IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTRAZENECA PHARMACEUTICALS LP, ASTRAZENECA AB, and AMYLIN PHARMACEUTICALS, LLC	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
TEVA PHARMACEUTICALS USA, INC., and TEVA PHARMACEUTICAL INDUSTRIES LTD.,	)	
Defendants	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AstraZeneca Pharmaceuticals LP and AstraZeneca AB (collectively, "AstraZeneca"), and Amylin Pharmaceuticals, LLC ("Amylin") (collectively "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This action is for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, against Defendants Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva"). This action relates to Abbreviated New Drug Application ("ANDA") No. 205984 filed by Teva USA, Inc. with the U.S. Food and Drug Administration ("FDA") for approval to market exenatide injection 300 mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL), generic versions of AstraZeneca's Byetta® drug product, prior to expiration of U.S. Patent Nos. 6,858,576 (the "'576 patent"), 6,872,700 (the "'700 patent"), 6,956,026 (the "'026 patent"), 7,297,761 (the "'761 patent"), 6,902,744 (the "'744 patent"), 7,521,423 (the "'423 patent") and 7,741,269 (the "'269 patent").

THE PARTIES

2. Plaintiff AstraZeneca Pharmaceuticals LP is a limited partnership organized under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19850.

3. Plaintiff AstraZeneca AB is a public, limited-liability company organized under the laws of Sweden with its principal place of business at Karlebyhus, Astraallén, Södertälje, S-151 85, Sweden.

4. Plaintiff Amylin Pharmaceuticals, LLC is an indirect, wholly-owned subsidiary of AstraZeneca PLC. Amylin Pharmaceuticals, LLC is organized under the laws of the State of Delaware, with its principal place of business at 9625 Towne Centre Drive, San Diego, California 92121.

5. AstraZeneca is engaged in the business of creating, developing, and bringing to market revolutionary biopharmaceutical products to help patients prevail against serious diseases, including treatments for Type II diabetes. Through its subsidiary, AstraZeneca Pharmaceuticals LP, AstraZeneca markets and sells Byetta® in this judicial district and throughout the United States.

6. Upon information and belief, Teva USA is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 425 Privet Road, Horsham Pennsylvania 19044.

7. On information and belief, Teva Ltd. is a corporation organized and existing under the laws of Israel, having its principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

8. Upon information and belief, Teva USA is a wholly-owned subsidiary and agent of Defendant Teva Ltd. Teva USA and Teva Ltd. have common officers.

9. Upon information and belief, the acts of Teva USA complained of herein were performed at the direction of, with the authorization of and with the cooperation, participation, assistance and at least in part the benefit of Teva Ltd.

JURISDICTION AND VENUE

10. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the '576 patent, the '700 patent, the '026 patent, the '744 patent, and the '423 patent (collectively, "the asserted patents"). This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. This Court has jurisdiction over Teva USA because, upon information and belief, Teva USA is a Delaware corporation, with its principal place of business in Delaware.

12. This Court also has jurisdiction over Teva USA because, *inter alia*, this action arises from actions of Teva USA directed toward Delaware, and Teva USA has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Teva USA regularly and continuously transacts business within the State of Delaware, including by selling and distributing pharmaceutical products in Delaware, either on its own or through affiliates. Upon information and belief, Teva USA derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

13. Teva USA has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertion of counterclaims and by filing suits in Delaware.

14. On information and belief, Teva Ltd. develops, formulates, manufactures, markets and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this judicial district, through various directly or indirectly owned operating subsidiaries, including its wholly-owned subsidiary Teva USA. On information and belief, Teva Ltd. and Teva USA work in concert for purposes of developing, formulating, manufacturing, marketing and selling its generic drug products throughout the United States, including Delaware, and Delaware is a likely destination of Teva Ltd.'s generic products. On information and belief, Teva Ltd. has purposely availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitting to personal jurisdiction in this Court and having engaged in systematic and continuous contacts with the State of Delaware.

15. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over Teva.

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

PLAINTIFFS' PATENTS AND APPROVED BYETTA® DRUG PRODUCT

17. Plaintiffs make and sell Byetta® (exenatide injection), a prescription medicine that may improve blood sugar (glucose) control in adults with Type II diabetes, when used with diet and exercise. Type II diabetes is a condition characterized by high blood sugar (glucose) levels caused by either a lack of insulin or the body's inability to use insulin efficiently. Type II diabetes develops most often in middle-aged and older adults but can appear in younger adults, and is the most common form of diabetes.

18. Byetta® is a GLP-1 receptor agonist that enhances glucose-dependent insulin secretion by the pancreatic beta-cell, suppresses inappropriately elevated glucagon secretion, and slows gastric emptying.

19. Plaintiff AstraZeneca AB is the holder of New Drug Application ("NDA") No. 021773 for Byetta® (300 mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL)). FDA initially approved NDA No. 021773 in April 2005 to improve glycemic control in patients with Type II diabetes mellitus who have not achieved adequate glycemic control on metformin, a sulfonylurea, or a combination of metformin and a sulfonylurea. On October 30, 2009, FDA approved the supplemental NDA No. 021773 for the use of Byetta® (exenatide) Injection as an adjunct to diet and exercise to improve glycemic control in adults with Type II diabetes mellitus.

20. The '576, '700, '026, '761, '744, '423, '269 patents and U.S. Patent No. 5,424,286 are listed in the *Approved Drug Products With Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book") for Byetta®.

21. On February 22, 2005, the United States Patent and Trademark Office ("USPTO") duly and lawfully issued the '576 patent, entitled "Methods for regulating gastrointestinal motility." The expiration date for the '576 patent, as listed in the Orange Book, is January 6, 2017. A true and correct copy of the '576 patent is attached as Exhibit A.

22. On March 29, 2005, the USPTO duly and lawfully issued the '700 patent, entitled "Methods for glucagon suppression." The expiration date for the '700 patent, as listed in the Orange Book, is January 14, 2020. A true and correct copy of the '700 patent is attached as Exhibit B.

23. On October 8, 2005, the USPTO duly and lawfully issued the '026 patent, entitled "Use of exendins for the reduction of food intake." The expiration date for the '026 patent, as

listed in the Orange Book, is January 7, 2018. A true and correct copy of the '026 patent is attached as Exhibit C.

24. On June 7, 2005, the USPTO duly and lawfully issued the '744 patent, entitled "Exendin agonist formulations and methods of administration thereof." The expiration date for the '744 patent, as listed in the Orange Book, is January 14, 2020. A true and correct copy of the '744 patent is attached as Exhibit D.

25. On April 21, 2009, the USPTO duly and lawfully issued the '423 patent, entitled "Exendin pharmaceutical compositions." The expiration date for the '423 patent, as listed in the Orange Book, is October 15, 2017. A true and correct copy of the '423 patent is attached as Exhibit E.

26. Each of the '576, '700, '026, '744, and '423 patents is jointly owned by Plaintiffs AstraZeneca Pharmaceuticals LP and Amylin Pharmaceuticals, LLC. Plaintiffs have all right, title, and interest to the '576, '700, '026, '744, and '423 patents, and are authorized to enforce them.

DEFENDANTS' ANDA

27. On information and belief, on or before October 30, 2014, Defendants submitted or caused to be submitted to FDA ANDA No. 205984 ("Teva's ANDA") and a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), seeking approval to engage in the commercial manufacture, use or sale of Exenatide Injection 300 mcg/1.2 mL and 600 mcg/2.4 mL (250 mcg/mL) ("ANDA Products"), as purported generic versions of Byetta®, prior to the expiration of the '576, '700, '026, '761, '744, '423, and '269 patents.

28. On information and belief, on or about October 30, 2014, Teva sent Plaintiffs a "Notice of ANDA No. 205984 Concerning Exenatide Injection 300 mcg/1.2 mL And 600

mcg/2.4 mL (250 mcg/mL) with Paragraph IV Certification Concerning U.S. Patent Nos. 6,858,576, 6,872,700, 6,902,744, 6,956,026, 7,297,761, 7,521,423 and 7,741,269" ("Notice Letter"). The Notice Letter represented that Teva had submitted to FDA ANDA No. 205984 and a purported Paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the products described in the Teva ANDA before the expiration of the patents listed in the Orange Book for NDA No. 021773, except U. S. Patent No. 5,424,286, which expires on December 1, 2016. Hence, Defendants' purpose in submitting the Teva ANDA is to manufacture and market the ANDA Products before the expiration of the '576, '700, '026, '761, '744, '423, and '269 patents.

29. The Notice Letter also stated that the Paragraph IV certification alleges that the '576, '700, '026, '761, '744, '423, and '269 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, or sale of the ANDA Products.

30. Defendants are liable for infringement of the '576, '700, '026, '744, and '423 patents the under 35 U.S.C. § 271(e)(2)(A) by virtue of filing ANDA No. 205984 with a Paragraph IV certification seeking FDA approval of ANDA No. 205984, prior to expiration of the '576, '700, '026, '761, '744, '423, and '269 patents.

31. On information and belief, if FDA approves the Teva ANDA, Defendants will manufacture, offer for sale, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States.

32. The conditions for use of the product(s) for which Teva seeks approval in ANDA No. 205984 fall within one or more of the claims of the asserted patents. If approved, use of Teva's ANDA product(s) in accordance with the proposed labeling submitted in ANDA No. 205984 would infringe one or more of the claims of the '576, '700, '026, '744, and '423 patents.

33. On information and belief, if FDA approves Teva's ANDA, the importation, manufacture, sale, offer for sale, or use of the product(s) that are the subject of ANDA No. 205984 would infringe one or more claims of the '576, '700, '026, '744, and '423 patents.

34. This action is being brought pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) within forty-five days of Plaintiffs' receipt of the Notice Letter.

COUNT I: CLAIM FOR INFRINGEMENT OF THE '576 PATENT

35. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

36. On information and belief, Teva has submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

37. Teva has infringed the '576 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 205984 with a Paragraph IV certification and seeking FDA approval of ANDA No. 205984 prior to the expiration of the '576 patent.

38. If approved the product(s) for which approval is sought in Teva's ANDA will be administered to human patients to improve glycemic control in adults with Type II diabetes mellitus, reduce gastric motility, delay gastric emptying, reduce food intake, reduce appetite, or lower plasma glucagon, which administration would constitute direct infringement of one or more claims of the '576 patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that is in contravention of Plaintiffs' rights under the '576 patent.

39. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and

would actively induce and contribute to infringement of the '576 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 205984, Teva will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '576 patent.

40. On information and belief, upon FDA approval of ANDA No. 205984, Teva will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Teva will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using the ANDA Products. Accordingly, Teva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '576 patent. In addition, on information and belief, Teva will encourage acts of direct infringement with knowledge of the '576 patent and knowledge that it is encouraging infringement.

41. Teva had actual and constructive notice of the '576 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '576 patent would constitute an act of infringement of the '576 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '576 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the '576 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Teva's conduct in

certifying invalidity and non-infringement with respect to the '576 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

42. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '576 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT II: CLAIM FOR INFRINGEMENT OF THE '700 PATENT

43. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

44. On information and belief, Teva has submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

45. Teva has infringed the '700 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Teva ANDA with a Paragraph IV certification and seeking FDA approval of the Teva ANDA prior to the expiration of the '700 patent.

46. If approved the product(s) for which approval is sought in Teva's ANDA will be administered to human patients to improve glycemic control in adults with Type II diabetes mellitus, reduce gastric motility, delay gastric emptying, reduce food intake, reduce appetite, or lower plasma glucagon, which administration would constitute direct infringement of one or more claims of the '700 patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement, and Defendants will actively induce, encourage, aid, and abet this administration with knowledge that is in contravention of Plaintiffs' rights under the '700 patent.

47. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '700 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 205984, Teva will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '700 patent.

48. On information and belief, upon FDA approval of ANDA No. 205984, Teva will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Teva will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using the ANDA Products. Accordingly, Teva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '700 patent. In addition, on information and belief, Teva will encourage acts of direct infringement with knowledge of the '700 patent and knowledge that it is encouraging infringement.

49. Teva had actual and constructive notice of the '700 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '700 patent would constitute an act of infringement of the '700 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '700 patent. In addition, Teva filed the Teva ANDA without adequate

justification for asserting the '700 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Teva's conduct in certifying invalidity and non-infringement with respect to the '700 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

50. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '700 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT III: CLAIM FOR INFRINGEMENT OF THE '026 PATENT

51. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

52. On information and belief, Teva has submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

53. Teva has infringed the '026 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Teva ANDA with a Paragraph IV certification and seeking FDA approval of the Teva ANDA prior to the expiration of the '026 patent.

54. If approved the product(s) for which approval is sought in Teva's ANDA will be administered to human patients to improve glycemic control in adults with type 2 diabetes mellitus, reduce gastric motility, delay gastric emptying, reduce food intake, reduce appetite, or lower plasma glucagon, which administration would constitute direct infringement of one or more claims of the '026 patent. Upon information and belief, this infringement will occur at Defendants' behest, with their intent, knowledge, and encouragement, and Defendants will

actively induce, encourage, aid, and abet this administration with knowledge that is in contravention of Plaintiffs' rights under the '026 patent.

55. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '026 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 205984, Teva will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '026 patent.

56. On information and belief, upon FDA approval of ANDA No. 205984, Teva will market and distribute the ANDA Products to resellers, pharmacies, health care professionals and end users of the ANDA Products. Teva will also knowingly and intentionally accompany the ANDA Products with a product label and product insert that will include instructions for using the ANDA Products. Accordingly, Teva will induce physicians and other health care professionals, resellers, pharmacies, and end users of the ANDA Products to directly infringe one or more claims of the '026 patent. In addition, on information and belief, Teva will encourage acts of direct infringement with knowledge of the '026 patent and knowledge that it is encouraging infringement.

57. Teva had actual and constructive notice of the '026 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '026 patent would constitute an act of infringement of the '026 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale

of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '026 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the '026 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Teva's conduct in certifying invalidity and non-infringement with respect to the '026 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

58. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '026 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT IV: CLAIM FOR INFRINGEMENT OF THE '744 PATENT

59. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

60. On information and belief, Teva has submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

61. Teva has infringed the '744 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Teva ANDA with a Paragraph IV certification and seeking FDA approval of the Teva ANDA prior to the expiration of the '744 patent.

62. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '744 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by

this Court, upon FDA approval of ANDA No. 205984, Teva will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '744 patent.

63. Teva had actual and constructive notice of the '744 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '744 patent would constitute an act of infringement of the '744 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '744 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the '744 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Teva's conduct in certifying invalidity and non-infringement with respect to the '744 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

64. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '744 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

COUNT V: CLAIM FOR INFRINGEMENT OF THE '423 PATENT

65. Plaintiffs restate, re-allege, and incorporate by reference the foregoing paragraphs as if fully set forth herein.

66. On information and belief, Teva has submitted or caused the submission of ANDA No. 205984 to FDA, and continues to seek FDA approval of ANDA No. 205984.

67. Teva has infringed the '423 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Teva ANDA with a Paragraph IV certification and seeking FDA approval of the Teva ANDA prior to the expiration of the '423 patent.

68. Teva's commercial manufacture, use, sale, offer for sale, or importation into the United States of the ANDA Products would directly infringe under 35 U.S.C. § 271(a), and would actively induce and contribute to infringement of the '423 patent, such that Teva would be liable as an infringer under 35 U.S.C. §§ 271(b) and/or 271(c). Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 205984, Teva will make, use, offer to sell, or sell the ANDA Products within the United States, or will import the ANDA Products into the United States, and will thereby infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '423 patent.

69. Teva had actual and constructive notice of the '423 patent prior to filing the Teva ANDA, and was aware that the filing of the ANDA with the request for FDA approval prior to the expiration of the '423 patent would constitute an act of infringement of the '423 patent. Teva has no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of the ANDA Products will not infringe, contribute to the infringement of, or induce the infringement of the '423 patent. In addition, Teva filed the Teva ANDA without adequate justification for asserting the '423 patent to be invalid, unenforceable, and/or not infringed by the commercial manufacture, use, offer for sale, or sale of the ANDA Products. Teva's conduct in certifying invalidity and non-infringement with respect to the '423 patent renders this case "exceptional" as that term is set forth in 35 U.S.C. § 285.

70. Plaintiffs will be irreparably harmed if Teva is not enjoined from infringing, and from actively inducing or contributing to the infringement of the '423 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment that Defendants have infringed the '576, '700, '026,'744, and '423 patents under 35 U.S.C. § 271(e)(2)(A);

(B) A judgment declaring that the making, using, selling, offering to sell, or importing of the products for which approval is sought in Teva's ANDA, or inducing or contributing to such conduct, would constitute infringement of the '576, '700, '026, '744, and '423 patents by Defendants pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c);

(C) A judgment that the claims of the '576, '700, '026,'744, and '423 patents are valid and enforceable;

(D) A permanent injunction enjoining Defendants and its officers, directors, agents, servants, employees, parents, subsidiaries, affiliate companies, other related business entities, and all other persons acting in concert, participation, or in privity with Defendants, and its successors or assigns, from making, using, selling, offering for sale, or importing the ANDA Products in the United States until expiration of the last of the asserted patents and associated regulatory exclusivities extending that date;

(E) The entry of an order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of ANDA No. 205984 shall be a date that is not earlier than the last

expiration date of any of the '576, '700, '026, '744, and '423 patents, or any later expiration of exclusivity for any of the patents, including any extensions or regulatory exclusivities;

(F) A finding that this is an exceptional case, and an award of Plaintiffs' attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(G) An award to Plaintiffs of their costs and expenses in this action; and

(H) Such other and further relief as the Court deems just and proper.

DATED: December 12, 2014

MCCARTER & ENGLISH, LLP

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