IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, AVENTISUB LLC, SANOFI, and GENZYME CORPORATION, Plaintiffs, v. ALEMBIC PHARMACEUTICALS LTD., ALEMBIC LIMITED, ALEMBIC GLOBAL HOLDING SA, and ALEMBIC PHARMACEUTICALS, 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 Alembic Pharmaceuticals Ltd., Alembic Limited, Alembic Global Holding SA, and Alembic Pharmaceuticals, Inc. (collectively, "Alembic" or "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. 209572, filed by Alembic Pharmaceuticals Ltd. 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 Alembic Pharmaceuticals Ltd. ("APL") is a company organized and existing under the laws of the India with its principal place of business at Alembic Road, Vadodara 390003 Gujarat, India. On information and belief, APL 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.

7. On information and belief, Defendant Alembic Limited is a company organized and existing under the laws of India, with a principal place of business at Alembic Road,

Vadodara 390003 Gujarat, India. On information and belief, Alembic Limited is in the business of manufacturing and marketing fermentation and chemistry-based active pharmaceutical ingredients for use in generic versions of pharmaceutical products for the United States market. *See* http://www.alembicpharmaceuticals.com/group-companies/. On information and belief, Alembic Limited is the majority shareholder of APL, and controls APL. *See* http://www.alembicpharmaceuticals.com/wp-content/uploads/2016/07/05Alembic-Pharmaceuticals-Limited-Annual-Report-2015-16.pdf, at p. 78.

8. On information and belief, Defendant Alembic Global Holding SA ("AGH") is a company organized and existing under the laws of Switzerland, having a principal place of business at Rue Fritz-Courvoisier 40, 2300 La Chaux-de-Fonds, Switzerland. On information and belief, AGH is in the business of manufacturing and selling generic versions of pharmaceutical products for the United States market. On information and belief, AGH is a wholly-owned subsidiary of APL, is controlled by APL, and is an agent or affiliate of APL.

9. On information and belief, Defendant Alembic Pharmaceuticals, Inc. ("API") is a company organized and existing under the laws of Delaware, having a principal place of business at 116 Village Blvd., Suite 200 Princeton, New Jersey 08650. On information and belief, API is in the business of manufacturing and selling generic versions of pharmaceutical products for the United States market. On information and belief, API is a wholly-owned subsidiary of AGH, is controlled by AGH, and is an agent or affiliate of AGH.

10. On information and belief, Alembic Limited, APL, and AGH operate in the United States through API.

11. On information and belief, the acts of APL complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance

of Alembic Limited, AGH, and API. On information and belief, the acts of APL complained of herein were done at least in part for the benefit of Alembic Limited, AGH, and API.

ALEMBIC PHARMACEUTICALS LTD.'S ANDA

12. On information and belief and as stated in the letter dated November 17, 2016, and received by Plaintiffs on or about November 18, 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"), APL submitted ANDA No. 209572 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

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

14. On information and belief, Defendants collectively develop, formulate, manufacture, import, offer for sale, sell, commercialize, market, and/or distribute generic versions of branded pharmaceutical products in/into the United States, including in the State of Delaware.

15. On information and belief, APL prepared and filed ANDA No. 209572, seeking approval from the FDA to sell the Teriflunomide ANDA Products throughout the United States, including within the State of Delaware.

16. This Court has personal jurisdiction over APL because, *inter alia*, APL has committed an act of patent infringement under 35 U.S.C. § 271 (e)(2), and intends 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. 209572, APL will make, use, import, sell, and/or offer for sale the 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 APL because, *inter alia*, APL, on information and belief: (1) maintains substantial, systematic, and continuous contacts with the State of Delaware, including, but not limited to, ongoing communications and contacts with its U.S. subsidiary, API; (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. 209572; (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; (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, APL has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections afforded by this Court by asserting counterclaims in suits brought in Delaware. *See e.g.*, *Pfizer Inc. et al v. Alembic Limited et al.*, Civil Case No. 11-cv-01213-GMS (D. Del.); *Pfizer Inc. v. Breckenridge Pharm., Inc.*, 12-cv-810-SLR (D. Del.), *Teijin Ltd. v. Alembic Pharm. Ltd.*, 13-cv-1939-SLR (D. Del.)

and *Sanofi v. Alembic Pharm. Ltd.*, 14-cv-424-RGA (D. Del.); *Bayer Pharma AG et al v. Alembic Pharmaceuticals Limited et al.*, Civil Case No. 15-cv-00832-GMS (D. Del).

19. Alternatively, to the extent the above facts do not establish personal jurisdiction over APL, this Court may exercise jurisdiction over APL pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) APL would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) APL has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over APL satisfies due process.

20. This Court has personal jurisdiction over Alembic Limited because, *inter alia*, Alembic Limited, 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; (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; (6) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of Delaware.

21. Additionally, on information and belief, Alembic Limited has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections afforded by this Court by asserting counterclaims in suits brought in Delaware. *See e.g.*, *Pfizer Inc. et al v. Alembic Limited et al.*, Civil Case No. 11-cv-01213-GMS (D. Del.).

22. Alternatively, to the extent the above facts do not establish personal jurisdiction over Alembic Limited, this Court may exercise jurisdiction over Alembic Limited pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alembic Limited would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Alembic Limited has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Limited satisfies due process.

23. This Court has personal jurisdiction over AGH because, *inter alia*, AGH, on information and belief: (1) maintains substantial, systematic, and continuous contacts with the State of Delaware, including, but not limited to, ongoing communications and contacts with its U.S. wholly-owned subsidiary, API; (2) intends to manufacture, market, sell, or distribute the Teriflunomide ANDA Products to residents of this State; (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; (6) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of Delaware.

24. Additionally, on information and belief, AGH has not contested personal jurisdiction in several Delaware litigations. *See e.g.*, *Forest Laboratories LLC et al v. Alembic Pharmaceuticals Ltd. et al.*, Civil Case No. 15-cv-00158-SLR (D. Del.); *Forest Laboratories LLC et al v. Alembic Pharmaceuticals Ltd. et al.*, Civil Case No. 15-cv-00273-GMS (D. Del.).

25. Alternatively, to the extent the above facts do not establish personal jurisdiction over AGH, this Court may exercise jurisdiction over AGH pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) AGH would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) AGH has sufficient contacts with the United States as a whole, including, but not limited to, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over AGH satisfies due process.

26. This Court has personal jurisdiction over API because, *inter alia*, API, 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; (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; (6) generates substantial revenue and income from sales of its generic pharmaceutical products throughout the United States, including within the State of Delaware.

27. Additionally, on information and belief, API has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections afforded by this Court by asserting counterclaims in suits brought in Delaware. *See e.g.*, *Bayer Pharma AG et al v. Alembic Pharmaceuticals Limited et al.*, Civil Case No. 15-cv-00832-GMS (D. Del).

28. On information and belief, API is qualified to do business in Delaware and appointed a registered agent for service of process, by filing with the Secretary of State on August 10, 2012: (1) a certificate of incorporation, under file number 5197177; and (2) a

statement naming "National Registered Agents, Inc." located at 160 Greentree Drive, Suite 101, Dover, Delaware 19904, as its registered agent to accept service of process in the State of Delaware.

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

THE PATENTS

30. 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.

31. 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

32. 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®.

33. 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.

34. 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®.

35. 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.

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

37. By the Notice Letter, APL notified Plaintiffs that APL had submitted ANDA No. 209572 to the FDA seeking approval to engage in the commercial manufacture, importation, use, and/or sale of the Teriflunomide ANDA Products prior to the expiration of the '410 and '346 patents.

38. APL submitted ANDA No. 209572 to obtain FDA approval to engage in the commercial manufacture, importation, use, and/or sale of the Teriflunomide ANDA Products prior to the expiration of the '410 and '346 patents.

39. On information and belief, Defendants intend to engage in the commercial manufacture, importation, use, and/or sale of the 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.

40. In the Notice Letter, APL notified Plaintiffs that ANDA No. 209572 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in APL's 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 the Teriflunomide ANDA Products in/into the United States ("Paragraph IV Certification").

41. In addition to the information provided to Plaintiffs in the Notice Letter, counsel for Plaintiffs reviewed the portions of ANDA No. 209572 that were voluntarily provided by APL under the terms of a confidentiality agreement.

42. On information and belief, the active ingredient of the 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.

43. On information and belief, APL asserted in ANDA No. 209572 that the Teriflunomide ANDA Products are bioequivalent to Aubagio®.

44. On information and belief, ANDA No. 209572 refers to and relies upon the Aubagio® NDA and contains data that, according to APL, demonstrate the bioequivalence of the Teriflunomide ANDA Products and Aubagio®.

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

46. On information and belief, APL is seeking approval to market the 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.

47. On information and belief, APL is seeking approval to market the 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.

48. On information and belief, Alembic Limited, AGH, and API were actively involved in the preparation and/or submission of ANDA No. 209572 including the Paragraph IV certification against the ‘410 and ‘346 patents.

49. On information and belief, Alembic Limited, AGH, and API actively and knowingly provided APL with material information and support in preparing and submitting ANDA No. 209572 and have therefore aided and/or abetted in the filing of ANDA No. 209572.

50. On information and belief, Defendants will work in concert with one another to commercially manufacture, use, offer for sale, and/or sell the Teriflunomide ANDA Products throughout the United States, import the 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.

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

the 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.

52. On information and belief, Defendants' prescribing information for the Teriflunomide ANDA Products will instruct users to administer the 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.

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

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

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

56. 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 the Teriflunomide ANDA Products in accordance with the prescribing information provided by Defendants after the FDA approves ANDA No. 209572.

57. On information and belief, Defendants specifically intend that physicians, health care providers, and/or patients will use the 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.

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

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

60. 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 the 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 the Teriflunomide ANDA Products as claimed in one or more claims of the ‘410 and ‘346 patents.

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

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

62. Plaintiffs repeat and reallege the allegations of paragraphs 1-61 as if fully set forth herein.

63. APL’s submission of ANDA No. 209572 containing the Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of the 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).

64. Alembic Limited, AGH, and API actively and knowingly aided, abetted, and induced APL to submit ANDA No. 209572 containing the Paragraph IV Certification before the expiration of the '410 patent.

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

66. 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.

67. 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

68. Plaintiffs repeat and reallege the allegations of paragraphs 1-67 as if fully set forth herein.

69. 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. 209572, to obtain approval from the FDA to commercially manufacture, import, use, or sell the Teriflunomide ANDA Products prior to the expiration of the '410 patent.

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

71. Upon FDA approval of ANDA No. 209572, 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 the 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).

72. Upon FDA approval of ANDA No. 209572, use of the Teriflunomide ANDA Products as directed by the instructions to be included with the 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.

73. 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. 209572 is approved, unless enjoined by this Court.

74. 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.

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

76. The use of the 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 the 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 the Teriflunomide ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

77. Defendants’ manufacture, use, offering for sale, sale, and/or importation of the 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).

78. Defendants will have notice of the ‘410 patent at the time of their infringement. Defendants’ infringement of the ‘410 patent will be deliberate.

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

80. 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

81. Plaintiffs repeat and reallege the allegations of paragraphs 1-80 as if fully set forth herein.

82. APL's submission of ANDA No. 209572 containing the Paragraph IV Certification to obtain approval from the FDA to engage in the commercial manufacture, importation, use, or sale of the 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).

83. Alembic Limited, AGH, and API actively and knowingly aided, abetted, and induced APL to submit ANDA No. 209572 containing the Paragraph IV Certification before the expiration of the '346 patent.

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

85. 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.

86. 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

87. Plaintiffs repeat and reallege the allegations of paragraphs 1-86 as if fully set forth herein.

88. 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. 209572, to obtain approval from the FDA to commercially manufacture, import, use, or sell the Teriflunomide ANDA Products prior to the expiration of the '346 patent.

89. After obtaining FDA approval, Defendants plan to act in concert with each other to commercially manufacture, use, offer for sale, and/or sell the Teriflunomide ANDA Products in the United States, import the Teriflunomide ANDA Products into the United States, and/or induce or contribute to such acts prior to the expiration of the '346 patent.

90. Upon FDA approval of ANDA No. 209572, 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 the 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).

91. Upon FDA approval of ANDA No. 209572, use of the Teriflunomide ANDA Products as directed by the instructions to be included with the 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.

92. 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. 209572 is approved, unless enjoined by this Court.

93. 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.

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

95. The use of the 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 the 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 the Teriflunomide ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

96. Defendants' manufacture, use, offering for sale, sale, and/or importation of the 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).

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

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

99. 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. 209572;

(b) A judgment declaring that Defendants’ manufacturing, using, selling, offering for sale, or importing the 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. 209572 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 the 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 the 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 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 28, 2016

RATNERPRESTIA

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