**UNITED STATES DISTRICT COURT**
**SOUTHERN DISTRICT OF INDIANA**
**INDIANAPOLIS DIVISION**

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

**Plaintiffs,**

**v.**

**WATSON LABORATORIES, INC.,**
**ACTAVIS, INC., and**
**ACTAVIS PHARMA, INC.**

**Defendants.**

**Case No.**
**1:13-cv-1799 JMS-DKL**

## 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 Watson Laboratories, Inc., Actavis, Inc., and Actavis Pharma, Inc. (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. Actavis, Inc. is a Nevada corporation with its principal place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054. Actavis, Inc. is a pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States

5. Watson Laboratories, Inc. ("Watson Laboratories") is a Nevada corporation with its principal place of business at 311 Bonnie Circle, Corona, California 92880. Watson Laboratories is a 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 parent company Actavis, Inc. and related companies.

6. Actavis Pharma, Inc. ("Actavis Pharma") is a Delaware corporation with its principal place of business at Morris Corporate Center III, 400 Interspace Parkway, Parsippany, NJ 07054. Actavis Pharma is a 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 parent company Actavis, Inc. and related companies.

7. Watson Laboratories and Actavis Pharma are wholly owned subsidiaries of Actavis, Inc. Watson Laboratories, Actavis Pharma and Actavis, Inc. are collectively referred to herein as "Actavis."

## NATURE OF THE ACTION

8. This is an action for infringement of U.S. Patent Nos. 6,299,900 ("the '900 patent); 6,818,226 ("the '226 patent"); 6,923,983 ("the '983 patent"); 8,071,075 ("the '075 patent"); 8,419,307 ("the '307 patent"); and 8,435,944 ("the '944 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 205328 submitted in the name of Watson Laboratories 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 action 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

9. 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.

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

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

## PERSONAL JURISDICTION

12. The Court has personal jurisdiction over Defendants because they regularly and continuously transact business within the State of Indiana. Defendants market and sell pharmaceutical products throughout the United States, including the State of Indiana. Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of conducting business within the State of Indiana.

13. According to the website for Actavis, Inc. and its subsidiaries, Actavis "is a global, integrated specialty pharmaceutical company focused on developing, manufacturing and distributing generic, brand and biosimilar products."

14. According to Actavis's 2012 Annual Report Form 10-K ("Actavis's 2012 Annual Report"), "On October 31, 2012, Watson Pharmaceuticals, Inc. completed the acquisition of the Actavis Group. On January 24, 2013, the Company was renamed Actavis, Inc." The 2012 Annual Report further states that "[f]ollowing the renaming of Watson Pharmaceuticals, Inc. to Actavis, Inc. efforts are underway to change the underlying 'Watson' subsidiary and legal entity names to an 'Actavis' name. This process is expected to continue to roll out throughout the year."

15. According to Actavis's 2012 Annual Report, "[t]he Company operates in three business segments: Actavis Pharma; Actavis Specialty Brands; and Anda Distribution (also known as 'Anda')."

16. According to Actavis's 2012 Annual Report, the "United States of America ('U.S.') remains our largest commercial market and represented approximately 81% of total net revenues for 2012. As of December 31, 2012, we marketed approximately 250 generic pharmaceutical product families and over 40 brand pharmaceutical products in the U.S. and distributed approximately 11,450 stock-keeping units ('SKUs') through our Anda Distribution Division."

17. The 2012 Annual Report further states: "[i]n the U.S., we predominantly market our generic products to various drug wholesalers, mail order, government and national retail drug and food store chains utilizing a small team of sales and marketing professionals. We sell our

generic prescription products primarily under the 'Watson Laboratories', 'Watson Pharma' and 'Actavis Pharma' labels, and our over-the-counter generic products under private label."

18. According to Actavis's 2012 Annual Report: "[i]n our Actavis Pharma and Actavis Specialty Brand operations, we sell our generic and brand pharmaceutical products primarily to drug wholesalers, retailers and distributors, including national retail drug and food store chains, hospitals, clinics, mail order, government agencies and managed healthcare providers such as health maintenance organizations and other institutions. In our Anda Distribution business, we distribute generic and certain select brand pharmaceutical products to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains, physicians' offices and buying groups."

19. According to Actavis's 2012 Annual Report, "[o]ur Anda Distribution business primarily distributes generic and selected brand pharmaceutical products, vaccines, injectables and over-the-counter medicines to independent pharmacies, alternate care providers (hospitals, nursing homes and mail order pharmacies), pharmacy chains and physicians' offices. Additionally, we sell to members of buying groups, which are independent pharmacies that join together to enhance their buying power. We believe that we are able to effectively compete in the distribution market, and therefore optimize our market share, based on three critical elements: (i) competitive pricing, (ii) high levels of inventory for approximately 11,450 SKUs for responsive customer service that includes, among other things, next day delivery to the entire U.S., and (iii) well established telemarketing relationships with our customers, supplemented by our electronic ordering capabilities. While we purchase most of the approximate 11,450 SKUs in our Anda Distribution operations from third party manufacturers, we also distribute our own products and

our collaborative partners' products. We are the only U.S. pharmaceutical company that has meaningful distribution operations with direct access to independent pharmacies."

20. Upon information and belief, Watson Pharmaceuticals, Actavis Pharma, and/or Actavis, Inc. share common officers and directors.

21. Watson Laboratories, directly or through related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Watson Laboratories in Indiana on the basis of general jurisdiction.

22. Watson Laboratories develops and manufactures pharmaceutical products for sale throughout the United States, including the State of Indiana. Watson Laboratories, either directly or through wholesalers, sells pharmaceutical products to national and regional retail drug, supermarket, and/or mass merchandise chains in Indiana, and Watson Laboratories derives substantial revenue from these sales.

23. Actavis, Inc., directly or in concert with related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Actavis, Inc. in Indiana on the basis of general jurisdiction.

24. Actavis, Inc., either directly or through wholesalers, sells pharmaceutical products to national and regional retail drug, supermarket, and/or mass merchandise chains in Indiana, and Actavis, Inc. derives substantial revenue from these sales.

25. Actavis Pharma, directly or in concert with related companies, has engaged in substantial and continuous contacts with Indiana that satisfy due process and confer personal jurisdiction over Actavis Pharma in Indiana on the basis of general jurisdiction.

26. Actavis Pharma is a corporation registered with the Indiana Secretary of state as a "for-profit" corporation that may conduct business in the State of Indiana.

27. Actavis Pharma, either directly or through wholesalers, sells pharmaceutical products to national and regional retail drug, supermarket, and/or mass merchandise chains in Indiana, and Actavis Pharma derives substantial revenue from these sales.

28. As further evidence of personal jurisdiction over Defendants, Watson Laboratories, Actavis, Inc. (as Watson Pharmaceuticals, Inc.), and Actavis Pharma (as Watson Pharma, Inc.) have been sued for patent infringement in this district and have not contested personal jurisdiction. (*See* C.A. No. 1:11-cv-00786.) In addition, Watson Laboratories, Actavis, Inc. (as Watson Pharmaceuticals, Inc.) and Actavis Pharma (as Watson Pharma, Inc.) have purposefully availed themselves of the rights and benefits of this Court by asserting counterclaims in a lawsuit filed in this Court. (*See* C.A. No. 1:11-cv-00786.)

29. Watson Laboratories acts as the agent and official submitter to the FDA of ANDA No. 205328 at issue in this case. Actavis, Inc. and Actavis Pharma participated in the preparation and submission of ANDA No. 205328 and will benefit directly and indirectly upon the approval of ANDA No. 205328.

## FACTUAL BACKGROUND

### A. Axiron®

30. 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 '900 Patent**

31. United States Patent No. 6,299,900 ("the '900 patent") entitled "Dermal Penetration Enhancers and Drug Delivery Systems Involving Same," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on October 9, 2001. The '900 patent claims, *inter alia*, a transdermal drug delivery system that comprises at least one physiologically active agent and at least one dermal penetration enhancer. The '900 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Axiron®. A true and correct copy of the '900 patent is attached as Exhibit A. Acrux is the owner of the '900 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '900 patent. Eli Lilly Export S.A. has licensed its rights in the '900 patent to Lilly.

**C. The '226 Patent**

32. United States Patent No. 6,818,226 ("the '226 patent"), entitled "Dermal Penetration Enhancers and Drug Delivery Systems Involving Same," was duly and legally issued by the PTO on November 16, 2004. The '226 patent claims, *inter alia*, a transdermal drug delivery system that comprises at least one physiologically active agent and at least one dermal penetration enhancer. The '226 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '226 patent is attached as Exhibit B. Since its date of issue, Acrux has been, and continues to be, the owner of the '226 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '226 patent. Eli Lilly Export S.A. has licensed its rights in the '226 patent to Lilly.

**D. The '983 Patent**

33. United States Patent No. 6,923,983 ("the '983 patent"), entitled "Transdermal Delivery of Hormones," was duly and legally issued by the PTO on August 2, 2005. The '983 patent claims, *inter alia*, a transdermal drug delivery system comprising a therapeutically effective amount of a hormone and at least one dermal penetration enhancer. The '983 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '983 patent is attached as Exhibit C. Since its date of issue, Acrux has been, and continues to be, the owner of the '983 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '983 patent. Eli Lilly Export S.A. has licensed its rights in the '983 patent to Lilly.

**E. The '075 Patent**

34. United States Patent No. 8,071,075 ("the '075 patent"), entitled "Dermal Penetration Enhancers and Drug Delivery Systems Involving the Same," was duly and legally issued by the PTO on December 6, 2011. The '075 patent claims, *inter alia*, a transdermal drug delivery system comprising a therapeutically effective amount of testosterone and at least one dermal penetration enhancer. The '075 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '075 patent is attached as Exhibit D. Since its date of issue, Acrux has been, and continues to be, the owner of the '075 patent. Eli Lilly Export S.A. is the exclusive licensee worldwide for all uses of Axiron® under the '075 patent. Eli Lilly Export S.A. has licensed its rights in the '075 patent to Lilly.

**F. The '307 Patent**

35. United States Patent No. 8,419,307 ("the '307 patent"), entitled "Spreading Implement," was duly and legally issued by the PTO on April 16, 2013. The '307 patent claims, *inter alia*, a method 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 Orange Book in connection with Axiron®. A true and correct copy of the '307 patent is attached as Exhibit E. 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.

**G. The '944 Patent**

36. United States Patent No. 8,435,944 ("the '944 patent"), entitled "Method and Composition for Transdermal Drug Delivery," was duly and legally issued by the 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 F. 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.

**H. Actavis's ANDA No. 205328**

37. Defendants filed or caused to be filed with the FDA ANDA No. 205328 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of "Testosterone Topical Solution, for Topical Use, 30 mg of Testosterone per Pump Actuation" ("Actavis's Generic Product") in the United States before the expiration of the '900, '226, '983, '075, '307, and '944 patents.

38. Watson Laboratories, Actavis, Inc., and Actavis Pharma acted in concert to prepare and submit ANDA No. 205328.

39. ANDA No. 205328 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '900, '226, '983, '075, '307, and '944 patents are invalid, unenforceable, and/or would not be infringed by Actavis's Generic Product.

40. Defendants sent or caused to be sent to Lilly and Acrux a letter dated October 4, 2013 ("the Notice Letter"), notifying Lilly and Acrux that Defendants' ANDA No. 205328 includes paragraph IV certifications to obtain approval to engage in the commercial manufacture, use, or sale of Actavis's Generic Product before the expiration of the '900, '226, '983, '075, '307, and '944 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Defendants' Notice Letter states: "[Watson Laboratories] alleges, and has certified to FDA, that in [Watson Laboratories'] opinion and to the best of its knowledge, the '900, '226, '983, '075, '397, and '944 patent claims are invalid, unenforceable and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in [Watson Laboratories'] ANDA."

41. The Notice Letter purported to include an "Offer of Confidential Access" to Lilly and Acrux to ANDA No. 205328. Under the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j)(5)(III), restrictions to an Offer of Confidential Access must serve the purpose of protecting trade secrets and other confidential business information. Actavis's Offer of Confidential Access restricted disclosure to outside counsel only and required that such counsel (a) not be involved in patent prosecution matters, either formally or informally, for Lilly or Acrux without limitation as to time or subject matter, and (b) not be involved in any FDA

counseling, litigation or other work before or involving the FDA, without limitation as to time or subject matter. Actavis's offer was also restricted to certain unspecified information from its ANDA.

42. The proposed terms of Actavis's Offer of Confidential Access did not allow Acrux or Lilly in-house litigation team members who do not engage in patent prosecution relating to Axiron® or development of Axiron®, and who are crucial decision makers in the process of filing any infringement action, access to the necessary information with which to assess many of the details of Actavis's proposed generic copy of Axiron®. Actavis's proposed restrictions to other work performed by those having access to the ANDA were not directed to the purpose of protecting trade secrets and other confidential business information. Therefore, Actavis's Offer of Confidential Access was not on reasonable terms.

43. Lilly's and Acrux's outside counsel had a series of discussions with Actavis in an attempt to reach agreement on the terms and conditions of the Offer for Confidential Access; however, the parties did not reach agreement. Lilly and Acrux could not agree to all of the restrictions Actavis continued to place on its Offer of Confidential Access that were above and beyond those found in a reasonable protective order or as would be necessary to protect confidential business information, and Actavis did not provide Lilly or Acrux access to any portion of Actavis's ANDA.

44. The submission of ANDA No. 205328 to the FDA constitutes infringement by Defendants of the '900, '226, '983, '075, '307, and '944 patents under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Actavis's Generic Product would infringe the '900, '226, '983, '075, '307, and '944 patents under 35 U.S.C. § 271(a), (b), and/or (c).

45. Defendants know and intend that physicians will prescribe and patients will take Actavis's Generic Product for which approval is sought in ANDA No. 205328 and therefore, will infringe at least one claim of the patents in suit.

46. Defendants had knowledge of the patents-in-suit and by their promotional activities associated with Actavis's Generic Product, know 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.

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

48. Plaintiffs commenced this action within 45 days of receiving Actavis's October 4, 2013, Notice Letter.

**COUNT I FOR PATENT INFRINGEMENT**
**(Direct Infringement of U.S. Patent No. 6,299,900)**

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

50. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205328 to the FDA seeking approval of Actavis's Generic Product before expiration of the '900 patent was an act of infringement of the '900 patent by Defendants.

51. If ANDA No. 205328 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Actavis's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '900 patent under 35 U.S.C. § 271.

52. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '900 patent. Plaintiffs do not have an adequate remedy at law.

## COUNT II FOR PATENT INFRINGEMENT
**(Inducement to Infringe U.S. Patent No. 6,299,900)**

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

54. Defendants have knowledge of the '900 patent.

55. Upon FDA approval of ANDA No. 205328, Defendants will intentionally encourage acts of direct infringement of the '900 patent by others, with knowledge that their acts are encouraging infringement.

## COUNT III FOR PATENT INFRINGEMENT
**(Contributory Infringement of U.S. Patent No. 6,299,900)**

56. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 55 above as though fully restated herein.

57. If ANDA No. 205328 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Actavis's Generic Product.

58. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '900 patent.

59. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

## COUNT IV FOR PATENT INFRINGEMENT
**(Direct Infringement of U.S. Patent No. 6,818,226)**

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

61. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205328 to the FDA seeking approval of Actavis's Generic Product before expiration of the '226 patent was an act of infringement of the '226 patent by Defendants.

62. If ANDA No. 205328 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Actavis's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '226 patent under 35 U.S.C. § 271.

63. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '226 patent. Plaintiffs do not have an adequate remedy at law.

## COUNT V FOR PATENT INFRINGEMENT
**(Inducement to Infringe U.S. Patent No. 6,818,226)**

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

65. Defendants have knowledge of the '226 patent.

66. Upon FDA approval of ANDA No. 205328, Defendants will intentionally encourage acts of direct infringement of the '226 patent by others, with knowledge that their acts are encouraging infringement.

## COUNT VI FOR PATENT INFRINGEMENT
## (Contributory Infringement of U.S. Patent No. 6,818,226)

67. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 66 above as though fully restated herein.

68. If ANDA No. 205328 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Actavis's Generic Product.

69. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '226 patent.

70. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

## COUNT VII FOR PATENT INFRINGEMENT
## (Infringement of U.S. Patent No. 6,923,983)

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

72. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205328 to the FDA seeking approval of Actavis's Generic Product before expiration of the '983 patent was an act of infringement of the '983 patent by Defendants.

73. If ANDA No. 205328 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Actavis's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '983 patent under 35 U.S.C. § 271.

74. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '983 patent. Plaintiffs do not have an adequate remedy at law.

## COUNT VIII FOR PATENT INFRINGEMENT
**(Inducement to Infringe U.S. Patent No. 6,923,983)**

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

76. Defendants have knowledge of the '983 patent.

77. Upon FDA approval of ANDA No. 205328, Defendants will intentionally encourage acts of direct infringement of the '983 patent by others, with knowledge that their acts are encouraging infringement.

## COUNT IX FOR PATENT INFRINGEMENT
**(Contributory Infringement of U.S. Patent No. 6,923,983)**

78. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 77 above as though fully restated herein.

79. If ANDA No. 205328 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Actavis's Generic Product.

80. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '983 patent.

81. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

## COUNT X FOR PATENT INFRINGEMENT
**(Infringement of U.S. Patent No. 8,071,075)**

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

83. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205328 to the FDA seeking approval of Actavis's Generic Product before expiration of the '075 patent was an act of infringement of the '075 patent by Defendants.

84. If ANDA No. 205328 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Actavis's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '075 patent under 35 U.S.C. § 271.

85. Unless Defendants are enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Defendants' infringement of the '075 patent. Plaintiffs do not have an adequate remedy at law.

**COUNT XI FOR PATENT INFRINGEMENT**
**(Inducement to Infringe of U.S. Patent No. 8,071,075)**

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

87. Defendants have knowledge of the '075 patent.

88. Upon FDA approval of ANDA No. 205328, Defendants will intentionally encourage acts of direct infringement of the '075 patent by others, with knowledge that their acts are encouraging infringement.

**COUNT XII FOR PATENT INFRINGEMENT**
**(Contributory Infringement of U.S. Patent No. 8,071,075)**

89. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 88 above as though fully restated herein.

90. If ANDA No. 205328 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Actavis's Generic Product.

91. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '075 patent.

92. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

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

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

94. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205328 to the FDA seeking approval of Actavis's Generic Product before expiration of the '307 patent was an act of infringement of the '307 patent by Defendants.

95. If ANDA No. 205328 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Actavis'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.

96. 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 XIV FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,419,307)**

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

98. Defendants have knowledge of the '307 patent.

99. Upon FDA approval of ANDA No. 205328, Defendants will intentionally encourage acts of direct infringement of the '307 patent by others, with knowledge that their acts are encouraging infringement.

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

100. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 99 above as though fully restated herein.

101. If ANDA No. 205328 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Actavis's Generic Product.

102. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '307 patent.

103. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

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

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

105. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 205328 to the FDA seeking approval of Actavis's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendants.

106. If ANDA No. 205328 is approved by the FDA, Defendants' commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Actavis'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.

107. 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 XVII FOR PATENT INFRINGEMENT**
**(Inducement to Infringe U.S. Patent No. 8,435,944)**

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

109. Defendants have knowledge of the '944 patent.

110. Upon FDA approval of ANDA No. 205328, Defendants will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that their acts are encouraging infringement.

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

111. Plaintiffs incorporate by reference and reallege Paragraphs 1 through 110 above as though fully restated herein.

112. If ANDA No. 205328 is approved, Defendants intend to and will offer to sell, sell, or import into the United States Actavis's Generic Product.

113. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '944 patent.

114. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

**COUNT XIX FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 6,299,900)**

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

116. 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).

117. Defendants submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Actavis's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

118. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Actavis's Generic Product prior to expiration of the '900 patent.

119. 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 Actavis's Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

120. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Actavis's Generic Product would infringe one or more claims of the '900 patent under 35 U.S.C. § 271(a), (b), and/or (c).

121. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '900 patent.

122. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '900 patent.

123. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

124. 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 Actavis's Generic Product according to ANDA No. 205328 would infringe one or more claims of the '900 patent.

125. If Defendants' infringement of the '900 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XX FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 6,818,226)**

126. Plaintiffs incorporate by reference and reallege Paragraphs 1-125 above as though fully restated herein.

127. 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).

128. Defendants submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Actavis's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

129. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Actavis's Generic Product prior to expiration of the '226 patent.

130. 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 Actavis's Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

131. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Actavis's Generic Product would infringe one or more claims of the '226 patent under 35 U.S.C. § 271(a), (b), and/or (c).

132. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '226 patent.

133. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '226 patent.

134. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

135. 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 Actavis's Generic Product according to ANDA No. 205328 would infringe one or more claims of the '226 patent.

136. If Defendants' infringement of the '226 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXI FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 6,923,983)**

137. Plaintiffs incorporate by reference and reallege Paragraphs 1-136 above as though fully restated herein.

138. 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).

139. Defendants submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Actavis's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

140. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Actavis's Generic Product prior to expiration of the '983 patent.

141. 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 Actavis's Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

142. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Actavis's Generic Product would infringe one or more claims of the '983 patent under 35 U.S.C. § 271(a), (b), and/or (c).

143. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '983 patent.

144. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '983 patent.

145. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

146. 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 Actavis's Generic Product according to ANDA No. 205328 would infringe one or more claims of the '983 patent.

147. If Defendants' infringement of the '983 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm from which there is no remedy at law.

**COUNT XXII FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,071,075)**

148. Plaintiffs incorporate by reference and reallege Paragraphs 1-147 above as though fully restated herein.

149. 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).

150. Defendants submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Actavis's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

151. Defendants have made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Actavis's Generic Product prior to expiration of the '075 patent.

152. 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 Actavis's Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

153. Defendants' commercial manufacture, use, sale, or offer for sale within or importation into the United States of Actavis's Generic Product would infringe one or more claims of the '075 patent under 35 U.S.C. § 271(a), (b), and/or (c).

154. Defendants' threatened actions in actively aiding, abetting, encouraging, and inducing sales of Actavis's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '075 patent.

155. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '075 patent.

156. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

157. 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 Actavis's Generic Product according to ANDA No. 205328 would infringe one or more claims of the '075 patent.

158. If Defendants' infringement of the '075 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. 8,419,307)**

159. Plaintiffs incorporate by reference and reallege Paragraphs 1-158 above as though fully restated herein.

160. 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).

161. Defendants submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Actavis's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

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

163. 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 Actavis's Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

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

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

166. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '307 patent.

167. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

168. 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 Actavis's Generic Product according to ANDA No. 205328 would infringe one or more claims of the '307 patent.

169. 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 XXIV FOR DECLARATORY JUDGMENT**
**(Infringement of U.S. Patent No. 8,435,944)**

170. Plaintiffs incorporate by reference and reallege Paragraphs 1-169 above as though fully restated herein.

171. 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).

172. Defendants submitted ANDA No. 205328, seeking authorization to commercially manufacture, use, offer for sale, and sell Actavis's Generic Product in the United States. Defendants' Generic Product has no substantial non-infringing uses.

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

174. 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 Actavis's Generic Product upon receipt of final FDA approval of ANDA No. 205328, unless enjoined by the Court.

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

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

177. Defendants have had and continue to have knowledge that Actavis's Generic Product is especially adapted for a use that infringes the '944 patent.

178. Defendants have had and continue to have knowledge that there is no substantial non-infringing use for Actavis's Generic Product.

179. 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 Actavis's Generic Product according to ANDA No. 205328 would infringe one or more claims of the '944 patent.

180. 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.

## PRAYER FOR RELIEF

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

a) United States Patent Nos. Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; and 8,435,944 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; and 8,435,944 by submitting ANDA No. 205328 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Actavis'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 Actavis's Generic Product prior to the expiration of United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; and 8,435,944 would constitute infringement of said patents;

d) The effective date of any FDA approval of Actavis's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; and 8,435,944 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 Actavis's

Generic Product within the United States, or importing Actavis's Generic Product into the United States, until the expiration of United States Patent Nos. 6,299,900; 6,818,226; 6,923,983; 8,071,075; 8,419,307; and 8,435,944, 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: November 12, 2013 By: Jan M. Carroll

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