IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ACTAVIS ELIZABETH LLC, ACTAVIS LLC, and ACTAVIS INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Actavis Elizabeth LLC, Actavis LLC, and Actavis Inc. (collectively "Actavis"), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. Astellas Pharma Inc. was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

2. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff Astellas Pharma Inc.

3. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff Astellas Pharma Inc.

4. On information and belief, Defendant Actavis Elizabeth LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 200 Elmora Avenue, Elizabeth, New Jersey, 07202. On information and belief, Actavis Elizabeth LLC, by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

5. On information and belief, Defendant Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having its principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. On information and belief, Actavis LLC, by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

6. On information and belief, Defendant Actavis Inc. is a corporation organized and existing under the laws of the state of Nevada, having a principal place of business at 400 Interpace Parkway, Parsipanny, New Jersey 07054. On information and belief, Actavis Inc., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical

products for distribution and sale throughout the United States, including within this Judicial District.

7. On information and belief, Actavis Elizabeth LLC is a wholly-owned subsidiary of Actavis LLC. On information and belief Actavis LLC and Actavis Elizabeth LLC are wholly-owned by Actavis Inc.

8. On information and belief, Actavis Inc., Actavis LLC, and Actavis Elizabeth LLC have at least one officer and/or director in common.

9. On information and belief, Defendants Actavis Inc., Actavis LLC, and Actavis Elizabeth LLC have cooperated and assisted in the preparation and filing of Actavis's Abbreviated New Drug Application ("ANDA") No. 209368 and will be involved in the manufacture, importation, marketing and sale of the drug that is the subject of ANDA No. 209368 if it is approved.

NATURE OF ACTION

10. This is an action for patent infringement of United States Patent Nos. 6,346,532 ("the '532 patent"), 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Actavis's filing of ANDA No. 209368 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to market generic pharmaceutical products.

JURISDICTION AND VENUE

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

12. This Court has personal jurisdiction over each Defendant for purposes of this civil action.

13. This Court has jurisdiction over Actavis Inc. On information and belief, Actavis Inc. is the parent corporation of both Actavis LLC and Actavis Elizabeth LLC.

14. This Court has jurisdiction over Actavis LLC. On information and belief, Actavis LLC is a Delaware company. On information and belief, Actavis LLC is the parent company of Actavis Elizabeth LLC.

15. This Court has jurisdiction over Actavis Elizabeth LLC. On information and belief, Actavis Elizabeth LLC is a Delaware company.

16. On information and belief, Actavis, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this Judicial District. On information and belief, Actavis has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Actavis's generic drug products. On information and belief, Actavis has purposefully availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court and having engaged in systematic and continuous contacts with the State of Delaware.

17. On information and belief, Actavis Inc., Actavis LLC, and Actavis Elizabeth LLC are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic drug products. On information and belief, the acts of Actavis Elizabeth LLC complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of Actavis Inc. and Actavis LLC.

18. On information and belief, Actavis Elizabeth LLC filed an abbreviated new drug application seeking approval from the FDA to market and sell pharmaceutical products containing the compound mirabegron as active ingredient, for the treatment of overactive bladder, prior to the expiration of each of the '532, '117, '049, '474, and '872 patents.

19. This lawsuit arises in part from Actavis Elizabeth LLC sending Plaintiffs, one of which is a Delaware corporate entity, a letter dated August 24, 2016 purporting to be a "Notification of Certification for U.S. Patent Nos. 6,346,532; 6,562,375; 7,342,117; 7,982,049; 8,835,474; and RE44,872 Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act" ("Notice Letter"). The Notice Letter is signed by the Director, Regulatory Affairs of Actavis Elizabeth LLC and is on Actavis stationery. The Notice Letter refers to in-house legal personnel of Actavis Elizabeth LLC and designates an officer of Actavis Elizabeth LLC as the U.S. agent authorized to accept service.

20. When the Notice Letter was sent, Actavis knew or should have known that: (i) APGD is a Delaware corporation; and (ii) Plaintiffs would file suit against Actavis within 45 days of receiving the Notice Letter.

21. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b).

FACTUAL BACKGROUND

A. The '532 Patent

22. The United States Patent and Trademark Office ("PTO") duly and legally issued the '532 patent, entitled "Amide Derivatives or Salts Thereof," on February 12, 2002. On February 24, 2015, after an ex parte reexamination proceeding, the PTO duly and legally issued a reexamination certificate confirming the validity and patentability of the '532 patent. A true and correct copy of the '532 patent is attached as Exhibit A.

23. The ’532 patent claims, *inter alia*, the compound mirabegron and compositions containing mirabegron.

24. The ’532 patent also claims, *inter alia*, a pharmaceutical composition containing mirabegron as an active ingredient.

25. The Approved Drug Products with Therapeutic Equivalence Evaluations (“Orange Book”) lists the expiration date of the ’532 patent as March 27, 2022.

B. The ’117 Patent

26. The PTO duly and legally issued the ’117 patent, entitled “α-Form or β-Form Crystal of Acetanilide Derivative,” on March 11, 2008. A true and correct copy of the ’117 patent is attached as Exhibit B.

27. The ’117 patent claims, *inter alia*, crystal forms of mirabegron.

28. The Orange Book lists the expiration date of the ’117 patent as November 4, 2023.

C. The ’049 Patent

29. The PTO duly and legally issued the ’049 patent, entitled “α-Form or β-Form Crystal of Acetanilide Derivative,” on July 19, 2011. A true and correct copy of the ’049 patent is attached as Exhibit C.

30. The ’049 patent claims, *inter alia*, pharmaceutical compositions comprising crystal forms of mirabegron and a pharmaceutically acceptable carrier.

31. The Orange Book lists the expiration date of the ’049 patent as November 4, 2023.

D. The ’474 Patent

32. The PTO duly and legally issued the ’474 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on September 16, 2014. A true and correct copy of the ’474 patent is attached as Exhibit D.

33. The ’474 patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron.

34. The Orange Book lists the expiration date of the ’474 patent as November 4, 2023.

E. The ’872 Patent

35. The PTO duly and legally re-issued the ’872 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on April 29, 2014. A true and correct copy of the ’872 patent is attached as Exhibit E.

36. The ’872 patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron to adult subjects.

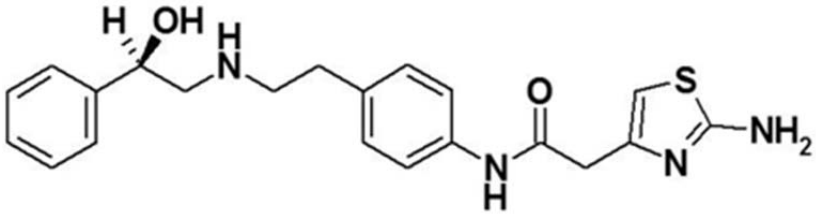
37. The ’872 patent also claims, *inter alia*, methods of treating overactive bladder by administering mirabegron, to non-adult subjects that are not suffering from diabetes.

38. The Orange Book lists the expiration date of the ’872 patent as November 4, 2023.

F. Myrbetriq®

39. APGD holds approved New Drug Application (“NDA”) No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. The FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets. The ’532, ’117, ’049, ’474 and ’872 patents are listed in the Orange Book for NDA No. 202611.

40. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, and 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



41. Myrbetriq® extended-release tablets, 25 mg and 50 mg, are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

42. Astellas Pharma Inc. is the record owner and assignee of the '532,'117, '049, '474 and '872 patents.

43. AICL is the exclusive licensee of the '532, '117, '049, '474 and '872 patents with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

44. APGD has contracted with Astellas Pharma US, Inc., a subsidiary of Astellas Pharma Inc., to market and sell Myrbetriq® extended-release tablets, 25 mg and 50 mg, in the United States on its behalf.

G. Infringement by Actavis

45. On information and belief, Actavis submitted to the FDA ANDA No. 209368 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the

commercial manufacture, use, offer for sale, sale, and/or importation of generic mirabegron extended-release tablets in 25 mg and 50 mg strengths ("ANDA Product"), as a pharmaceutical composition in an oral dosage form for the treatment of overactive bladder prior to the expiration of the '532, '117, '049, '474 and '872 patents.

46. On information and belief, Actavis intends to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the ANDA Product if and when it receives FDA approval to do so.

47. The Notice Letter advised Plaintiffs that Actavis submitted ANDA No. 209368 to the FDA seeking approval to manufacture, use, offer to sell, sell, and/or import the ANDA Product prior to the expiration of the '532, '117, '049, '474 and '872 patents. The Notice Letter advised Plaintiffs that Actavis's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Actavis's opinion, the claims of the '532, '117, '049, '474 and '872 patents are invalid, unenforceable and/or not infringed.

48. The submission of ANDA No. 209368 to the FDA constituted an act of infringement by Actavis of the '532, '117, '049, '474 and '872 patents under 35 U.S.C. § 271(e)(2).

49. Plaintiffs are commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

CLAIMS FOR RELIEF

COUNT I: DIRECT INFRINGEMENT OF THE '532 PATENT

50. Plaintiffs incorporate by reference and reallege paragraphs 1 through 49 above as though fully restated herein.

51. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 209368 to the FDA seeking approval of the ANDA Product was an act of infringement by Actavis of at least claims 1, 4, 5, 11 and 15 of the '532 patent which claim the compound mirabegron, the proposed active ingredient of the ANDA Product.

52. In the Notice Letter, Actavis does not deny that its ANDA Product is covered by claims 1, 4, 5, 11, and 15 of the '532 Patent.

53. The ANDA Product and the use thereof would infringe the '532 patent under 35 U.S.C. § 271(a), including at least claims 1, 4, 5, 11 and 15 which cover, *inter alia*, a pharmaceutical composition containing mirabegron as an active ingredient.

54. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '532 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II: DIRECT INFRINGEMENT OF THE '117 PATENT

55. Plaintiffs incorporate by reference and reallege paragraphs 1 through 54 above as though fully restated herein.

56. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 209368 to the FDA seeking approval of the ANDA Product was an act of infringement by Actavis of at least claim 1 of the '117 patent, which claims a crystal form of mirabegron that is contained in the ANDA Product.

57. The ANDA Product and the use thereof would infringe the '117 patent under 35 U.S.C. § 271(a), including at least claim 1, which covers, *inter alia*, a crystal form of mirabegron.

58. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '117 patent. Plaintiffs do not have an adequate remedy at law.

COUNT III: DIRECT INFRINGEMENT OF THE '049 PATENT

59. Plaintiffs incorporate by reference and reallege paragraphs 1 through 58 above as though fully restated herein.

60. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 209368 to the FDA seeking approval of the ANDA Product was an act of infringement by Actavis of at least claims 1, 5, 9 and 13 of the '049 patent which claim pharmaceutical compositions comprising a crystal form of mirabegron and a pharmaceutically acceptable carrier contained in the ANDA Product.

61. The ANDA Product and the use thereof would infringe the '049 patent under 35 U.S.C. § 271(a), including at least claims 1, 5, 9 and 13, which cover, *inter alia*, pharmaceutical compositions comprising a crystal form of mirabegron and a pharmaceutically acceptable carrier.

62. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '049 patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV: DIRECT INFRINGEMENT OF THE '474 PATENT

63. Plaintiffs incorporate by reference and reallege paragraphs 1 through 62 above as though fully restated herein.

64. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 209368 to the FDA seeking approval of the ANDA Product was an act of infringement by Actavis of at least claims 1, 3-4, 6-7, 9-10 and 12 the '474 patent which cover the method of treating

overactive bladder by administering mirabegron, the use for which Actavis seeks FDA approval in its ANDA.

65. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '474 patent. Plaintiffs do not have an adequate remedy at law.

COUNT V: INDUCEMENT TO INFRINGE THE '474 PATENT

66. Plaintiffs incorporate by reference and reallege paragraphs 1 through 65 above as though fully restated herein.

67. Actavis has knowledge of the '474 patent.

68. If the ANDA Product is approved by the FDA and is sold by Actavis, its use by healthcare providers and/or patients will directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

69. Actavis's proposed label for the ANDA Product explicitly instructs healthcare providers and/or patients to use the ANDA Product in a manner that will directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

70. Any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Actavis in its proposed label for the ANDA Product.

71. If the ANDA Product is approved by the FDA, Actavis will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12. Actavis has acted with knowledge that the induced acts would constitute infringement of the '474 patent.

72. Actavis specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

73. If and when FDA approves ANDA No. 209368, Actavis will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Actavis's proposed label, to use the ANDA Product in a manner that directly infringes one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12. Thus, Actavis will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 patent, and Actavis will affirmatively and specifically intend to cause direct infringement.

74. Actavis's actions will constitute inducement of infringement of the '474 patent pursuant to 35 U.S.C § 271(b).

COUNT VI: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

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

76. If ANDA No. 209368 is approved by the FDA, Actavis intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

77. The ANDA Product constitutes a material part of the inventions covered by the claims of the '474 patent and has no substantial non-infringing uses.

78. On information and belief, Actavis has had and continues to have knowledge that the ANDA Product is especially adapted for a use that infringes the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

79. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for the ANDA Product.

80. Actavis's actions will constitute contributory infringement of the '474 patent pursuant to 35 U.S.C. § 271(c).

COUNT VII: DIRECT INFRINGEMENT OF THE '872 PATENT

81. Plaintiffs incorporate by reference and reallege paragraphs 1 through 80 above as though fully restated herein.

82. Pursuant to 35 U.S.C. § 271(e)(2), Actavis's submission of ANDA No. 209368 to the FDA seeking approval of the ANDA Product was an act of infringement by Actavis of at least claims 1, 3-4, 6, 8-9 and 11-14 of the '872 patent which cover the method of treating overactive bladder by administering mirabegron, the use for which Actavis seeks FDA approval in its ANDA.

83. Unless Actavis is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Actavis's infringement of the '872 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VIII: INDUCEMENT TO INFRINGE THE '872 PATENT

84. Plaintiffs incorporate by reference and reallege paragraphs 1 through 83 above as though fully restated herein.

85. Actavis has knowledge of the '872 patent.

86. If the ANDA Product is approved by the FDA and is sold by Actavis, its use by healthcare providers and/or patients will directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

87. Actavis's proposed label for the ANDA Product explicitly instructs healthcare providers and/or patients to use the ANDA Product in a manner that will directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

88. Any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Actavis in its proposed label for the ANDA Product.

89. If the ANDA Product is approved by the FDA, Actavis will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14. Actavis has acted with knowledge that the induced acts would constitute infringement of the '872 patent.

90. Actavis specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

91. If and when FDA approves ANDA No. 209368, Actavis will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Actavis's proposed label, to use the ANDA Product in a manner that directly infringes one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14. Thus, Actavis will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 patent, and Actavis will affirmatively and specifically intend to cause direct infringement.

92. Actavis's actions will constitute inducement of infringement of the '872 patent pursuant to 35 U.S.C § 271(b).

COUNT IX: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

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

94. If ANDA No. 209368 is approved by the FDA, Actavis intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

95. The ANDA Product constitutes a material part of the inventions covered by the claims of the '872 patent and has no substantial noninfringing uses.

96. On information and belief, Actavis has had and continues to have knowledge that the ANDA Product is especially adapted for a use that infringes the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

97. On information and belief, Actavis has had and continues to have knowledge that there is no substantial non-infringing use for the ANDA Product.

98. Actavis's actions will constitute contributory infringement of the '872 patent pursuant to 35 U.S.C. § 271(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Astellas Pharma Inc., AICL, and APGD, pray for a judgment in their favor and against Defendants Actavis, and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Actavis has infringed one or more claims of each of the '532, '117, '049, '474 and '872 patents by Actavis's filing of ANDA No. 209368 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of those patents;

B. A judgment declaring that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Product will infringe the '532, '117, '049, '474 and '872 patents;

C. A judgment declaring that the '532, '117, '049, '474 and '872 patents remain valid and enforceable;

D. A permanent injunction restraining and enjoining Actavis and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, as

claimed in the '532, '117, '049, '474 and '872 patents, until the expiration of each of the '532, '117, '049, '474 and '872 patents, or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of ANDA No. 209368 be a date that is not earlier than the expiration of the right of exclusivity under any of the '532, '117, '049, '474 and '872 patents, or any later date of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Actavis has committed any acts with respect to the subject matter claimed in the '532, '117, '049, '474 and/or '872 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts;

G. A determination that this case is "exceptional" under 35 U.S.C. § 285, and an award of attorney fees;

H. An award of Plaintiffs' costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

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