IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS INTERNATIONAL GMBH, TAKEDA PHARMACEUTICALS USA, INC., TAKEDA PHARMACEUTICALS AMERICA, INC., and OREXIGEN THERAPEUTICS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS LABORATORIES FL, INC., ANDRX CORPORATION, ACTAVIS PHARMA, INC., and ACTAVIS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals International GmbH, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively, "Takeda") and Orexigen Therapeutics, Inc. ("Orexigen") (together with Takeda, "Plaintiffs"), for their Complaint against Defendants Actavis Laboratories FL, Inc. ("Actavis FL"), Actavis Pharma, Inc. ("Actavis Pharma"), Andrx Corporation ("Andrx"), and Actavis, Inc. ("Actavis Inc.") (collectively, "Actavis" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 *et seq.*, and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 208043 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' commercially successful CONTRAVE® product prior to

the expiration of various patents owned or exclusively licensed by Plaintiffs that cover CONTRAVE®.

THE PARTIES

2. Plaintiff Takeda Pharmaceutical Company Limited is a Japanese corporation having a principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

3. Plaintiff Takeda Pharmaceuticals International GmbH is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited in Switzerland, having a principal place of business at Thurgauerstrasse 130, 8152 Glattpark-Opfikon, Zurich, Switzerland.

4. Plaintiff Takeda Pharmaceuticals USA, Inc. is a wholly-owned subsidiary of Takeda Pharmaceutical Company Limited in the United States, having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

5. Plaintiff Takeda Pharmaceuticals America, Inc. is a wholly-owned subsidiary of Takeda Pharmaceuticals USA, Inc., having a principal place of business at One Takeda Parkway, Deerfield, Illinois 60015.

6. Plaintiff Orexigen is a corporation organized and existing under the laws of the State of Delaware, having its primary place of business at 3344 North Torrey Pines Court, Suite 200, La Jolla, California 92037.

7. On information and belief, Defendant Actavis FL is a corporation organized and existing under the laws of the State of Florida, having places of business at 400 Interpace Parkway, Parsippany, New Jersey 07054 and 2945 W. Corporate Lakes Blvd., Weston Florida. On information and belief, Actavis FL is a wholly-owned subsidiary of Andrx.

8. On information and belief, Actavis FL develops, manufactures, and packages numerous generic versions of branded pharmaceutical products for sale and use in the State of Delaware and throughout the United States.

9. On information and belief, Actavis FL is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License No. A4-0001263) and "Distributor/Manufacturer CSR" (License No. DS0499).

10. On information and belief, defendant Andrx is a corporation organized under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Andrx is a wholly-owned subsidiary of Actavis, Inc.

11. On information and belief, defendant Actavis Pharma is a corporation organized and existing under the laws of the State of Delaware, having designated its registered agent as The Corporation Trust Company, Corporation Trust Center, 1209 Orange St., Wilmington, DE 19801. On information and belief, Actavis Pharma is a wholly-owned subsidiary of Actavis, Inc.

12. On information and belief, Actavis Pharma is in the business of, among other things, marketing and distributing pharmaceutical products in the State of Delaware and throughout the United States, including those that are manufactured by Actavis FL. On information and belief, Actavis Pharma is registered with the Delaware Board of Pharmacy, pursuant to 24 Del. C. § 2540, as a licensed "Pharmacy-Wholesale" (License Nos. A4-0000627, A4-0000683 and A4-0001998) and "Distributor/Manufacturer CSR" (License Nos. DS0503 and DS0319).

13. On information and belief, defendant Actavis, Inc. is a corporation organized and existing under the laws of the State of Nevada, having a place of business at Morris Corporate Center III, 400 Interpace Parkway, Parsippany, NJ 07054.

14. On information and belief, Actavis, Inc. is in the business of, among other things, marketing and distributing pharmaceutical products in the State of Delaware and throughout the United States, including those that are manufactured by Actavis FL.

JURISDICTION AND VENUE

15. This is a civil action for infringement of United States Patent Nos. 7,375,111; 7,462,626; 8,088,786; 8,318,788; 8,722,085; 8,815,889 and 8,916,195 (collectively, "the patents-in-suit"). This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 *et seq*.

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

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

18. This Court has personal jurisdiction over Defendants because they have purposefully availed themselves of the privilege of selling their pharmaceutical products in the State of Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of Delaware, including, but not limited to, the distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic.

19. On information and belief, Defendants share common officers and directors and are agents of each other, or work in concert with each other with respect to the development, regulatory approval, marketing, sale, and distribution of pharmaceutical products throughout the United States, including in the State of Delaware.

20. Defendants have previously submitted to the jurisdiction of the United States District Court for the District of Delaware and have previously availed themselves of this Court by initiating lawsuits, consenting to this Court's jurisdiction, and asserting counterclaims in other civil actions initiated in this District. *See e.g., Duchesnay Inc. et al. v. Actavis Laboratories FL, Inc. et al.*, No. 14-912-SLR, D.I. 9 (D. Del. Sept. 14, 2014) (Actavis FL, Actavis Pharma, and Actavis Inc. submitted to jurisdiction; Actavis FL asserted counterclaims); *Cephalon, Inc. v. Actavis Laboratories FL, Inc. et al.*, No. 14-776-SLR-SRF, D.I. 16 (D. Del. July 25, 2014) (Actavis FL submitted to jurisdiction and asserted counterclaims; Actavis Inc. and Actavis Pharma did not seek jurisdictional relief); *Acorda Therapeutics, Inc. v. Actavis Laboratories FL, Inc. et al.*, No. 14-882-LPS, D.I. 14 (D. Del. Aug. 22, 2014) (Actavis FL submitted to jurisdiction and asserted counterclaims); *Sciele Pharma, Inc., Andrx Corporation et al. v. Lupin Ltd et al.*, No. 09-00037-RBK-JS, D.I. 1 (Complaint for Patent Infringement) (D. Del. Jan. 15, 2009); and *Kissei Pharmaceutical Co., Ltd., Watson Laboratories, Inc. and Actavis, Inc. v. Sandoz Inc.*, No. 13-1092-LPS, D.I. 1 (Complaint for Patent Infringement) (D. Del. June 17, 2013); *Tris Pharma Inc. v. Actavis Laboratories FL Inc*., No. 14-1309-GMS, D.I. 16 (D. Del. December 5, 2014) (Actavis FL submitted to jurisdiction and asserted counterclaims).

21. On information and belief, Actavis FL, Andrx and Actavis Pharma operate as an integrated business ultimately owned and controlled by Actavis, Inc.

22. On information and belief, this Court has personal jurisdiction over Actavis FL by virtue of, *inter alia*: (1) its presence in Delaware, including through Andrx and Actavis Pharma; (2) its course of conduct that is designed to cause the sale of its products in Delaware, including the proposed generic product at issue in this action; (3) its licenses to distribute/manufacture and

pharmacy-wholesale license in Delaware; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

23. On information and belief, this Court has personal jurisdiction over Actavis Pharma by virtue of, *inter alia*: (1) its presence in Delaware, including its incorporation in Delaware; (2) its course of conduct that is designed to cause the sale of its products in Delaware, including the proposed generic product at issue in this action; (3) its licenses to distribute/manufacture and pharmacy-wholesale license in Delaware; and (4) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

24. On information and belief, this Court has personal jurisdiction over Andrx by virtue of, *inter alia*: (1) its presence in Delaware, including its incorporation in Delaware; (2) its course of conduct that is designed to cause the sale of its products in Delaware, including the proposed generic product at issue in this action; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

25. On information and belief, this Court has personal jurisdiction over Actavis, Inc. by virtue of, *inter alia*: (1) its presence in Delaware, including through Actavis Pharma; (2) its course of conduct that is designed to cause the sale of its products in Delaware, including the proposed generic product at issue in this action; and (3) its purposeful availment of this forum previously for the purpose of litigating patent disputes.

RELEVANT FACTS

THE BRAND NAME PRODUCT

26. Plaintiff Takeda Pharmaceuticals USA, Inc. holds approved New Drug Application ("NDA") No. 200063, under which the United States Food and Drug Administration ("FDA") granted approval on September 10, 2014 for Extended-Release Tablets containing 8 mg of Naltrexone Hydrochloride and 90 mg of Bupropion Hydrochloride. Takeda Pharmaceuticals

USA, Inc. markets and sells these tablets in the United States under the brand name CONTRAVE®.

27. CONTRAVE® contains a combination of naltrexone, an opioid antagonist, and bupropion, an aminoketone antidepressant, indicated as an adjunct to a reduced-calorie diet and increased physical activity for chronic weight management in adults with an initial body mass index (BMI) of (1) 30 kg/m^2 or greater (obese), or (2) 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia).

THE PATENTS-IN-SUIT

28. Orexigen owns United States Patent No. 7,375,111 ("the '111 patent") titled "Compositions for Affecting Weight Loss." The '111 patent was duly and legally issued on May 20, 2008. The expiry date for the '111 patent is March 26, 2025. A copy of the '111 patent is attached as Exhibit A.

29. Orexigen owns United States Patent No. 7,462,626 ("the '626 patent") titled "Compositions for Affecting Weight Loss." The '626 patent was duly and legally issued on December 9, 2008. The expiry date for the '626 patent is July 20, 2024. A copy of the '626 patent is attached as Exhibit B.

30. Orexigen owns United States Patent No. 8,088,786 ("the '786 patent") titled "Layered Pharmaceutical Formulations." The '786 patent was duly and legally issued on January 3, 2012. The expiry date for the '786 patent is February 3, 2029. A copy of the '786 patent is attached as Exhibit C.

31. Orexigen owns United States Patent No. 8,318,788 ("the '788 patent") titled "Layered Pharmaceutical Formulations." The '788 patent was duly and legally issued on

November 27, 2012. The expiry date for the ’788 patent is November 8, 2027. A copy of the ’788 patent is attached as Exhibit D.

32. Orexigen owns United States Patent No. 8,722,085 (“the ’085 patent”) titled “Methods for Administering Weight Loss Medications.” The ’085 patent was duly and legally issued on May 13, 2014. The expiry date for the ’085 patent is November 8, 2027. A copy of the ’085 patent is attached as Exhibit E.

33. Orexigen owns United States Patent No. 8,815,889 (“the ’889 patent”) titled “Composition and Methods for Increasing Insulin Sensitivity.” The ’889 patent was duly and legally issued on August 26, 2014. The expiry date for the ’889 patent is July 20, 2024. A copy of the ’889 patent is attached as Exhibit F.

34. Orexigen owns United States Patent No. 8,916,195 (“the ’195 patent”) titled “Sustained Release Formulation of Naltrexone.” The ’195 patent was duly and legally issued on December 23, 2014. The expiry date for the ’195 patent is February 2, 2030. A copy of the ’195 patent is attached as Exhibit G.

35. Takeda Pharmaceutical Company Limited is an exclusive licensee to the patents-in-suit. Takeda Pharmaceuticals International GmbH is a sublicensee of Takeda Pharmaceutical Company Limited. Takeda Pharmaceuticals USA, Inc. is a sublicensee of Takeda Pharmaceuticals International GmbH. Takeda Pharmaceuticals America, Inc. is a sublicensee of Takeda Pharmaceuticals USA, Inc.

36. Pursuant to 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (“the Orange Book”), as covering CONTRAVE® or its use.

ACTAVIS'S ANDA

37. On information and belief, Defendants acted in concert to submit ANDA No. 208043 to the FDA ("Actavis's ANDA"), including a certification with respect to the patents-in-suit under § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of generic extended-release tablets containing 8 mg of Naltrexone Hydrochloride and 90 mg of Bupropion Hydrochloride ("Actavis ANDA Product") prior to expiration of the patents-in-suit.

38. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act, ANDA No. 208043 includes a certification that the claims the patents-in-suit are invalid, unenforceable, or would not be infringed by the commercial manufacture, use or sale of the Actavis ANDA Product.

39. Plaintiffs received written notification of Actavis's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certifications by a letter dated April 20, 2015 ("Notice Letter") and filed this suit within 45 days of receipt of the Notice Letter.

40. In the Notice Letter, Actavis notified Plaintiffs that Actavis's ANDA contains a Paragraph IV certification of the type described in 21 U.S.C. § 355(j)(2)(A) with respect to the patents-in-suit. This statutory section requires, *inter alia*, certification by the ANDA applicant that the subject patents, here the patents-in-suit, are "invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted . . . ." 21 U.S.C. § 355(j)(2)(A)(vii)(IV). The statute (21 U.S.C. § 355(j)(2)(B)(iv)) also requires a Paragraph IV notice to "include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." The FDA Rules and Regulations (21 C.F.R.

§ 314.95(c)(6)) specify, *inter alia*, that a Paragraph IV notification must include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation."

41. On information and belief, at the time the Notice Letter was served, Actavis was aware of the statutory provisions and regulations referred to in paragraph 40 above.

42. Defendants acknowledged and represented that the Notice Letter meets the statutory and regulatory requirements referred to in paragraph 40, above.

43. The Notice Letter included an Offer of Confidential Access ("OCA") to certain Actavis confidential information regarding the Actavis ANDA Product. Following receipt of the original OCA, Plaintiffs attempted to negotiate a revised OCA with Actavis containing reasonable terms. Plaintiffs and Actavis were not able to reach agreement on a revised OCA. By letter dated May 28, 2015 from Actavis to Takeda's outside counsel, Actavis declared that the parties were "at an impasse" with respect to the OCA.

44. As of the date of this Complaint, Actavis has not provided any portions of the Actavis ANDA or other information regarding the Actavis ANDA Product beyond the information contained in the Notice Letter.

45. Plaintiffs are not aware of any other means of obtaining additional information regarding the Actavis ANDA Product. In the absence of such information, Plaintiffs resort to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm their allegations of infringement and to present to the Court

evidence that the Actavis ANDA Product falls within the scope of one or more claims of each of the patents-in-suit.

46. The Notice Letter does not deny infringement of any claims of the ’111 patent. Thus, Actavis acknowledges that Actavis’s ANDA product infringes all valid and enforceable claims of the ‘111 patent.

47. The Notice Letter does not deny induced or contributory infringement of any of claims 1, 2, 4, 6–16, 19–26, 28, 30, 31, 34–41, or 44–49 of the ’626 patent. Thus, Actavis acknowledges that Actavis’s ANDA product or the use thereof indirectly infringes of claims 1, 2, 4, 6–16, 19–26, 28, 30, 31, 34–41, or 44–49 of the ’626 patent as long as the claims are valid and enforceable.

48. The Notice Letter does not deny contributory infringement of any claims of the ’085 patent, thus acknowledging contributory infringement of all valid and enforceable claims of the ’085 patent.

49. The limited information contained within the Notice Letter does not demonstrate that the Actavis ANDA Product fails to fall within the scope of at least one claim in each of the patents-in-suit. The allegations of infringement in this Complaint will likely have further evidentiary support after a reasonable opportunity for further investigation and discovery.

50. On information and belief, upon FDA approval, Actavis will sell Actavis’s ANDA Product, in the State of Delaware and throughout the United States, in competition with Plaintiffs’ CONTRAVE® product.

ACTAVIS'S INFRINGEMENT OF THE PATENTS-IN-SUIT

COUNT 1: '111 PATENT

51. Plaintiffs repeat and re-allege paragraphs 1–50 as if fully set forth herein.

52. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the '111 patent, Defendants have infringed the '111 patent under 35 U.S.C. § 271(e)(2)(A).

53. Defendants are jointly and severally liable for infringement of the '111 patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Actavis's ANDA seeking 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 ANDA Products prior to the expiration of the '111 patent.

54. Unless enjoined by this Court, Actavis will directly infringe the '111 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States.

55. Unless enjoined by this Court, Actavis will induce the infringement of the '111 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs' rights under the '111 patent and in violation of 35 U.S.C. § 271(b).

56. Unless enjoined by this Court, Actavis will induce the infringement of the ’111 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs’ rights under the ’111 patent and in violation of 35 U.S.C. § 271(b).

57. Unless enjoined by this Court, Actavis will contribute to the infringement of the ’111 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis’s ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis’s ANDA Product in contravention of Plaintiffs’ rights under the ’111 patent in violation of 35 U.S.C. § 271(c).

58. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 2: ’626 PATENT

59. Plaintiffs repeat and re-allege paragraphs 1–58 as if fully set forth herein.

60. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the ’626 patent, Defendants have infringed the ’626 patent under 35 U.S.C. § 271(e)(2)(A).

61. Defendants are jointly and severally liable for infringement of the ’626, patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted,

assisted with, participated in, contributed to, or directed the submission of Actavis's ANDA seeking 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 ANDA Products prior to the expiration of the '626 patent.

62. Unless enjoined by this Court, Actavis will directly infringe the '626 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States.

63. Unless enjoined by this Court, Actavis will induce the infringement of the '626 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs' rights under the '626 patent and in violation of 35 U.S.C. § 271(b).

64. Unless enjoined by this Court, Actavis will induce the infringement of the '626 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs' rights under the '626 patent and in violation of 35 U.S.C. § 271(b).

65. Unless enjoined by this Court, Actavis will contribute to the infringement of the '626 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis's ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce

suitable for substantial non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Plaintiffs' rights under the '626 patent in violation of 35 U.S.C. § 271(c).

66. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 3: '786 PATENT

67. Plaintiffs repeat and re-allege paragraphs 1–66 as if fully set forth herein.

68. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the '786 patent, Defendants have infringed the '786 patent under 35 U.S.C. § 271(e)(2)(A).

69. Defendants are jointly and severally liable for infringement of the '786, patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Actavis's ANDA seeking 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 ANDA Products prior to the expiration of the '786 patent.

70. Unless enjoined by this Court, Actavis will directly infringe the '786 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States.

71. Unless enjoined by this Court, Actavis will induce the infringement of the ’786 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis’s ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs’ rights under the ’786 patent and in violation of 35 U.S.C. § 271(b).

72. Unless enjoined by this Court, Actavis will induce the infringement of the ’786 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis’s ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs’ rights under the ’786 patent and in violation of 35 U.S.C. § 271(b).

73. Unless enjoined by this Court, Actavis will contribute to the infringement of the ’786 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis’s ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis’s ANDA Product in contravention of Plaintiffs’ rights under the ’786 patent in violation of 35 U.S.C. § 271(c).

74. Plaintiffs will be irreparably harmed by Defendants’ infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 4: ’788 PATENT

75. Plaintiffs repeat and re-allege paragraphs 1–74 as if fully set forth herein.

76. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the ’788 patent, Defendants have infringed the ’788 patent under 35 U.S.C. § 271(e)(2)(A).

77. Defendants are jointly and severally liable for infringement of the ’788, patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Actavis’s ANDA seeking 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 ANDA Products prior to the expiration of the ’788 patent.

78. Unless enjoined by this Court, Actavis will directly infringe the ’788 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis’s ANDA Product in the United States.

79. Unless enjoined by this Court, Actavis will induce the infringement of the ’788 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis’s ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs’ rights under the ’788 patent and in violation of 35 U.S.C. § 271(b).

80. Unless enjoined by this Court, Actavis will induce the infringement of the ’788 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis’s

ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs' rights under the '788 patent and in violation of 35 U.S.C. § 271(b).

81. Unless enjoined by this Court, Actavis will contribute to the infringement of the '788 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis's ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Plaintiffs' rights under the '788 patent in violation of 35 U.S.C. § 271(c).

82. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 5: '085 PATENT

83. Plaintiffs repeat and re-allege paragraphs 1–82 as if fully set forth herein.

84. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the '085 patent, Defendants have infringed the '085 patent under 35 U.S.C. § 271(e)(2)(A).

85. Defendants are jointly and severally liable for infringement of the '085, patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Actavis's ANDA seeking 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 ANDA Products prior to the expiration of the '085 patent.

86. Unless enjoined by this Court, Actavis will directly infringe the '085 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States.

87. Unless enjoined by this Court, Actavis will induce the infringement of the '085 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs' rights under the '085 patent and in violation of 35 U.S.C. § 271(b).

88. Unless enjoined by this Court, Actavis will induce the infringement of the '085 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs' rights under the '085 patent and in violation of 35 U.S.C. § 271(b).

89. Unless enjoined by this Court, Actavis will contribute to the infringement of the '085 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis's ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are made or adapted especially for use in the

manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Plaintiffs' rights under the '085 patent in violation of 35 U.S.C. § 271(c).

90. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 6: '889 PATENT

91. Plaintiffs repeat and re-allege paragraphs 1–90 as if fully set forth herein.

92. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States of the ANDA Products prior to the expiration of the '889 patent, Defendants have infringed the '889 patent under 35 U.S.C. § 271(e)(2)(A).

93. Defendants are jointly and severally liable for infringement of the '889, patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Actavis's ANDA seeking 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 ANDA Products prior to the expiration of the '889 patent.

94. Unless enjoined by this Court, Actavis will directly infringe the '889 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis's ANDA Product in the United States.

95. Unless enjoined by this Court, Actavis will induce the infringement of the '889 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and

abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis's ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs' rights under the '889 patent and in violation of 35 U.S.C. § 271(b).

96. Unless enjoined by this Court, Actavis will induce the infringement of the '889 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis's ANDA Product in the United States, by others, including distributors, prescribers, and/or consumers, in contravention of Plaintiffs' rights under the '889 patent and in violation of 35 U.S.C. § 271(b).

97. Unless enjoined by this Court, Actavis will contribute to the infringement of the '889 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis's ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Plaintiffs' rights under the '889 patent in violation of 35 U.S.C. § 271(c).

98. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT 7: '195 PATENT

99. Plaintiffs repeat and re-allege paragraphs 1–98 as if fully set forth herein.

100. By seeking approval of their ANDA No. 208043 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United

States of the ANDA Products prior to the expiration of the ’195 patent, Defendants have infringed the ’195 patent under 35 U.S.C. § 271(e)(2)(A).

101. Defendants are jointly and severally liable for infringement of the ’195, patent under 35 U.S.C. § 271(e)(2)(A). This is because, upon information and belief, Actavis FL, Andrx, Actavis Inc., and Actavis Pharma actively and knowingly caused to be submitted, assisted with, participated in, contributed to, or directed the submission of Actavis’s ANDA seeking 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 ANDA Products prior to the expiration of the ’195 patent.

102. Unless enjoined by this Court, Actavis will directly infringe the ’195 patent (either literally or under the doctrine of equivalents) under 35 U.S.C. § 271(a), upon receiving FDA approval, by making, using, offering to sell, importing, and/or selling Actavis’s ANDA Product in the United States.

103. Unless enjoined by this Court, Actavis will induce the infringement of the ’195 patent, upon receiving FDA approval, by actively and intentionally encouraging, aiding, and abetting the manufacture, offer for sale, sale, and use in the United States and/or import into the United States of Actavis’s ANDA Product by others, including manufacturers, distributors, and/or consumers, with knowledge that such infringing acts are in contravention of Plaintiffs’ rights under the ’195 patent and in violation of 35 U.S.C. § 271(b).

104. Unless enjoined by this Court, Actavis will induce the infringement of the ’195 patent by actively and intentionally encouraging, through its label, the infringing use of Actavis’s ANDA Product in the United States, by others, including distributors, prescribers, and/or

consumers, in contravention of Plaintiffs' rights under the '195 patent and in violation of 35 U.S.C. § 271(b).

105. Unless enjoined by this Court, Actavis will contribute to the infringement of the '195 patent by knowingly and intentionally selling components of the inventions claimed in the patents-in-suit, including Actavis's ANDA Product, to others, including distributors, prescribers, and/or consumers, where such components are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are made or adapted especially for use in the manufacture, use, sale, or offer for sale of Actavis's ANDA Product in contravention of Plaintiffs' rights under the '195 patent in violation of 35 U.S.C. § 271(c).

106. Plaintiffs will be irreparably harmed by Defendants' infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

Plaintiffs request that the Court grant the following relief:

A. An Order adjudging and decreeing that Defendants have infringed the '111, '626, '786, '788, '085, '889, and '195 patents by submitting Actavis's ANDA to the FDA;

B. A permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with them, from infringing the '111, '626, '786, '788, '085, '889, and '195 patents by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the aforementioned patents-in-suit;

C. A permanent injunction pursuant to 35 U.S.C. § 283 restraining and enjoining Defendants, their directors, officers, agents, attorneys, affiliates, divisions, successors and employees, and those acting in concert with them, from infringing the '111, '626, '786, '788,

’085, ’889, and ’195 patents by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product claimed in the aforementioned patents-in-suit;

D. An Order pursuant to 35 U.S.C, § 271(e)(4)(A) decreeing that the effective date of any approval of Actavis’s ANDA be a date that is not earlier than the expiration date of the ’111, ’626, ’786, ’788, ’085, ’889, and ’195 patents, or any later expiration of any patent term extension or exclusivity for the aforementioned patents-in-suit to which Plaintiffs are or become entitled;

E. That Plaintiffs be awarded monetary relief to the extent Defendants commercially manufacture, use, offer for sale, or sell within the United States, or import into the United States any product that infringes or induces or contributes to the infringement of the ’111, ’626, ’786, ’788, ’085, ’889, and ’195 patents within the United States prior to the expiration of the aforementioned patents, including any later expiration of any patent term extension or exclusivity for the patents to which Plaintiffs are or become entitled, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

F. That Plaintiffs be awarded the attorney fees, costs, and expenses that they incur prosecuting this action; and

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

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