IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GLAXO GROUP LTD., Plaintiff, v. TEVA PHARMACEUTICALS USA, INC., Defendant	C. A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

For its Complaint against Teva Pharmaceuticals USA, Inc. ("Teva"), Plaintiff Glaxo Group Ltd. DBA GlaxoSmithKline ("GSK"), by its attorneys, alleges as follow:

NATURE OF ACTION

1. This is an action for infringement of United States Patent Nos. 7,500,444 ("the '444 patent") and 7,832,351 ("the '351 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq.*, including §§ 271(e)(2), and for Declaratory Judgment of infringement under 28 U.S.C. §§ 2201-2 and 35 U.S.C. §§ 271(a), (b), and (c), relating to Plaintiff's commercially successful Flovent® HFA aerosol inhalers indicated for treatment of asthma for patients requiring oral corticosteroid therapy.

THE PARTIES

2. Plaintiff Glaxo Group Ltd. is a private company, limited by shares, organized under the laws of England and Wales, with its principal place of business located at 980 Great West Road, Brentford, Middlesex, England.

3. Upon information and belief, Teva Pharmaceuticals USA, Inc. is a Delaware corporation with its principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454-1090.

4. Upon information and belief, Teva is in the business of, among other things, developing, manufacturing, packaging, distributing, marketing, and selling generic versions of branded pharmaceutical products for the United States market, including in this judicial district and the State of Delaware, through its own systemic, continuous, constant and pervasive actions and through those of its agents and operating subsidiaries.

5. On information and belief, Teva has previously submitted to this Court's jurisdiction. *See, e.g.*, *Momenta Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, 1:17-cv-00109, D.I. 12 (D. Del. Mar. 9, 2017); *Sanofi-Aventis U.S. LLC et al. v. Teva Pharmaceuticals USA, Inc.*, No. 1:17-cv-00018, D.I. 16 (D. Del. Feb. 24, 2017); *GlaxoSmithKline LLC et al v. Teva Pharmaceuticals USA Inc.*, No. 1:14-cv-00878, D.I. 105 (D. Del. Feb. 9, 2016).

6. Teva has purposefully availed itself of the jurisdiction of this Court by, *inter alia*, asserting claims for patent infringement in this District. *See, e.g.*, *Teva Pharmaceuticals USA, Inc. et al. v. Doctor Reddys Laboratories, Ltd. et al.*, No. 1:16-cv-01267, D.I. 1 (D. Del. Dec. 19, 2016); *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:17-cv-00249, D.I. 1 (D. Del. Jan. 17, 2017).

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*., including §§ 271(e)(2), 271(a), (b), and (c) and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

8. This Court has personal jurisdiction over Teva by virtue of, *inter alia*, the fact that Teva is incorporated in the state of Delaware.

9. This Court has personal jurisdiction over Teva by virtue of the fact that Teva has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff in the state of Delaware, and because Teva has engaged in purposeful systematic and continuous contacts with the State of Delaware.

10. This Court has personal jurisdiction over Teva because, upon information and belief, Teva regularly does business in Delaware and has engaged in a persistent course of purposeful conduct within Delaware by continuously and systematically placing pharmaceutical goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware. For example, Teva is registered with the Delaware Board of Pharmacy as a "Pharmacy-Wholesale[r]" (License No. A4-0001447) and "Distributor/Manufacturer" (License No. DM-0007115) pursuant to 24 Del. C. § 2450. As another example, Teva is registered to do business with the Delaware Department of State Division of Corporations (File No. 2053734). *See Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 593 (D. Del. 2015); *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 763 (Fed. Cir. 2016).

11. This Court also has personal jurisdiction over Teva by virtue of, *inter alia*, the fact that it has availed itself of the rights and benefits of Delaware law, that it has engaged in systematic, continuous, constant and pervasive contacts with the State, and that by filing an ANDA, Teva has made clear that it intends to use its distribution channels to market its proposed generic drug in Delaware.

12. This Court has personal jurisdiction over Teva because Teva has previously been sued in this district and has not challenged personal jurisdiction, and Teva has affirmatively availed itself of the jurisdiction of this Court by filing lawsuits in this district. *See, e.g.*, *Momenta Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA, Inc. et al.*, 1:17-cv-00109, D.I. 12 (D. Del. Mar. 9, 2017); *Sanofi-Aventis U.S. LLC et al. v. Teva Pharmaceuticals USA, Inc.*, No. 1:17-cv-00018, D.I. 16 (D. Del. Feb. 24, 2017); *GlaxoSmithKline LLC et al v. Teva Pharmaceuticals USA Inc.*, No. 1:14-cv-00878, D.I. 105 (D. Del. Feb. 9, 2016); *Teva Pharmaceuticals USA, Inc. et al. v. Doctor Reddys Laboratories, Ltd. et al.*, No. 1:16-cv-01267, D.I. 1 (D. Del. Dec. 19, 2016); *Teva Pharmaceuticals USA, Inc. et al. v. Mylan Pharmaceuticals Inc. et al.*, No. 1:17-cv-00249, D.I. 1 (D. Del. Jan. 17, 2017).

13. For at least the reasons stated above venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b)(1).

FACTUAL BACKGROUND

14. The ’444 patent, entitled “Actuation Indicator for a Dispensing Device,” issued on March 10, 2009 and names Stanley George Bonney, Peter John Brand, James William Godfrey, and Paul Kenneth Rand as inventors. A true and accurate copy of the ’444 patent is attached hereto as Exhibit A.

15. GSK, as assignee, owns the entire right, title and interest in the ’444 patent.

16. The ’351 patent, entitled “Actuation Indicator for a Dispensing Device,” issued on November 16, 2010 and names Stanley George Bonney, Peter John Brand, James William Godfrey, and Paul Kenneth Rand as inventors. A true and accurate copy of the ’351 patent is attached hereto as Exhibit B.

17. GSK, as assignee, owns the entire right, title, and interest in the ’351 patent.

18. GSK is the holder of an approved New Drug Application ("NDA") No. 21433 for Fluticasone Propionate Aerosol, Metered 0.11 mg/inh, sold under the Flovent® HFA registered trademark.

19. In conjunction with that NDA, GSK has listed with the FDA the ’444 patent and the ’351 patent (collectively, “the asserted patents”). The FDA has published the asserted patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.”

20. Flovent® HFA is covered by at least one claim of each of the asserted patents.

21. On or about February 16, 2017, Plaintiff received a letter, dated February 15, 2017, signed on behalf of Teva Pharmaceuticals USA Inc. by Lauren Rabinovic, (“Teva’s Paragraph IV Letter”).

22. Teva’s Paragraph IV Letter stated that Teva had submitted, and the FDA had received, an Abbreviated New Drug Application (“ANDA”) under section 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of a metered dose inhaler device configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh, a generic version of Plaintiff’s Flovent® HFA product, prior to expiration of the asserted patents. The ANDA Number for Teva’s application is 209917.

23. Teva's Paragraph IV Letter stated that the asserted patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic product.

24. In filing its ANDA No. 209917, Teva has requested the FDA's approval to market a generic version of Plaintiff's Flovent® HFA product throughout the United States, including in this judicial district.

25. On information and belief, following FDA approval of ANDA No. 209917, Teva will manufacture, sell, offer to sell, and/or import the approved generic version of Plaintiff's Flovent® HFA product—a metered dose inhaler device configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh—throughout the United States, including in this judicial district.

26. Since receiving Teva's Paragraph IV Letter, Plaintiff procured a copy of ANDA No. 209917 from Teva pursuant to Teva's Offer of Confidential Access. Plaintiff's counsel reviewed the limited technical information in Teva's Paragraph IV letter and Teva's ANDA. The technical information however was insufficient to conclusively determine whether Teva infringes. Moreover, Plaintiff's pre-suit analysis was further hindered by the provisions in Teva's offer of confidential access that prevented Plaintiff from disclosing Teva's ANDA to an expert.[1]

27. In the absence of an expert's analysis and opinion, Plaintiff resorts to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present the Court evidence that Teva's proposed generic product falls within the scope of one or more claims of

[1] During the negotiations on Teva's Offer of Confidential Access, Plaintiff's counsel specifically asked Teva to allow Plaintiff to disclose the ANDA to an expert, but Teva refused.

the asserted patents. Plaintiff alleges the causes herein to the best of Plaintiff's knowledge, information, and belief, formed after a reasonable inquiry reasonable under the circumstances based primarily on the representations contained in Teva's Paragraph IV Letter and ANDA and the other facts alleged herein.

COUNT I

(Infringement of the '444 Patent Under 35 U.S.C. § 271(e)(2) by Tevas's Proposed Generic Metered Dose Inhaler Configured to Deliver Fluticasone Propionate at a Strength of 0.11mg/inh)

28. Paragraphs 1-27 are incorporated herein as set forth above.

29. Teva submitted ANDA No. 209917 to the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh throughout the United States. By submitting this application, Teva has committed an act of infringement of the '444 patent under 35 U.S.C. § 271(e)(2)(A).

30. The commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will constitute an act of direct infringement of the '444 patent.

31. The commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will cause harm to Plaintiff for which damages are inadequate.

32. Unless and until Teva is enjoined from infringing the '444 patent Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT II

(Declaratory Judgment of Infringement of the '444 Patent Under 35 U.S.C. § 271(a) by Tevas's Proposed Generic Metered Dose Inhaler Configured to Deliver Fluticasone Propionate at a Strength of 0.11mg/inh)

33. Paragraphs 1-32 are incorporated herein as set forth above.

34. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

35. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

36. On information and belief, Teva will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh immediately and imminently upon approval of ANDA No. 209917.

37. Teva's actions, including but not limited to, the development of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh, the filing of an ANDA with a Paragraph IV certification, and, on information and belief, the manufacture of exhibit batches of its proposed generic product, indicate a refusal to change the course of its actions in the face of acts by Plaintiff.

38. On information and belief, Teva has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh.

39. The commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will constitute an act of direct infringement of the '444 patent.

40. The commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

41. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh by Teva will constitute direct infringement of the '444 patent.

42. Unless and until Teva is enjoined from infringing the '444 patent Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT III

(Declaratory Judgment of Infringement of the '444 Patent Under 35 U.S.C. § 271(b) and (c) by Tevas's Proposed Generic Metered Dose Inhaler Configured to Deliver Fluticasone Propionate at a Strength of 0.11mg/inh)

43. Paragraphs 1-42 are incorporated herein as set forth above.

44. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

45. There is an actual case or controversy such that the Court may entertain

46. GSK's request for declaratory relief is consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

47. Teva has actual knowledge of the '444 patent.

48. On information and belief, Teva became aware of the ’444 patent no later than the date on which that patent was listed in the Orange Book.

49. On information and belief, Teva has acted with full knowledge of the ’444 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the ’444 patent.

50. On information and belief, Teva will encourage another’s infringement of the ’144 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh. Specifically, on information and belief, Teva will include patient instructions for using Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh.

51. Teva’s acts of infringement will be done with knowledge of the ’444 patent and with the intent to encourage infringement.

52. The foregoing actions by Teva will constitute active inducement of infringement of the ’444 patent.

53. On information and belief, Teva knows or should know that its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh be especially made or especially adapted for use in an infringement of the ’444 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

54. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will contribute to the actual infringement of the ’444 patent.

55. On information and belief, Teva knows or should know that its offer for sale, sale and/or importation of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will contribute to the actual infringement of the ’444 patent.

56. The foregoing actions by Teva will constitute contributory infringement of the ’444 patent.

57. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the ’444 patent when ANDA No. 209917 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

58. GSK is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh by Teva will induce and/or contribute to infringement of the ’444 patent.

59. The commercial manufacture, use, offer for sale, sale and/or importation of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh, which will actively induce and/or contribute to infringement of the ’444 patent, in violation of GSK’s patent rights, will cause harm to GSK for which damages are inadequate.

60. Unless Teva is enjoined from actively inducing and contributing to the infringement the ’444 patent, GSK will suffer irreparable injury for which damages are an inadequate remedy.

61. On information and belief, despite having actual notice of the ’444 patent, Teva. continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to

infringement of the ’444 patent in disregard of GSK’s rights, making this case exceptional and entitling GSK to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

COUNT IV

(Infringement of the ’351 Patent Under 35 U.S.C. § 271(e)(2) by Tevas’s Proposed Generic Metered Dose Inhaler Configured to Deliver Fluticasone Propionate at a Strength of 0.11mg/inh)

62. Paragraphs 1-61 are incorporated herein as set forth above.

63. Teva submitted ANDA No. 209917 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh throughout the United States. By submitting this application, Teva has committed an act of infringement of the ’351 patent under 35 U.S.C. § 271(e)(2)(A).

64. The commercial manufacture, importation, use, sale, or offer for sale of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will constitute an act of direct infringement of the ’351 patent.

65. The commercial manufacture, importation, use, sale, or offer for sale of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will cause harm to Plaintiff for which damages are inadequate.

66. Unless and until Teva is enjoined from infringing the ’351 patent Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT V

(Declaratory Judgment of Infringement of the ’351 Patent Under 35 U.S.C. § 271(a) by Tevas’s Proposed Generic Metered Dose Inhaler Configured to Deliver Fluticasone Propionate at a Strength of 0.11mg/inh)

67. Paragraphs 1-66 are incorporated herein as set forth above.

68. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

69. There is an actual case or controversy such that the Court may entertain Plaintiff's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

70. On information and belief, Teva will engage in the commercial manufacture, use, offer for sale, sale and/or importation of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh immediately and imminently upon approval of ANDA No. 209917.

71. Teva's actions, including but not limited to, the development of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh, the filing of an ANDA with a Paragraph IV certification, and, on information and belief, the manufacture of exhibit batches of its proposed generic product, indicate a refusal to change the course of its actions in the face of acts by Plaintiff.

72. On information and belief, Teva has made and will continue to make, substantial preparation in the United States, including the District of Delaware, to manufacture, sell, offer to sell, and/or import Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh.

73. The commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will constitute an act of direct infringement of the '351 patent.

74. The commercial manufacture, importation, use, sale, or offer for sale of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength

of 0.11mg/inh in violation of Plaintiff's patent rights will cause harm to Plaintiff for which damages are inadequate.

75. Plaintiff is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale and/or importation of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh by Teva will constitute direct infringement of the '351 patent.

76. Unless and until Teva is enjoined from infringing the '351 patent Plaintiff will suffer irreparable injury for which damages are an inadequate remedy.

COUNT VI

(Declaratory Judgment of Infringement of the '351 Patent Under 35 U.S.C. § 271(b) and (c) by Tevas's Proposed Generic Metered Dose Inhaler Configured to Deliver Fluticasone Propionate at a Strength of 0.11mg/inh)

77. Paragraphs 1-76 are incorporated herein as set forth above.

78. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

79. There is an actual case or controversy such that the Court may entertain GSK's request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

80. Teva has actual knowledge of the '351 patent.

81. On information and belief, Teva became aware of the '351 patent no later than the date on which that patent was listed in the Orange Book.

82. On information and belief, Teva has acted with full knowledge of the '351 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '351 patent.

83. On information and belief, Teva will encourage another's infringement of the '351 patent by and through the commercial manufacture, use, sale, offer for sale, and/or

importation of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh. Specifically, on information and belief, Teva will include patient instructions for using Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh in an infringing manner.

84. Teva's acts of infringement will be done with knowledge of the '351 patent and with the intent to encourage infringement.

85. The foregoing actions by Teva will constitute active inducement of infringement of the '351 patent.

86. On information and belief, Teva knows or should know that its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh be especially made or especially adapted for use in an infringement of the '351 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

87. The commercial manufacture, use, sale, offer for sale, and/or importation of Teva's proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will contribute to the actual infringement of the '351 patent.

88. On information and belief, Teva knows or should know that its offer for sale, sale and/or importation of its proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh will contribute to the actual infringement of the '351 patent.

89. The foregoing actions by Teva will constitute contributory infringement of the '351 patent.

90. On information and belief, Teva intends to, and will, actively induce and contribute to the infringement of the ’351 patent when ANDA No. 209917 is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

91. GSK is entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh by Teva will induce and/or contribute to infringement of the ’351 patent.

92. The commercial manufacture, use, offer for sale, sale and/or importation of Teva’s proposed generic metered dose inhaler configured to deliver Fluticasone Propionate at a strength of 0.11mg/inh, which will actively induce and/or contribute to infringement of the ’351 patent, in violation of GSK’s patent rights, will cause harm to GSK for which damages are inadequate.

93. Unless Teva is enjoined from actively inducing and contributing to the infringement of the ’351 patent, GSK will suffer irreparable injury for which damages are an inadequate remedy.

94. On information and belief, despite having actual notice of the ’351 patent, Teva continues to willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the ’351 patent in disregard of GSK’s rights, making this case exceptional and entitling GSK to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff hereby requests a trial by jury of all issues so triable.

PRAYER FOR RELIEF

Plaintiff respectfully prays for the following relief:

a. That judgment be entered that Teva has infringed the ’444 patent and the ’351 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 209917 under section 505(j) of the FDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Teva’s proposed generic product will constitute an act of infringement of the ’444 patent and the ’351 patent.

b. That an Order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Teva’s ANDA No. 209917 shall be a date which is not earlier than the expiration date of the later of the asserted patents, as extended by any applicable period of exclusivity;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) permanently enjoining Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the asserted patents;

d. If Teva engages in the commercial manufacture, use, offer to sell, sale, or importation of Teva’s generic product disclosed in its ANDA No. 209917 prior to the later of the expiration dates of the asserted patents, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

e. If Teva engages in the commercial manufacture, use, offer to sell, sale, or importation of Teva's generic product disclosed in its ANDA No. 209917 prior to the later of the expiration dates of the asserted patents, as extended by any applicable period of exclusivity, judgment awarding Plaintiff damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C);

f. That a declaration be issued under 28 U.S.C. § 2201 that if Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic product prior to the later of the expiration dates of the asserted patents, it will constitute an act of infringement;

g. That this is an exceptional case under 35 U.S.C. § 285, and that Plaintiff be awarded reasonable attorneys' fees and costs;

h. An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

i. That this Court award such other and further relief as It may deem just and proper.

Dated: March 31, 2017

FISH & RICHARDSON P.C.

By: */s/ Martina Tyreus Hufnal*

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