IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
MARSHALL DIVISION

ENDO PHARMACEUTICALS INC. and STRAKAN INTERNATIONAL S.á r.l., Plaintiffs, v. WATSON PHARMACEUTICALS, INC., WATSON LABORATORIES, INC., WATSON PHARMA, INC., and ACTAVIS, INC. Defendants.	Civil Action No: 2:13-cv-192 **Jury Trial Demanded**

ENDO'S AND STRAKAN'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Endo Pharmaceuticals Inc. ("Endo") and Strakan International S.á r.l. ("Strakan") (collectively, "Plaintiffs"), by and through their attorneys, for their complaint against Defendants Watson Laboratories, Inc., Watson Pharmaceuticals, Inc., Watson Pharma, Inc., and Actavis, Inc. (collectively, "Defendants"), hereby allege as follows:

THE NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 6,319,913 ("the '913 patent") and 6,579,865 ("the '865 patent"), arising under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq*. and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq*.

THE PARTIES

2. Endo is a Delaware corporation, having its principal place of business at 1400 Atwater Drive, Malvern, Pennsylvania 19355. Endo is a specialty pharmaceutical company engaged in the research, development, marketing, and sale of prescription pharmaceuticals.

Endo markets and distributes Fortesta®, an innovative testosterone-containing gel product for testosterone replacement therapy in males for conditions associated with a deficiency or absence of endogenous testosterone.

3. Strakan is a company organized under the Laws of Luxembourg having an office at 13-15, avenue de la Liberté, L-1931 Luxembourg, Luxembourg.

4. On information and belief, Watson Pharmaceuticals, Inc. ("Watson Pharmaceuticals") is a corporation organized and existing under the laws of the State of Nevada, having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

5. On information and belief, Watson Laboratories, Inc. ("Watson Laboratories") is a Nevada corporation having a principal place of business at 311 Bonnie Circle, Corona, California 92880.

6. On information and belief, Watson Laboratories is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers and directors.

7. On information and belief, Watson Pharma, Inc. ("Watson Pharma") is a Delaware corporation having a principal place of business at 360 Mount Kemble Avenue, Morristown, New Jersey 07962.

8. On information and belief, Watson Pharma is a wholly-owned subsidiary of Watson Pharmaceuticals, and the two share at least some common officers and directors.

9. On information and belief, Actavis, Inc. ("Actavis") is a Delaware corporation having a principal place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

10. On information and belief, Watson Pharmaceuticals acquired Actavis, and on or about January 24, 2013, Actavis became the new name for Watson Pharmaceuticals and its wholly-owned subsidiaries.

11. On information and belief, Watson Pharmaceuticals, Watson Laboratories, Watson Pharma, and Actavis are in the business of manufacturing, distributing and selling generic drugs throughout the United States, including in this judicial jurisdiction.

JURISDICTION AND VENUE

12. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

13. This Court has personal jurisdiction over Watson Pharmaceuticals, Watson Laboratories, Watson Pharma, and Actavis by virtue of their systematic and continuous contacts with this jurisdiction.

14. Specifically, this Court has personal jurisdiction over defendants Watson Pharmaceuticals, Watson Laboratories, Watson Pharma, and Actavis because they, either directly or through an agent, including each other, regularly do or solicit business in this jurisdiction, engage in other persistent courses of conduct in this jurisdiction, and/or derive substantial revenue from services or things used or consumed in this jurisdiction.

15. On information and belief, Watson Pharmaceuticals, Watson Laboratories, Watson Pharma, and Actavis are agents of each other and/or work in active concert with respect to the development, regulatory approval, marketing, sale and distribution of pharmaceutical products, including the generic testosterone gel product for topical use described in ANDA No. 20-4571 (defined below).

16. On information and belief, Watson Laboratories, Watson Pharma, and Actavis are licensed drug distributors in Texas. On information and belief, Watson Pharma sells over 380 products in Texas.

17. On information and belief, Defendants have entered into contracts with the Texas Department of State Health Service to sell prescription drugs in Texas.

18. On information and belief, drug products of Watson Laboratories, Watson Pharma, and Actavis are listed on the Texas prescription drug formulary.

19. On information and belief, Watson Pharma markets and sells generic drugs manufactured by Watson Laboratories throughout the United States, including this judicial district.

20. On information and belief, from 2008 to 2010, Watson Pharma sold over $2.5 billion of products in Texas, over $150 million of which were sold in this judicial district.

21. On information and belief, in 2011, Watson Pharma sold over $1 billion of products in Texas, over $60 million of which were sold in this judicial district.

22. On information and belief, Defendants' products appear on the Preferred Drug List for the Texas Medicaid program, and are available to the millions of Texans in this judicial district and throughout the State who participate in the Texas Medicaid program.

23. On information and belief, as a Medicaid participant, Defendants are required to sell products to Veterans Administration and Public Health Services facilities, of which there are over 200 in Texas. The Department of Veteran Affairs Formulary listed Watson products as being available to its participants.

24. On information and belief, Watson Laboratories previously admitted to this Court that it markets and sells products in Texas, including in this judicial district. *See Allergan, Inc. v. Watson Laboratories, Inc.*, Case No. 2:10-cv-00344, D.I.17 (E.D. Tex.).

25. On information and belief, Watson Laboratories has previously availed itself of this forum for purposes of litigating its patent disputes regarding its ANDA products. For example, Watson Laboratories has submitted to the jurisdiction of this Court and filed counterclaims in *Allergan, Inc. v. Watson Laboratories, Inc.,* Case No. 2:10-cv-00344 (E.D. Tex.) and *Allergan Inc. v. Watson Laboratories, Inc.,* Case No. 6:12-cv-00197 (E.D. Tex.).

26. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

BACKGROUND

27. The ’913 patent, entitled “Penetration Enhancing and Irritation Reducing Systems,” issued to Vivien H. W. Mak and Stephen Grayson on November 20, 2001. A copy of the ’913 patent is attached to this complaint as Exhibit A.

28. The ’865 patent, entitled “Penetration Enhancing and Irritation Reducing Systems,” issued to Vivien H. W. Mak and Stephen Grayson on June 17, 2003. A copy of the ’865 patent is attached to this complaint as Exhibit B.

29. By virtue of an assignment from the inventors Vivien H. W. Mak and Stephen Grayson, Cellegy Pharmaceuticals, Inc. (“Cellegy”) owned the entire right, title, and interest in the ’913 and ’865 patents. Cellegy assigned the entire right, title, and interest in the ’913 and ’865 patents to Strakan International Limited. Strakan International Limited changed its name to Strakan International S.á r.l. and recorded the name change with the United States Patent and Trademark Office (“USPTO”) on November 17, 2011.

30. Strakan has granted Endo an exclusive license to make, use, market, distribute, import, offer to sell, and sell testosterone gel products for topical use in the United States that are claimed in the '913 and '865 patents.

31. Endo is the holder of the approved New Drug Application ("NDA") No. 21-463 for testosterone-containing gel for topical use, which is marketed under the Fortesta® trademark.

32. In conjunction with the NDA, two patents ("the Listed Patents") are listed with the United States Food and Drug Administration ("FDA") that cover the approved formulation of Fortesta®. The Listed Patents are the '913 and '865 patents. The FDA has published the Listed Patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book."

33. Fortesta® is covered by at least one claim of each of the Listed Patents.

34. On January 17, 2013, Watson Laboratories sent a letter to Endo signed on behalf of Watson Laboratories by Janie Gwinn. Endo received the letter via certified mail on January 18, 2013. The letter stated that Watson Laboratories had filed Abbreviated New Drug Application ("ANDA") No. 20-4571 with the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to market a generic version of Endo's Fortesta® product before expiration of the Listed Patents.

35. The stated purpose of the January 17, 2013 letter was to notify Endo that ANDA No. 20-4571 contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '913 and '865 patents. The letter alleged that the claims of the Listed Patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' proposed generic testosterone gel product.

36. Attached to the January 17, 2013 letter was a "Detailed Statement" of the factual and legal basis for Defendants' opinion that the claims of the Listed Patents are invalid, unenforceable, and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' proposed generic testosterone gel product. The Detailed Statement alleged that certain claims of the Listed Patents were invalid, and therefore would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' proposed generic testosterone gel product, and that certain claims of the Listed Patents would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendants' proposed generic testosterone gel product.

37. Defendants had knowledge of the '913 and '865 patents at least since the date on which ANDA No. 20-4571 was filed with the FDA because Defendants' ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '913 and '865 patents.

38. In filing its ANDA, Defendants have requested the FDA's approval to market a generic version of Endo's Fortesta® product throughout the United States, including in Texas.

39. On information and belief, following FDA approval of its ANDA, Defendants will sell the approved generic version of Endo's Fortesta® product throughout the United States, including in Texas.

COUNT I
(Infringement of the '913 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Testosterone Gel Product)

40. Paragraphs 1 to 39 are incorporated herein as set forth above.

41. Defendants submitted ANDA No. 20-4571 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of their proposed testosterone gel product throughout the United States. By submitting ANDA No. 20-4571 to the FDA, Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

42. The commercial use of Defendants' proposed testosterone gel product will constitute an act of direct infringement of the '913 patent.

43. The commercial manufacture, offer for sale, sale and/or importation of Defendants' proposed testosterone gel product, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '913 patent by doctors and/or patients, including in this district.

44. Because Defendants' proposed testosterone gel product is especially made or adapted for use in the methods claimed in the '913 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of Defendants' proposed testosterone gel product will constitute an act of contributory infringement of the '913 patent.

45. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic testosterone gel product in violation of Endo's and Strakan's patent rights will cause harm to Endo and Strakan for which damages are inadequate.

COUNT II
(Declaratory Judgment of Infringement of the '913 Patent Under 35 U.S.C. § 271(b)-(c))

46. Paragraphs 1 to 45 are incorporated herein as set forth above.

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

48. There is an actual case or controversy such that the Court may entertain Endo's and Strakan'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.

49. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Defendants' proposed generic testosterone gel product.

50. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Endo and Strakan.

51. The commercial use of Defendants' proposed generic testosterone gel product will directly infringe the '913 patent.

52. The commercial offer for sale and sale of Defendants' proposed testosterone gel product, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '913 patent by doctors and/or patients, including in this district.

53. Defendants had knowledge of the '913 patent at least since the date on which ANDA No. 20-4571 was filed with the FDA because Defendants' ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '913 patent.

54. Because Defendants' proposed testosterone gel product is especially made or adapted for use in the methods claimed in the '913 patent, and has no substantially non-infringing use, the commercial manufacture, offer for sale, sale and/or importation of Defendants' proposed testosterone gel product will constitute an act of contributory infringement of the '913 patent.

55. Endo and Strakan are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic testosterone gel product by any or all of Defendants will infringe the '913 patent.

COUNT III
(Infringement of the '865 Patent Under 35 U.S.C. § 271(e)(2) by Watson's Proposed Generic Testosterone Gel Product)

56. Paragraphs 1 to 39 are incorporated herein as set forth above.

57. Defendants submitted ANDA No. 20-4571 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the commercial manufacture, use or sale of their proposed testosterone gel product throughout the United States. By submitting ANDA No. 20-4571 to the FDA, Defendants have committed an act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

58. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed testosterone gel product will constitute an act of direct infringement of the '865 patent.

59. The commercial manufacture, offer for sale, sale and/or importation of Defendants' proposed testosterone gel product, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '865 patent by doctors and/or patients, including in this district.

60. The commercial manufacture, use, offer for sale, sale and/or importation of Defendants' proposed generic testosterone gel product in violation of Endo's and Strakan's patent rights will cause harm to Endo and Strakan for which damages are inadequate.

COUNT IV
(Declaratory Judgment of Infringement of the '856 Patent Under 35 U.S.C. § 271(a)-(b))

61. Paragraphs 1 to 39 and 56 to 60 are incorporated herein as set forth above.

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

63. There is an actual case or controversy such that the Court may entertain Endo's and Strakan'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.

64. On information and belief, Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell, and/or import Defendants' proposed generic testosterone gel product.

65. Defendants' actions indicate a refusal to change the course of their actions in the face of acts by Endo and Strakan.

66. The commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic testosterone gel product will directly infringe the '865 patent.

67. Defendants had knowledge of the '865 patent at least since the date on which ANDA No. 20-4571 was filed with the FDA because Defendants' ANDA contained a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding the '865 patent.

68. The commercial use, manufacture, offer for sale, sale and/or importation of Defendants' proposed testosterone gel product, in conjunction with Defendants' labeling and instructions for the use thereof, will constitute an act of inducement of infringement of the '865 patent by doctors and/or patients, including in this district.

69. Endo and Strakan are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' proposed generic testosterone gel product by any or all of Defendants will infringe the '865 patent.

JURY TRIAL DEMAND

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed and that Defendants' making, using, selling, offering to sell, marketing, distributing, or importing the proposed generic testosterone gel product described in ANDA No. 20-4571 will constitute infringement, contributory infringement, and active inducement of infringement of the '913 patent.

B. A judgment that Defendants have infringed, and that Defendants' making, using, selling, offering to sell, marketing, distributing, or importing the proposed generic testosterone gel product described in ANDA No. 20-4571 will constitute infringement and active inducement of infringement of the '865 patent.

C. A declaration that Defendants' commercial manufacture, distribution, use, and sale of the proposed generic testosterone gel product would infringe the '913 patent;

D. A declaration that Defendants' commercial manufacture, distribution, use, and sale of the proposed generic testosterone gel product would infringe the '865 patent;

E. An order that Defendants are not entitled to obtain FDA approval of their ANDA No. 20-4571 before expiration of the '913 and '865 patents, including any extensions;

F. An injunction enjoining Defendants and Defendants' officers, agents, servants, employees, and those persons in active concert or participation with any of them from making, using, selling, offering to sell, marketing, distributing, or importing products made under the ANDA No. 20-4571 before expiration of the '913 and '865 patents, including any extensions;

G. If Defendants attempt to engage in the commercial manufacture, use, offer for sale, sale, or importation of Defendants' generic product disclosed in ANDA No. 20-4571 prior to the expiration of the '913 and '865 patents, including any extensions, that judgment be entered

awarding Plaintiffs damages, including prejudgment interest, resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

H. A declaration that this is an exceptional case and an award of reasonable attorneys' fees pursuant to U.S.C. § 285;

I. Costs and expenses in this action; and

J. Such other and further relief as the Court may deem just and proper.

Dated: February 28, 2013

Respectfully submitted,

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