UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ELI LILLY AND COMPANY, Plaintiff, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICAL INDUSTRIES LTD., Defendants.	Civil Action No. 1:16-cv-596

COMPLAINT

Plaintiff Eli Lilly and Company ("Lilly") files this Complaint for patent infringement against Teva Pharmaceuticals USA, Inc. ("Teva USA") and Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") (collectively, "Teva") under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Forteo®.

THE PARTIES

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Teva USA is organized and exists under the laws of the State of Delaware and has a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

3. On information and belief, Teva USA is a generic drug company that develops, manufactures, markets, sells, and distributes generic pharmaceutical products in the State of Indiana and throughout the United States in concert with its parent company Teva Ltd. and related companies.

4. Teva Ltd. is organized under the laws of Israel and has a principal place of business at 5 Basel Street, Petach Tikva 49131, Israel.

5. On information and belief, Teva Ltd. is a generic drug company that develops, manufactures, markets, sells, and distributes generic pharmaceutical products in the State of Indiana and throughout the United States.

6. On information and belief, the acts of Teva USA complained of herein were done with the cooperation, participation, and assistance of Teva Ltd. Teva USA and Teva Ltd. are collectively referred to herein as "Teva."

NATURE OF THE ACTION

7. This is an action for infringement of U.S. Patent Nos. 6,770,623 ("the '623 patent"); 7,144,861 ("the '861 patent"); 7,550,434 ("the '434 patent"); 6,977,077 ("the '077 patent"); 7,163,684 ("the '684 patent"); and 7,351,414 ("the '414 patent") (collectively, "Lilly's Patents"). This action relates to Abbreviated New Drug Application ("ANDA") No. 208569 submitted in the name of Teva USA to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Lilly's Forteo® (teriparatide [rDNA origin] injection) product, which constitutes an action of infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

SUBJECT MATTER JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

PERSONAL JURISDICTION

11. This Court has personal jurisdiction over Defendants because they have purposefully directed activities at residents of the State of Indiana and this action arises out of or relates to those activities. On information and belief, Defendants develop, manufacture, market, and sell pharmaceutical products throughout the United States, including the State of Indiana. Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of doing business within the State of Indiana. Exercising personal jurisdiction over Defendants is reasonable and fair.

12. Teva Ltd.'s 2015 Annual Report states that Teva Ltd. is "the leading generic drug company in the United States" and "market[s] approximately 370 generic products in more than 1,100 dosage strengths and packaging sizes, including oral, injectable and inhaled products." Teva Ltd.'s 2015 Annual Report further states "[a] substantial majority of our U.S. generic sales are made to retail drug chains and wholesalers" and that "[o]ur portfolio selection, breadth of products offerings and our global network capabilities, have provided mutual strategic advantages to our customers."

13. Teva Ltd.'s 2015 Annual Report states: "We operate our business globally and believe that our global infrastructure provides us with the following capabilities and advantages: global research and development facilities that enable us to have a leading global generic

pipeline and a broad generic product line in the United States, as well as a strong pipeline of innovative products in our key therapeutic areas . . . ."

14. Teva Ltd.'s 2015 Annual Report states: "The Global Generic Medicines group is responsible globally for all generic commercial activities. This includes portfolio management and selection, product launch and commercial execution. Bringing all of our regional generic businesses under one roof highlights our strong focus on, and commitment to, our generic business." Teva Ltd.'s 2015 Annual Report further states: "Our worldwide operations are conducted through a network of global subsidiaries [including Teva USA]."

15. Teva Ltd.'s 2015 Annual Report states that its "[r]evenues from generic medicines in the United States in 2015 amounted to $4.8 billion." Teva Ltd.'s 2015 Annual Report further states: "We expect that our generic medicines revenues in the U.S. will continue to benefit from our strong generic pipeline, which, as of January 22, 2016, had 107 product registrations awaiting FDA approval, including 28 tentative approvals. Collectively, these 107 products had U.S. sales in 2015 exceeding $72 billion. Of these applications, 76 were 'Paragraph IV' applications challenging patents of branded products."

16. Teva filed its ANDA for approval to market its Teriparatide Injection 600 µg/2.4 ml (250 µg/ml) ("Teva's ANDA Product") and sent and/or caused to be sent to Lilly in Indiana a letter dated February 3, 2016 ("Notice Letter"), notifying Lilly that Teva's ANDA No. 208569 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product before the expiration of Lilly's Patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B).

17. Upon information and belief, Teva, either directly or through distributors or related entities, intentionally markets and provides its generic pharmaceutical drug products to

residents of Indiana, sells products to retail drug chains in Indiana, maintains a broad distributorship network within Indiana, and derives substantial revenue from sales of its generic pharmaceutical drug products in Indiana. Upon information and belief, Teva has employees based in Indiana.

18. Teva would not be unfairly burdened by participating in patent litigation in this judicial district. Teva should have reasonably anticipated being sued in Indiana. Teva has litigated other ANDA cases in Indiana, and on information and belief, its business model is dependent on such litigation. When Teva sent its Notice Letter to Lilly in Indiana, it knew or should have known that Lilly was an Indiana corporation, that Lilly has brought suit in Indiana against ANDA filers, including Teva, in the past, and that if Lilly were to bring suit against Teva within 45 days of receiving the Notice Letter, suit would likely be brought in Indiana. As further evidence of personal jurisdiction over Teva, Teva USA has been sued for patent infringement in this district and has not contested personal jurisdiction. *See, e.g.*, *Eli Lilly & Co. v. Accord Healthcare Inc., USA*, No. 1:14-cv-00389-SEB-TAB; *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, No. 1:08-cv-01302-DFH-TAB; *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, No. 1:06-cv-01017-SEB-JMS. In addition, Teva USA has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. *See, e.g.*, *Eli Lilly & Co. v. Accord Healthcare Inc., USA*, No. 1:14-cv-00389-SEB-TAB; *Eli Lilly & Co. v. Teva Pharm. USA, Inc.*, No. 1:06-cv-01017-SEB-JMS.

19. Lilly and the State of Indiana have a substantial interest in resolving this suit in an Indiana forum. The Notice Letter was sent to Lilly in Indiana and, if Teva's ANDA is approved, infringement would occur in, and Lilly would be injured in, the State of Indiana, its state of incorporation.

FACTUAL BACKGROUND

A. Forteo®

20. Lilly is the holder of approved New Drug Application ("NDA") No. 021318 for the manufacture and sale of teriparatide [rDNA origin] injection, approved by the FDA for: (1) treatment of postmenopausal women with osteoporosis at high risk for fracture; (2) increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; and (3) treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture. Lilly markets and sells teriparatide [rDNA origin] injection under the trade name Forteo®. Forteo® was approved by the FDA on November 26, 2002.

B. The '623 Patent

21. The '623 patent, titled "Stabilized Teriparatide Solutions," and owned by Lilly, was duly and legally issued by the United States Patent and Trademark Office ("PTO") on August 3, 2004, from U.S. Patent Application No. 09/555,476, filed as PCT Application No. PCT/US98/26043 on December 8, 1998. The '623 patent claims priority to U.S. Provisional Application No. 60/069,075, filed December 9, 1997. The '623 patent claims, *inter alia*, a sealed cartridge containing a pharmaceutical composition in the form of a sterile solution ready for parenteral administration by a human patient, said formulation comprising: a. human parathyroid hormone, and b. a buffer to maintain a pH from greater than 3 to less than 7. The '623 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Forteo®. A true and correct copy of the '623 patent is attached as ***Exhibit A***.

C. The '861 Patent

22. The '861 patent, titled "Stabilized Teriparatide Solutions," and owned by Lilly, was duly and legally issued by the PTO on December 5, 2006, from U.S. Patent Application No. 10/055,509, filed on January 23, 2002, as a continuation of the '623 patent application. The '861 patent claims, *inter alia*, an aqueous pharmaceutical solution comprising human parathyroid hormone (1-34) in a concentration of about 100-500 µg/ml; an acetate buffer to maintain the pH range of the solution from 3 to 6; a stabilizing agent selected from the group consisting of glucose, trehalose, raffinose, sucrose, mannitol, sorbitol, inositol, glycerine, propylene glycol, and mixtures thereof; a parenterally acceptable preservative; and water; wherein said solution is sterile and ready for parenteral administration to a human patient. The '861 patent is listed in the FDA's Orange Book in connection with Forteo®. A true and correct copy of the '861 patent is attached as ***Exhibit B***.

D. The '434 Patent

23. The '434 patent, titled "Stabilized Teriparatide Solutions," and owned by Lilly, was duly and legally issued by the PTO on June 23, 2009, from U.S. Patent Application No. 11/541,862, filed October 2, 2006, as a continuation of the '861 patent application. The '434 patent claims, *inter alia*, a sealed vial or sealed cartridge containing a pharmaceutical solution comprising: a) human parathyroid hormone (1-34) at a concentration of 100 µg/ml to 500 µg/ml; b) a buffering system to maintain the pH range of the solution from greater than 3 to 6; c) a polyol stabilizing agent; and d) a parenterally acceptable preservative; wherein the solution is sterile and ready for parenteral administration by a human patient without undergoing a step of lyophilization prior to use by the patient. The '434 patent is listed in the FDA's Orange Book in connection with Forteo®. A true and correct copy of the '434 patent is attached as ***Exhibit C***.

E. The '077 Patent

24. The '077 patent, titled "Method of Increasing Bone Toughness and Stiffness and Reducing Fractures," and owned by Lilly, was duly and legally issued by the PTO on December 20, 2005, from U.S. Patent Application No. 09/647,278, filed as PCT Application No. PCT/US99/18961 on August 19, 1999. The '077 patent claims priority to U.S. Provisional Application Nos. 60/097,151, filed August 19, 1998, and 60/099,746, filed September 10, 1998. The '077 patent claims, *inter alia*, a method for the treatment of osteoporosis in a human subject, comprising administering to said subject human parathyroid hormone (1-34) in a daily dose of 20 µg, without concurrent administration of an antiresorptive agent other than vitamin D or calcium, said treatment for reducing the risk of vertebral and non-vertebral bone fracture. The '077 patent is listed in the FDA's Orange Book in connection with Forteo®. A true and correct copy of the '077 patent is attached as ***Exhibit D***.

F. The '684 Patent

25. The '684 patent, titled "Method of Increasing Bone Toughness and Stiffness and Reducing Fractures," and owned by Lilly, was duly and legally issued by the PTO on January 16, 2007, from U.S. Patent Application No. 11/098,894, filed April 5, 2005, as a continuation of the '077 patent application. The '684 patent claims, *inter alia*, a method for treating osteoporosis in a post-menopausal woman at high risk for fracture, comprising administering to said woman human parathyroid hormone (1-34) in a daily dose of 20 µg, without concurrent administration of an antiresorptive agent other than supplemental vitamin D or supplemental calcium, said treatment for increasing bone mineral density and reducing the risk of vertebral and non-vertebral bone fracture. The '684 patent is listed in the FDA's Orange Book in connection with Forteo®. A true and correct copy of the '684 patent is attached as ***Exhibit E***.

G. The '414 Patent

26. The '414 patent, titled "Method of Reducing the Risk of Bone Fracture," and owned by Lilly, was duly and legally issued by the PTO on April 1, 2008, from U.S. Patent Application No. 11/684,996, filed March 12, 2007, as a continuation of the '077 patent application. The '414 patent claims, *inter alia*, a method for the treatment of a woman with osteoporosis and at risk for bone fracture, comprising administering to said woman human parathyroid hormone (1-34) in a daily dose of 20 µg, without concurrent administration of an antiresorptive agent other than vitamin D or calcium, said treatment reducing the risk of vertebral and non-vertebral bone fracture. The '414 patent is listed in the FDA's Orange Book in connection with Forteo®. A true and correct copy of the '414 patent is attached as ***Exhibit F***.

H. Teva's ANDA No. 208569

27. Teva filed or caused to be filed with the FDA ANDA No. 208569 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Teriparatide Injection 600 µg/2.4 mL (250 µg/mL) ("Teva's Generic Product") in the United States before the expiration of Lilly's Patents.

28. Teva USA and Teva Ltd. acted in concert to prepare and submit ANDA No. 208569.

29. Teva's ANDA No. 208569 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of Lilly's Patents are invalid, unenforceable, and/or would not be infringed by Teva's Generic Product.

30. Teva sent or caused to be sent to Lilly a letter dated February 3, 2016 ("Notice Letter"), notifying Lilly that Teva's ANDA No. 208569 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Teva's Generic Product before the expiration of Lilly's Patents and providing information pursuant to 21 U.S.C.

§ 355(j)(2)(B). Teva's Notice Letter states that "the [FDA] has received an [ANDA] and amendments thereto containing any required bioavailability or bioequivalence data or information submitted by Teva USA which seeks approval to engage in the commercial manufacture, use, or sale of [Teva's Generic Product] prior to expiration of [Lilly's Patents]."

31. The submission of ANDA No. 208569 to the FDA constitutes infringement by Teva of Lilly's Patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Teva's Generic Product would infringe Lilly's Patents under 35 U.S.C. § 271(a), (b), and/or (c).

32. Teva knows and intends that physicians will prescribe, and patients will take, Teva's Generic Product for which approval is sought in ANDA No. 208569. Teva will therefore infringe at least one claim of each of Lilly's Patents.

33. Teva had knowledge of Lilly's Patents and, by its promotional activities and proposed Generic Product, knows or should know that it will aid and abet in another's direct infringement of at least one of the claims of each of Lilly's Patents, either literally or under the doctrine of equivalents.

34. Teva plans to make, use, sell, offer to sell, and/or import its Generic Product for uses that will infringe Lilly's Patents. Teva's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

35. Lilly commenced this action within 45 days of receiving Teva's Notice Letter.

COUNT I FOR PATENT INFRINGEMENT (DIRECT INFRINGEMENT OF U.S. PATENT NO. 6,770,623)

36. Lilly incorporates by reference and realleges Paragraphs 1-35 above as though fully restated herein.

37. Pursuant to 35 U.S.C. § 271(e)(2), Teva's submission of ANDA No. 208569 to the FDA seeking approval of Teva's Generic Product before expiration of the '623 patent was an act of infringement of at least claims 18 and 27 of the '623 patent by Teva.

38. If ANDA No. 208569 is approved by the FDA, Teva's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Teva's Generic Product would directly infringe, either literally or under the doctrine of equivalents, at least claim 27 of the '623 patent under 35 U.S.C. § 271.

39. Unless Teva is enjoined by this Court, Lilly will be substantially and irreparably harmed by Teva's infringement of the '623 patent. Lilly does not have an adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 6,770,623)

40. Lilly incorporates by reference and realleges Paragraphs 1-39 above as though fully restated herein.

41. Teva has knowledge of the '623 patent.

42. Upon FDA approval of ANDA No. 208569, Teva will intentionally encourage acts of direct infringement of at least claims 18 and 27 of the '623 patent by others, with knowledge that their acts are encouraging infringement.

COUNT III FOR PATENT INFRINGEMENT
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 6,770,623)

43. Lilly incorporates by reference and realleges Paragraphs 1-42 above as though fully restated herein.

44. If ANDA No. 208569 is approved, Teva intends to and will offer to sell, sell, and/or import into the United States Teva's Generic Product.

45. On information and belief, Teva has had and continues to have knowledge that Teva's Generic Product is especially adapted for a use that infringes at least claim 18 of the '623 patent.

46. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for Teva's Generic Product.

COUNT IV FOR PATENT INFRINGEMENT
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,144,861)

47. Lilly incorporates by reference and realleges Paragraphs 1-46 above as though fully restated herein.

48. Pursuant to 35 U.S.C. § 271(e)(2), Teva's submission of ANDA No. 208569 to the FDA seeking approval of Teva's Generic Product before expiration of the '861 patent was an act of infringement of at least claim 1 of the '861 patent by Teva.

49. If ANDA No. 208569 is approved by the FDA, Teva's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Teva's Generic Product would directly infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '861 patent under 35 U.S.C. § 271.

50. Unless Teva is enjoined by this Court, Lilly will be substantially and irreparably harmed by Teva's infringement of the '861 patent. Lilly does not have an adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 7,144,861)

51. Lilly incorporates by reference and realleges Paragraphs 1-50 above as though fully restated herein.

52. Teva has knowledge of the '861 patent.

53. Upon FDA approval of ANDA No. 208569, Teva will intentionally encourage acts of direct infringement of at least claim 1 of the ’861 patent by others, with knowledge that their acts are encouraging infringement.

COUNT VI FOR PATENT INFRINGEMENT
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,550,434)

54. Lilly incorporates by reference and realleges Paragraphs 1-53 above as though fully restated herein.

55. Pursuant to 35 U.S.C. § 271(e)(2), Teva’s submission of ANDA No. 208569 to the FDA seeking approval of Teva’s Generic Product before expiration of the ’434 patent was an act of infringement of at least claims 12 and 24 the ’434 patent by Teva.

56. If ANDA No. 208569 is approved by the FDA, Teva’s commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Teva’s Generic Product would directly infringe, either literally or under the doctrine of equivalents, at least claim 12 of the ’434 patent under 35 U.S.C. § 271.

57. Unless Teva is enjoined by this Court, Lilly will be substantially and irreparably harmed by Teva’s infringement of the ’434 patent. Lilly does not have an adequate remedy at law.

COUNT VII FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 7,550,434)

58. Lilly incorporates by reference and realleges Paragraphs 1-57 above as though fully restated herein.

59. Teva has knowledge of the ’434 patent.

60. Upon FDA approval of ANDA No. 208569, Teva will intentionally encourage acts of direct infringement of at least claims 12 and 24 of the '434 patent by others, with knowledge that their acts are encouraging infringement.

COUNT VIII FOR PATENT INFRINGEMENT
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 7,550,434)

61. Lilly incorporates by reference and realleges Paragraphs 1-60 above as though fully restated herein.

62. If ANDA No. 208569 is approved, Teva intends to and will offer to sell, sell, and/or import into the United States Teva's Generic Product.

63. On information and belief, Teva has had and continues to have knowledge that Teva's Generic Product is especially adapted for a use that infringes at least claim 24 of the '434 patent.

64. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for Teva's Generic Product.

COUNT IX FOR PATENT INFRINGEMENT
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 6,977,077)

65. Lilly incorporates by reference and realleges Paragraphs 1-64 above as though fully restated herein.

66. Pursuant to 35 U.S.C. § 271(e)(2), Teva's submission of ANDA No. 208569 to the FDA seeking approval of Teva's Generic Product before expiration of the '077 patent was an act of infringement of at least claim 1 of the '077 patent by Teva.

67. Unless Teva is enjoined by this Court, Lilly will be substantially and irreparably harmed by Teva's infringement of the '077 patent. Lilly does not have an adequate remedy at law.

COUNT X FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 6,977,077)

68. Lilly incorporates by reference and realleges Paragraphs 1-67 above as though fully restated herein.

69. Teva has knowledge of the ’077 patent.

70. Upon FDA approval of ANDA No. 208569, Teva will intentionally encourage acts of direct infringement of at least claim 1 of the ’077 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XI FOR PATENT INFRINGEMENT
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 6,977,077)

71. Lilly incorporates by reference and realleges Paragraphs 1-70 above as though fully restated herein.

72. If ANDA No. 208569 is approved, Teva intends to and will offer to sell, sell, and/or import into the United States Teva’s Generic Product.

73. On information and belief, Teva has had and continues to have knowledge that Teva’s Generic Product is especially adapted for a use that infringes at least claim 1 of the ’077 patent.

74. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for Teva’s Generic Product.

COUNT XII FOR PATENT INFRINGEMENT
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,163,684)

75. Lilly incorporates by reference and realleges Paragraphs 1-74 above as though fully restated herein.

76. Pursuant to 35 U.S.C. § 271(e)(2), Teva's submission of ANDA No. 208569 to the FDA seeking approval of Teva's Generic Product before expiration of the '684 patent was an act of infringement of at least claim 1 of the '684 patent by Teva.

77. Unless Teva is enjoined by this Court, Lilly will be substantially and irreparably harmed by Teva's infringement of the '684 patent. Lilly does not have an adequate remedy at law.

COUNT XIII FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 7,163,684)

78. Lilly incorporates by reference and realleges Paragraphs 1-77 above as though fully restated herein.

79. Teva has knowledge of the '684 patent.

80. Upon FDA approval of ANDA No. 208569, Teva will intentionally encourage acts of direct infringement of at least claim 1 of the '684 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XIV FOR PATENT INFRINGEMENT
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 7,163,684)

81. Lilly incorporates by reference and realleges Paragraphs 1-80 above as though fully restated herein.

82. If ANDA No. 208569 is approved, Teva intends to and will offer to sell, sell, and/or import into the United States Teva's Generic Product.

83. On information and belief, Teva has had and continues to have knowledge that Teva's Generic Product is especially adapted for a use that infringes at least claim 1 of the '684 patent.

84. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for Teva's Generic Product.

COUNT XV FOR PATENT INFRINGEMENT
(DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,351,414)

85. Lilly incorporates by reference and realleges Paragraphs 1-84 above as though fully restated herein.

86. Pursuant to 35 U.S.C. § 271(e)(2), Teva's submission of ANDA No. 208569 to the FDA seeking approval of Teva's Generic Product before expiration of the '414 patent was an act of infringement of at least claim 1 of the '414 patent by Teva.

87. Unless Teva is enjoined by this Court, Lilly will be substantially and irreparably harmed by Teva's infringement of the '414 patent. Lilly does not have an adequate remedy at law.

COUNT XVI FOR PATENT INFRINGEMENT
(INDUCEMENT TO INFRINGE U.S. PATENT NO. 7,351,414)

88. Lilly incorporates by reference and realleges Paragraphs 1-87 above as though fully restated herein.

89. Teva has knowledge of the '414 patent.

90. Upon FDA approval of ANDA No. 208569, Teva will intentionally encourage acts of direct infringement of at least claim 1 of the '414 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XVII FOR PATENT INFRINGEMENT
(CONTRIBUTORY INFRINGEMENT OF U.S. PATENT NO. 7,351,414)

91. Lilly incorporates by reference and realleges Paragraphs 1-90 above as though fully restated herein.

92. If ANDA No. 208569 is approved, Teva intends to and will offer to sell, sell, and/or import into the United States Teva's Generic Product.

93. On information and belief, Teva has had and continues to have knowledge that Teva's Generic Product is especially adapted for a use that infringes at least claim 1 of the '414 patent.

94. On information and belief, Teva has had and continues to have knowledge that there is no substantial non-infringing use for Teva's Generic Product.

PRAYER FOR RELIEF

Wherefore, Lilly respectfully requests that this Court enter judgment in its favor as follows:

A. U.S. Patent Nos. 6,770,623; 7,144,861; 7,550,434; 6,977,077; 7,163,684; and 7,351,414 are valid and enforceable;

B. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed U.S. Patent Nos. 6,770,623; 7,144,861; 7,550,434; 6,977,077; 7,163,684; and 7,351,414 by submitting ANDA No. 208569 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import into the United States Teva's Generic Product prior to expiration of these patents;

C. Defendants' threatened acts of commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Teva's Generic Product prior to expiration of U.S. Patent Nos. 6,770,623; 7,144,861; 7,550,434; 6,977,077; 7,163,684; and 7,351,414 would constitute infringement of these patents;

D. The effective date of any FDA approval of Teva's Generic Product shall be no earlier than the latest expiration date of U.S. Patent Nos. 6,770,623; 7,144,861; 7,550,434;

6,977,077; 7,163,684; and 7,351,414 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. Defendants, and all persons acting in concert with Defendants, shall be enjoined from commercially manufacturing, using, offering for sale, or selling Teva's Generic Product within the United States, or importing Teva's Generic Product into the United States, until the expiration of U.S. Patent Nos. 6,770,623; 7,144,861; 7,550,434; 6,977,077; 7,163,684; and 7,351,414 in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. This is an exceptional case, and Lilly should be awarded its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. Lilly is entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. Lilly is entitled to any further and additional relief that this Court deems just and proper.

Dated: March 16, 2016

Respectfully submitted,

/s/ Jan M. Carroll

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