

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION



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ELI LILLY AND COMPANY,
ELI LILLY EXPORT S.A. AND
ACRUX DDS PTY LTD.,

Plaintiffs,

v.

TWi PHARMACEUTICALS, INC. AND TWi
PHARMACEUTICALS USA, INC.,

Defendants.

C.A. No. 1:17-cv-491

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Eli Lilly and Company (“Lilly”), Eli Lilly Export S.A., and Acrux DDS Pty Ltd. (“Acrux”) file this Complaint for patent infringement against TWi Pharmaceuticals, Inc. (“TWi Inc.”) and TWi Pharmaceuticals USA, Inc. (“TWi USA”) (collectively, “Defendants”) under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Axiron[®].

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. Eli Lilly Export S.A. is a Swiss corporation that has its corporate office at 16 Chemin des Coquelicots, The Air Centre, 1214 Vernier/Geneva, Switzerland. Eli Lilly Export S.A. is a wholly owned subsidiary of Lilly.

3. Acrux is an Australian corporation that has its corporate offices and principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux is

engaged in the development and commercialization of pharmaceutical products for sale throughout the world.

4. TWi USA is a Delaware corporation with a principal place of business at 115 West Century Road, Suite 180, Paramus, N.J. 07652. On information and belief, TWi USA is an indirect, wholly-owned subsidiary of TWi Inc.

5. On information and belief, TWi USA is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States.

6. TWi Inc. is a Taiwan corporation with its principal place of business at 4F, No. 41, Lane 221, Kang Chien Rd., Nei Hu Dis., Taipei 114, Taiwan.

7. On information and belief, TWi Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States in concert with its subsidiary TWi USA.

8. On information and belief, the acts of TWi Inc. complained of herein were done with the cooperation, participation, and assistance of TWi USA.

NATURE OF THE ACTION

9. This is an action for infringement of U.S. Patent Nos. 8,435,944 (“the ’944 patent”), 8,993,520 (“the ’520 patent”), 9,180,194 (“the ’194 patent”), 8,419,307 (“the ’307 patent”), 8,177,449 (“the ’449 patent”), 8,807,861 (“the ’861 patent”), and 9,289,586 (“the ’586 patent”). This action relates to Abbreviated New Drug Application (“ANDA”) No. 209836 (“TWi Inc.’s ANDA”) submitted in the name of TWi Inc. to the U.S. Food and Drug Administration (“FDA”) for approval to market a generic version of Lilly’s Axiron[®] (testosterone) product, which constitutes an act of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

SUBJECT MATTER JURISDICTION AND VENUE

10. 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.

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

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

PERSONAL JURISDICTION

13. On information and belief, this Court has personal jurisdiction over Defendants because they regularly and continuously transact business within the State of Indiana. On information and belief, Defendants develop, manufacture, market, and sell pharmaceutical products throughout the United States, including the State of Indiana. On information and belief, Defendants maintain a broad distributorship network within Indiana. On information and belief, Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of conducting business within the State of Indiana.

14. Defendants' website states that "TWi Pharmaceuticals USA Inc. is a wholly-owned subsidiary of TWi Pharmaceuticals Inc., a Taiwan-based specialty pharmaceutical company focusing on the development and commercialization of 'High Barrier Generics' drugs" and that "[t]he TWi USA team is responsible for strategic decision making, business development and portfolio selection and oversight of all Sales and Marketing and Trade Relations activities in the United States." http://twipharma.com/usa/aboutUs_introduction.aspx.

15. Defendants' website further states that "Below are companies that TWi has identified as authorized distributors in the United States." http://twipharma.com/usa/forCustomers_authorizedDistributors.aspx. The list includes several entities, such as Wal-Mart and CVS/Caremark, that sell pharmaceuticals in the State of Indiana.

16. On information and belief, directors of TWi USA are employees of TWi Inc.

17. On information and belief, TWi USA, either directly or through distributors, currently sells significant quantities of generic drug products in the State of Indiana. Those products include, for example, generic versions of Aricept[®], Megace[®], and Procardia[®]. A list of generic products sold by TWi USA in the United States can be found at http://twipharma.com/usa/product_approvedProducts.aspx.

18. TWi USA, through its website, solicits customers and potential customers from across the U.S., including in the Southern District of Indiana, who can search and access prescribing information for Defendant's full product line and learn how to return TWi USA's products.

19. TWi Inc. and TWi USA, either directly or through distributors, sell products to national and regional retail drug, supermarket, and mass merchandise chains in Indiana, and TWi Inc. and TWi USA derive substantial revenue from these sales.

20. TWi Inc. and TWi USA develop and manufacture pharmaceutical products for the United States market, including the State of Indiana.

21. On information and belief, TWi USA participated in the preparation and submission of ANDA No. 209836 and will benefit directly and indirectly from the approval of ANDA No. 209836.

22. This Court has personal jurisdiction over Defendants by virtue of their course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Indiana. Defendants "ha[ve] taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, the Southern District of Indiana and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir.

2016). Defendants’ “ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs.” *Id.* at 760. On information and belief, Defendants “intend[] to direct sales of [their] drugs into [Indiana], among other places, once it has the requested FDA approval to market them.” *Id.* at 758. On information and belief, TWi USA will engage in marketing of its proposed ANDA product in Indiana upon approval of its ANDA.

23. TWi Inc.’s ANDA filing, including its Paragraph IV certifications regarding the ’944, ’520, ’194, ’307, ’861, and ’586 patents, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities by Defendants in this District. “[T]he minimum-contacts standard is satisfied by the particular actions [Defendants] ha[ve] already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in” this District. *Id.* at 760. Exercising personal jurisdiction over Defendants in this District would not be unreasonable given their contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

24. Alternatively, assuming that the above facts do not establish personal jurisdiction over TWi Inc., this Court may exercise jurisdiction over TWi Inc. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs’ claims arise under federal law; (b) TWi Inc. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) TWi Inc. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products.

FACTUAL BACKGROUND

A. Axiron[®]

25. Lilly is the holder of approved New Drug Application (“NDA”) No. 022504 for the manufacture and sale of testosterone metered transdermal solution, 30mg/1.5mL used to treat males for conditions associated with a deficiency or absence of endogenous testosterone. Lilly markets and sells testosterone metered transdermal solution, 30mg/1.5mL under the trade name Axiron[®]. Axiron[®] was approved by the FDA on November 23, 2010.

B. The '944 Patent

26. United States Patent No. 8,435,944 (“the '944 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on May 7, 2013. The '944 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male comprising applying a transdermal drug delivery composition that contains testosterone. The '944 patent is listed in the Orange Book in connection with Axiron[®]. A true and correct copy of the '944 patent is attached as Exhibit A. Since its date of issue, Acrux has been, and continues to be, the owner of the '944 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron[®] under the '944 patent. Eli Lilly Export S.A. has licensed its rights in the '944 patent to Lilly.

C. The '520 Patent

27. United States Patent No. 8,993,520 (“the '520 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the PTO on March 31, 2015. The '520 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male subject comprising applying a transdermal drug delivery composition. The '520 patent is listed in the Orange Book in connection with Axiron[®]. A true and correct copy of the '520 patent is attached as Exhibit B. Since its date of issue, Acrux has been, and continues to be,

the owner of the '520 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron[®] under the '520 patent. Eli Lilly Export S.A. has licensed its rights in the '520 patent to Lilly.

D. The '194 Patent

28. United States Patent No. 9,180,194 (“the '194 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the PTO on November 10, 2015. The '194 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male subject comprising applying a transdermal drug delivery composition. The '194 patent is listed in the Orange Book in connection with Axiron[®]. A true and correct copy of the '194 patent is attached as Exhibit C. Since its date of issue, Acrux has been, and continues to be, the owner of the '194 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron[®] under the '194 patent. Eli Lilly Export S.A. has licensed its rights in the '194 patent to Lilly.

E. The '307 Patent

29. United States Patent No. 8,419,307 (“the '307 patent”), titled “Spreading Implement,” was duly and legally issued by the Patent and Trademark Office (“PTO”) on April 16, 2013. The '307 patent claims, *inter alia*, methods of increasing the testosterone blood level of a person in need thereof comprising applying a liquid pharmaceutical composition that contains testosterone. The '307 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) in connection with Axiron[®]. A true and correct copy of the '307 patent is attached as Exhibit D. Since its date of issue, Acrux has been, and continues to be, the owner of the '307 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron[®] under the '307 patent. Eli Lilly Export S.A. has licensed its rights in the '307 patent to Lilly.

F. The '449 Patent

30. United States Patent No. 8,177,449 (“the ’449 patent”), titled “Spreading Implement,” was duly and legally issued by the PTO on May 15, 2012. The ’449 patent claims, *inter alia*, a method of transdermal administration of a physiologically active agent. A true and correct copy of the ’449 patent is attached as Exhibit E. Since its date of issue, Acrux has been, and continues to be, the owner of the ’449 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron[®] under the ’449 patent. Eli Lilly Export S.A. has licensed its rights in the ’449 patent to Lilly.

G. The '861 Patent

31. United States Patent No. 8,807,861 (“the ’861 patent”), titled “Spreading Implement,” was duly and legally issued by the PTO on August 19, 2014. The ’861 patent claims, *inter alia*, methods of transdermal administration of a physiologically active agent. The ’861 patent is listed in the Orange Book in connection with Axiron[®]. A true and correct copy of the ’861 patent is attached as Exhibit F. Since its date of issue, Acrux has been, and continues to be, the owner of the ’861 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron[®] under the ’861 patent. Eli Lilly Export S.A. has licensed its rights in the ’861 patent to Lilly.

H. The '586 Patent

32. United States Patent No. 9,289,586 (“the ’586 patent”), titled “Spreading Implement,” was duly and legally issued by the PTO on March 22, 2016. The ’586 patent claims, *inter alia*, methods of transdermal administration of a physiologically active agent. The ’586 patent is listed in the Orange Book in connection with Axiron[®]. A true and correct copy of the ’586 patent is attached as Exhibit G. Since its date of issue, Acrux has been, and continues to be, the owner of the ’586 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all

uses of Axiron[®] under the '586 patent. Eli Lilly Export S.A. has licensed its rights in the '586 patent to Lilly.

I. Infringement by TWi Inc. and TWi USA

33. TWi Inc. and/or TWi USA filed or caused to be filed with the FDA ANDA No. 209836 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of a transdermal “Testosterone Topical Solution, 30 mg/1.5mL Actuation” (“TWi’s Generic Product”) in the United States before the expiration of the '944, '520, '194, '307, '861, and '586 patents.

34. Defendants’ ANDA No. 209836 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certifications”), alleging that the claims of the '944, '520, '194, '307, '861, and '586 patents are invalid, unenforceable, and/or would not be infringed by TWi’s Generic Product.

35. TWi Inc. and/or TWi USA sent or caused to be sent to Plaintiffs a letter dated January 5, 2017 (“Notice Letter”), received by Lilly January 6, 2017, notifying Plaintiffs that TWi Inc.’s ANDA No. 209836 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of TWi’s Generic Product before the expiration of the '944, '520, '194, '307, '861, and '586 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). TWi Inc.’s Notice Letter states that: “FDA has received an Abbreviated New Drug Application (‘ANDA’) from TWi for Testosterone Topical Solution, 30 mg/1.5 mL Actuation. TWi’s ANDA contains the required bioavailability and/or bioequivalence data and/or bioequivalence waiver. The ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (j)(2)(A) and contains, or has been amended to contain, paragraph IV certification(s) to obtain approval to engage in the commercial manufacture, use, sale or importation of Testosterone Topical Solution, 30 mg/1.5 mL Actuation, before the expiration of the Listed Patents [i.e., the ‘307,

'944, '878, '861, '520, '194, and '586 patents'] which are listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with NDA No. 022504.”

36. TWi Inc.'s Notice Letter also state: “TWi alleges, and has certified to FDA, that in TWi's opinion and to the best of its knowledge, the Listed Patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale or importation of the drug product described in TWi's ANDA. Therefore, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6), TWi's detailed statement of the legal and factual basis for the paragraph IV certification(s) set forth in TWi's ANDA is attached hereto and is made part hereof.”

37. The submission of ANDA No. 209836 to the FDA constitutes infringement by Defendants of the '944 patent, the '520 patent, the '194 patent, the '307 patent, the '449 patent, the '861 patent, and the '586 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of TWi's Generic Product would infringe the '944 patent, the '520 patent, the '194 patent, the '307 patent, the '449 patent, the '861 patent, and the '586 patent under 35 U.S.C. § 271(a), (b), and/or (c).

38. Defendants know and intend that physicians will prescribe and patients will take TWi's Generic Product for which approval is sought in ANDA No. 209836 and therefore, will infringe at least one claim of the patents-in-suit.

39. Defendants had knowledge of the patents-in-suit and by their promotional activities and proposed Twi Generic Product, knew or should know that they will aid and abet another's direct infringement of at least one of the claims of the patents-in-suit either literally or under the doctrine of equivalents.

40. Defendants plan to make, use, sell, offer to sell and/or import their Generic Product for uses that will infringe the patents-in-suit. TWi's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

41. Plaintiffs commenced this action within 45 days of receiving TWi Inc.'s January 5, 2017, Notice Letter.

COUNT I FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,435,944)

42. Plaintiffs incorporate by reference and reallege Paragraphs 1-41 above as though fully restated herein.

43. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendants.

44. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

45. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '944 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,435,944)

46. Plaintiffs incorporate by reference and reallege Paragraphs 1-45 above as though fully restated herein.

47. Defendants have knowledge of the '944 patent.

48. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that their acts are encouraging infringement.

COUNT III FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,435,944)

49. Plaintiffs incorporate by reference and reallege Paragraphs 1-48 above as though fully restated herein.

50. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

51. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '944 patent.

52. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT IV FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,993,520)

53. Plaintiffs incorporate by reference and reallege Paragraphs 1-52 above as though fully restated herein.

54. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Defendants.

55. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '520 patent under 35 U.S.C. § 271.

56. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '520 patent. Plaintiffs do not have an adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,993,520)

57. Plaintiffs incorporate by reference and reallege Paragraphs 1-56 above as though fully restated herein.

58. Defendants have knowledge of the '520 patent.

59. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that their acts are encouraging infringement.

COUNT VI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,993,520)

60. Plaintiffs incorporate by reference and reallege Paragraphs 1-59 above as though fully restated herein.

61. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

62. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '520 patent.

63. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT VII FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 9,180,194)

64. Plaintiffs incorporate by reference and reallege Paragraphs 1-63 above as though fully restated herein.

65. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '194 patent was an act of infringement of the '194 patent by Defendants.

66. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '194 patent under 35 U.S.C. § 271.

67. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '194 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 9,180,194)

68. Plaintiffs incorporate by reference and reallege Paragraphs 1-67 above as though fully restated herein.

69. Defendants have knowledge of the '194 patent.

70. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '194 patent by others, with knowledge that their acts are encouraging infringement.

COUNT IX FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 9,180,194)

71. Plaintiffs incorporate by reference and reallege Paragraphs 1-70 above as though fully restated herein.

72. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

73. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '194 patent.

74. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT X FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,419,307)

75. Plaintiffs incorporate by reference and reallege Paragraphs 1-74 above as though fully restated herein.

76. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendants.

77. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '307 patent under 35 U.S.C. § 271.

78. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '307 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XI FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,419,307)

79. Plaintiffs incorporate by reference and reallege Paragraphs 1-78 above as though fully restated herein.

80. Defendants have knowledge of the '307 patent.

81. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XII FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,419,307)

82. Plaintiffs incorporate by reference and reallege Paragraphs 1-81 above as though fully restated herein.

83. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

84. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '307 patent.

85. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT XIII FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,177,449)

86. Plaintiffs incorporate by reference and reallege Paragraphs 1-85 above as though fully restated herein.

87. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '449 patent was an act of infringement of the '449 patent by Defendants.

88. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '449 patent under 35 U.S.C. § 271.

89. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '449 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XIV FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,177,449)

90. Plaintiffs incorporate by reference and reallege Paragraphs 1-89 above as though fully restated herein.

91. Defendants have knowledge of the '449 patent.

92. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '449 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XV FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,177,449)

93. Plaintiffs incorporate by reference and reallege Paragraphs 1-92 above as though fully restated herein.

94. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

95. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '449 patent.

96. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT XVI FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,807,861)

97. Plaintiffs incorporate by reference and reallege Paragraphs 1-96 above as though fully restated herein.

98. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '861 patent was an act of infringement of the '861 patent by Defendants.

99. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '861 patent under 35 U.S.C. § 271.

100. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '861 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XVII FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,807,861)

101. Plaintiffs incorporate by reference and reallege Paragraphs 1-100 above as though fully restated herein.

102. Defendants have knowledge of the '861 patent.

103. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '861 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XVIII FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,807,861)

104. Plaintiffs incorporate by reference and reallege Paragraphs 1-103 above as though fully restated herein.

105. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

106. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '861 patent.

107. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT XIX FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 9,289,586)

108. Plaintiffs incorporate by reference and reallege Paragraphs 1-107 above as though fully restated herein.

109. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 209836 to the FDA seeking approval of TWi's Generic Product before expiration of the '586 patent was an act of infringement of the '586 patent by Defendants.

110. If ANDA No. 209836 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of TWi's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '586 patent under 35 U.S.C. § 271.

111. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '586 patent. Plaintiffs do not have an adequate remedy at law.

COUNT XX FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 9,289,586)

112. Plaintiffs incorporate by reference and reallege Paragraphs 1-111 above as though fully restated herein.

113. Defendants have knowledge of the '586 patent.

114. Upon FDA approval of ANDA No. 209836, Defendants will intentionally encourage acts of direct infringement of the '586 patent by others, with knowledge that their acts are encouraging infringement.

COUNT XXI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 9,289,586)

115. Plaintiffs incorporate by reference and reallege Paragraphs 1-114 above as though fully restated herein.

116. If ANDA No. 209836 is approved, Defendants intend to and will offer to sell, sell, or import into the United States TWi's Generic Product.

117. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '586 patent.

118. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

COUNT XXII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,435,944)

119. Plaintiffs incorporate by reference and reallege Paragraphs 1-118 above as though fully restated herein.

120. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

121. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

122. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '944 patent.

123. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

124. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

125. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

126. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '944 patent.

127. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

128. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '944 patent.

129. If Defendants' infringement of the '944 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XXIII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,993,520)

130. Plaintiffs incorporate by reference and reallege Paragraphs 1-129 above as though fully restated herein.

131. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

132. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

133. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '520 patent.

134. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

135. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '520 patent under 35 U.S.C. § 271(a), (b), and/or (c).

136. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '520 patent.

137. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '520 patent.

138. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

139. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '520 patent.

140. If Defendants' infringement of the '520 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XXIV FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 9,180,194)

141. Plaintiffs incorporate by reference and reallege Paragraphs 1-140 above as though fully restated herein.

142. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

143. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

144. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '194 patent.

145. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

146. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '194 patent under 35 U.S.C. § 271(a), (b), and/or (c).

147. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '194 patent.

148. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '194 patent.

149. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

150. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '194 patent.

151. If Defendants' infringement of the '194 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XXV FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,419,307)

152. Plaintiffs incorporate by reference and reallege Paragraphs 1-151 above as though fully restated herein.

153. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

154. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

155. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '307 patent.

156. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

157. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '307 patent under 35 U.S.C. § 271(a), (b), and/or (c).

158. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '307 patent.

159. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '307 patent.

160. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

161. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '307 patent.

162. If Defendants' infringement of the '307 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XXVI FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,177,449)

163. Plaintiffs incorporate by reference and reallege Paragraphs 1-162 above as though fully restated herein.

164. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

165. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

166. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '449 patent.

167. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

168. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '449 patent under 35 U.S.C. § 271(a), (b), and/or (c).

169. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '449 patent.

170. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '449 patent.

171. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

172. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '449 patent.

173. If Defendants' infringement of the '449 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XXVII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,807,861)

174. Plaintiffs incorporate by reference and reallege Paragraphs 1-173 above as though fully restated herein.

175. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

176. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

177. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '861 patent.

178. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

179. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '861 patent under 35 U.S.C. § 271(a), (b), and/or (c).

180. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '861 patent.

181. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '861 patent.

182. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

183. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '861 patent.

184. If Defendants' infringement of the '861 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XXVIII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 9,289,586)

185. Plaintiffs incorporate by reference and reallege Paragraphs 1-184 above as though fully restated herein.

186. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

187. Defendants submitted ANDA No. 209836, seeking authorization to commercially manufacture, use, offer for sale, and sell TWi's Generic Product in the United States. TWi's Generic Product has no substantial non-infringing uses.

188. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import TWi's Generic Product prior to expiration of the '586 patent.

189. Defendants intend to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of TWi's Generic Product upon receipt of final FDA approval of ANDA No. 209836, unless enjoined by the Court.

190. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of TWi's Generic Product would infringe one or more claims of the '586 patent under 35 U.S.C. § 271(a), (b), and/or (c).

191. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of TWi's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '586 patent.

192. On information and belief, Defendants have had and continue to have knowledge that TWi's Generic Product is especially adapted for a use that infringes the '586 patent.

193. On information and belief, Defendants have had and continue to have knowledge that there is no substantial non-infringing use for TWi's Generic Product.

194. There is a justiciable case or controversy between Plaintiffs and Defendants regarding whether Defendants' commercial manufacture, use, sale, offer for sale, or importation into the United States of TWi's Generic Product according to ANDA No. 209836 would infringe one or more claims of the '586 patent.

195. If Defendants' infringement of the '586 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court enter judgment in their favor as follows:

a) United States Patent Nos. 8,435,944, 8,993,520, 9,180,194, 8,419,307, 8,177,449, 8,807,861, and 9,289,586 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 8,435,944, 8,993,520, 9,180,194, 8,419,307, 8,177,449, 8,807,861, and 9,289,586 by submitting ANDA No. 209836 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States TWi's Generic Product prior to expiration of said patents;

c) Defendants' threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of TWi's Generic Product prior to the expiration of United States Patent Nos. 8,435,944, 8,993,520, 9,180,194, 8,419,307, 8,177,449, 8,807,861, and 9,289,586 would constitute infringement of said patents;

d) The effective date of any FDA approval of TWi's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944, 8,993,520, 9,180,194, 8,419,307, 8,177,449, 8,807,861, and 9,289,586 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 TWi's Generic Product within the United States, or importing TWi's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944, 8,993,520, 9,180,194, 8,419,307, 8,177,449, 8,807,861, and 9,289,586 in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

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

g) Plaintiffs are entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

h) Plaintiffs are entitled to any further and additional relief that this Court deems just and proper.

Respectfully submitted,

Dated: February 15, 2017

By: /s/ Anne N. DePrez

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