infringed patents, or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(d) Injunctive relief under 35 U.S.C. § 271 (e)(4)(B) preliminarily and permanently enjoining Defendants from making, using, selling, offering for sale, or importing Teriflunomide ANDA Products in/into the United States until after expiration of the ‘410 and ‘346 patents or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(e) A permanent injunction pursuant to 35 U.S.C. § 271 (e)(4)(B) restraining and enjoining Defendants from practicing any methods as claimed in the ‘410 and ‘346 patents, or from actively inducing or contributing to the infringement of any claim of the ‘410 and ‘346 patents, until after the expiration of the ‘410 and ‘346 patents or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(f) A Declaration that the commercial manufacture, use, sale, offer for sale, and importation in/into the United States of Teriflunomide ANDA Products will directly infringe, induce, and/or contribute to infringement of the '410 and '346 patents;

(g) Damages under 35 U.S.C. § 271 (e)(4)(C), which this Court should treble pursuant to 35 U.S.C. § 284, if Defendants infringe the '410 and '346 patents by engaging in the commercial manufacture, importation, use, sale, offer for sale, or import the Teriflunomide ANDA Products in/into the United States prior to the expiration of the '410 and '346 patents or the expiration of any other exclusivity to which Plaintiffs are or become entitled;

(h) An award of reasonable attorney fees in this action pursuant to 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

(j) Such further and other relief as this Court may deem just and proper.

DATED: December 22, 2016

RATNERPRESTIA

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