IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SANOFI-AVENTIS U.S. LLC, AVENTISUB LLC, SANOFI, and GENZYME CORPORATION, Plaintiffs, v. ACCORD HEALTHCARE, INC., ACCORD HEALTHCARE LTD., and INTAS PHARMACEUTICALS LTD., 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 Accord Healthcare, Inc., Accord Healthcare Ltd., and Intas Pharmaceuticals Ltd. (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. 209690, filed by

Accord Healthcare 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 Accord Healthcare Inc. ("Accord Inc.") is a company organized and existing under the laws of the North Carolina with its principal place of business at 1009 Slater Rd., Suite 210B, Durham, North Carolina 27703. On information and belief, Accord Inc. is in the business of, among other things, marketing and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district, and including as an agent of Intas Pharmaceuticals Ltd.

7. On information and belief, Defendant Accord Healthcare Ltd. ("Accord Ltd.") is a company organized and existing under the laws of India, with a principal place of business at 2nd Floor, Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad, India - 380 009.

On information and belief, Accord Ltd. is in the business of manufacturing and selling generic versions of pharmaceutical products for the United States market.

8. On information and belief, Defendant Intas Pharmaceuticals Ltd. ("Intas") is a company organized and existing under the laws of India, having a principal place of business at 2nd Floor, Chinubhai Centre, Off. Nehru Bridge, Ashram Road, Ahmedabad, India - 380 009. On information and belief, Intas is in the business of manufacturing and selling generic versions of pharmaceutical products for the United States market, alone and/or through its wholly-owned subsidiaries and agents.

9. On information and belief, Accord Inc. and Accord Ltd. are wholly-owned subsidiaries of Intas, controlled by Intas, and are agents or affiliates of Intas.

10. On information and belief, Accord Ltd. and Intas operate in the United States through Accord Inc.

11. On information and belief, the acts of Accord Inc. complained of herein were done at the direction of, with the authorization of, and/or with the cooperation, participation, and assistance of Accord Ltd. and Intas. On information and belief, the acts of Accord Inc. complained of herein were done at least in part for the benefit of Accord Ltd. and Intas.

ACCORD INC.'S ANDA

12. On information and belief and as stated in the letter dated November 16, 2016, and received by Plaintiffs on or about November 17, 2016, purporting to be a notice pursuant to Section 505(j)(2)(B)(ii) and (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"), Accord Inc. submitted ANDA No. 209690 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, Accord Inc., with the assistance and/or direction of Accord Ltd. and/or Intas, 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.

15. On information and belief, Accord Ltd. and Intas acted in concert with Accord Inc. to develop Accord Inc.'s generic copy of the Aubagio® (teriflunomide) drug product.

16. On information and belief, Accord Inc. prepared and filed ANDA No. 209690, seeking approval from the FDA to sell the Teriflunomide ANDA Products throughout the United States, including within the State of Delaware.

17. On information and belief, Accord Ltd. and/or Intas participated in the preparation and/or filing of ANDA No. 209690, seeking approval from the FDA to sell the Teriflunomide ANDA Products throughout the United States, including within the State of Delaware.

18. 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. 209690, Defendants will work in concert to 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.

19. This Court has personal jurisdiction over Accord Inc. because, *inter alia*, Accord Inc., 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. 209690; (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.

20. Additionally, on information and belief, Accord Inc. 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.*, *Pfizer Inc., et al. v. Accord Healthcare, Inc.*, Civil Action No. 16-79-SLR (D. Del.); *Cephalon, Inc. v. Accord Healthcare, Inc., Intas Pharmaceuticals Ltd., at el.*, Civil Action No. 15-00178-GMS (D. Del.); *Acorda Therapeutics, Inc., et al. v. Accord Healthcare, Inc.*, Civil Action No. 14-932-LPS (D. Del.).

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

22. Also, on information and belief, Accord Ltd. and Accord Inc. operate as an integrated, unitary generic pharmaceutical business. For example, Accord Inc. has admitted that "Intas identifies Accord Ltd. as a 'Key Subsidiary' on its website, describing it as the 'the offshore identity of Intas' and 'marketing arm of Intas;' that Intas includes Accord Healthcare, Inc., [and] Accord Healthcare Ltd. in the Annual Report, published on its website, identifying both as subsidiaries; that Intas, Accord Healthcare, Inc., [and] Accord Healthcare Ltd. have overlapping officers and directors; that according to a Draft Red Herring Prospectus for Intas, dated June 14, 2013, references to 'we' or 'us' or 'our' refer to 'Our Company, and where the context requires, our Company, our Subsidiaries and other entities which are consolidated in the financial statements of our Company,' (available at: http://www.sebi.gov.in/cms/sebi_data /attachdocs/1371534868962.pdf); that the Intas website identifies http://www.accord-healthcare.com/ as the website for Accord Ltd.; and that the Accord Ltd. website lists Accord Inc. as the sole contact information for the United States." *See* Civil Action No. 16-79, D.I. 14.

23. This Court has personal jurisdiction over Intas because, *inter alia*, Intas, 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, Accord Inc.; (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; and (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, Intas 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., Cephalon, Inc. v. Accord Healthcare, Inc., Intas Pharmaceuticals Ltd., at el.*, Civil Action No. 15-00178-GMS (D. Del.); *Cephalon, Inc. v. Accord Healthcare, Inc. and Intas Pharmaceuticals Ltd.*, Civil Action No. 13-2095-GMS (D. Del.); *UCB, Inc., et al. v. Accord Healthcare, Inc. and Intas Pharmaceuticals, Ltd.*, Civil Action No. 13-1206-LPS (D. Del.).

25. Alternatively, to the extent the above facts do not establish personal jurisdiction over Accord Ltd. and Intas, this Court may exercise jurisdiction over Accord Ltd. and Intas pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Accord Ltd. and Intas would be foreign defendants not subject to personal jurisdiction in the courts of any State; and (c) Accord Ltd. and Intas have 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 Accord Ltd. and Intas satisfies due process.

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

THE PATENTS

27. 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.

28. 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

29. 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®.

30. 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.

31. 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®.

32. 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.

33. Defendants have knowledge of the ‘410 and ‘346 patents.

34. By the Notice Letter, Accord Inc. notified Plaintiffs that it had submitted ANDA No. 209690 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.

35. Accord Inc. submitted ANDA No. 209690 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.

36. 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.

37. In the Notice Letter, Accord Inc. notified Plaintiffs that ANDA No. 209690 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Accord Inc.'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").

38. In addition to the information provided to Plaintiffs in the Notice Letter, counsel for Plaintiffs reviewed the portions of ANDA No. 209690 that were voluntarily provided by Accord Inc. under the terms of a confidentiality agreement.

39. 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.

40. On information and belief, Accord Inc. asserted in ANDA No. 209690 that the Teriflunomide ANDA Products are bioequivalent to Aubagio®.

41. On information and belief, ANDA No. 209690 refers to and relies upon the Aubagio® NDA and contains data that, according to Accord Inc., demonstrate the bioequivalence of the Teriflunomide ANDA Products and Aubagio®.

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

43. On information and belief, Accord Inc. 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.

44. On information and belief, Accord Inc. 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.

45. On information and belief, Accord Ltd. and Intas were actively involved in the preparation and/or submission of ANDA No. 209690 including the Paragraph IV certification against the ‘410 and ‘346 patents.

46. On information and belief, Accord Ltd. and Intas actively and knowingly provided Accord Inc. with material information and support in preparing and submitting ANDA No. 209690 and have therefore aided and/or abetted in the filing of ANDA No. 209690.

47. 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.

48. 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.

49. 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.

50. 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.

51. 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.

52. 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.

53. 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. 209690.

54. 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.

55. 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.

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

57. 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.

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

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

59. Plaintiffs repeat and reallege the allegations of paragraphs 1-58 as if fully set forth herein.

60. Accord Inc.’s submission of ANDA No. 209690 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).

61. Accord Ltd. and Intas actively and knowingly aided, abetted, and induced Accord Inc. to submit ANDA No. 209690 containing the Paragraph IV Certification before the expiration of the '410 patent.

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

63. 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.

64. 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

65. Plaintiffs repeat and reallege the allegations of paragraphs 1-64 as if fully set forth herein.

66. 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. 209690, 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.

67. 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.

68. Upon FDA approval of ANDA No. 209690, 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).

69. Upon FDA approval of ANDA No. 209690, 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.

70. 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. 209690 is approved, unless enjoined by this Court.

71. Defendants have knowledge of the ‘410 patent and, by the prescribing information that will be included with the 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.

72. 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).

73. 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.

74. 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).

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

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

77. 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

78. Plaintiffs repeat and reallege the allegations of paragraphs 1-77 as if fully set forth herein.

79. Accord Inc.'s submission of ANDA No. 209690 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).

80. Accord Ltd. and Intas actively and knowingly aided, abetted, and induced Accord Inc. to submit ANDA No. 209690 containing the Paragraph IV Certification before the expiration of the '346 patent.

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

82. 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.

83. 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

84. Plaintiffs repeat and reallege the allegations of paragraphs 1-83 as if fully set forth herein.

85. 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. 209690, 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.

86. 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.

87. Upon FDA approval of ANDA No. 209690, 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).

88. Upon FDA approval of ANDA No. 209690, 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.

89. 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. 209690 is approved, unless enjoined by this Court.

90. Defendants have knowledge of the '346 patent and, by the prescribing information that will be included with the 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.

91. 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).

92. 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.

93. 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).

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

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

96. 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. 209690;

(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. 209690 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 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 27, 2016

RATNERPRESTIA

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