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. 16-905-SLR
ACTAVIS ELIZABETH LLC and ACTAVIS LLC,	)	
Defendants.	)	

ACTAVIS ELIZABETH LLC'S AND ACTAVIS LLC'S AMENDED ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS

Defendants Actavis Elizabeth LLC and Actavis LLC (collectively, "Actavis"[1]), by and through the undersigned attorneys, submit their amended answer, affirmative defenses, and counterclaims to the Complaint of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs"). Actavis denies all allegations in Plaintiffs' Complaint except those admitted specifically below. This pleading is based upon Actavis's knowledge as to its own activities and upon information and belief as to the activities of others.

[1] The Complaint uses "Actavis" to collectively include Actavis, Inc., Actavis Elizabeth LLC, and Actavis LLC. Actavis, Inc., which is a separate company now known as Allergan Finance LLC, is no longer a party to this case. Pursuant to the Stipulation submitted on October 31, 2016 and so ordered on November 1, 2016, the parties have stipulated to dismissal of the action against Actavis, Inc. Accordingly, all responses herein are made solely on behalf of Actavis Elizabeth LLC and Actavis LLC, and no response is made on behalf of Actavis, Inc. (n/k/a Allergan Finance LLC).

THE PARTIES

1. Admitted, on information and belief.

2. Admitted, on information and belief.

3. Admitted, on information and belief.

4. Actavis admits that 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. Actavis further admits that Actavis Elizabeth LLC is a pharmaceutical company that, by itself and/or through its affiliates and agents, develops and obtains regulatory approval for pharmaceutical products, including generic pharmaceutical products, that are distributed and sold in the United States. Actavis denies the remaining allegations in this paragraph.

5. Actavis admits that Actavis LLC is a limited liability company organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. Actavis further admits that Actavis LLC is a pharmaceutical company that owns ANDAs for generic pharmaceutical products that are distributed and sold in the United States. Actavis denies the remaining allegations in this paragraph

6. To the extent the allegations in this paragraph are directed to Actavis, Inc., which is no longer a party to this case, no response is required. To the extent a response is required, Actavis denies that Actavis, Inc. is a "Defendant" to this action. Further answering, Actavis is without knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore denies the same.

7. Denied. Answering further, Actavis states that Actavis Elizabeth LLC and Actavis LLC are separate, sister entities, both of which are indirect wholly-owned subsidiaries of Teva

Pharmaceuticals USA, Inc., which is an indirect wholly-owned subsidiary of Teva Pharmaceuticals, Ltd.

8. Denied.

9. Actavis admits that Actavis Elizabeth LLC was involved in the preparation and filing of Actavis's ANDA No. 209368 with the FDA pursuant to applicable laws and regulations to obtain approval to manufacture, use, and sell the drug that is the subject of ANDA No. 209368. Actavis denies that Actavis LLC or Actavis, Inc. had any involvement in the preparation and filing of ANDA No. 209368. Actavis further denies that Actavis LLC or Actavis, Inc. will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 209368 if approved. Actavis denies that Actavis, Inc. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Actavis, Inc., no response is required. Actavis denies the remaining allegations in this paragraph.

NATURE OF THE ACTION

10. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis admits that the Complaint purports to bring an action for infringement of U.S. 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. Actavis further admits that the Complaint purports to bring this action relating to the filing of ANDA No. 209368 with the United States Food and Drug Administration seeking approval to manufacture, use, or sell generic pharmaceutical products. Actavis denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

11. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis does not contest subject matter jurisdiction for purposes of this case only. Actavis denies the remaining allegations of this paragraph.

12. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis does not contest personal jurisdiction for purposes of this case only. Further answering, Actavis denies that Actavis, Inc. is a "Defendant" to this action. To the extent the allegations in this paragraph are directed toward Actavis, Inc., no response is required. Actavis denies the remaining allegations of this paragraph.

13. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis denies that Actavis, Inc. is a "Defendant" to this action. Further answering, Actavis denies that Actavis, Inc. is the parent corporation of both Actavis LLC and Actavis Elizabeth LLC. To the extent the allegations in this paragraph are directed toward Actavis, Inc., no response is required. Actavis denies the remaining allegations in this paragraph.

14. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis admits that Actavis LLC is organized and existing under the laws of the State of Delaware and does not contest personal jurisdiction for purposes of this case only. Actavis denies the remaining allegations of this paragraph.

15. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis admits that Actavis Elizabeth LLC is organized and existing under the laws of the State of Delaware and does not contest personal jurisdiction for purposes of this case only. Actavis denies the remaining allegations of this paragraph.

16. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis admits that Actavis Elizabeth LLC and Actavis LLC are pharmaceutical companies that own ANDAs for drugs that may be manufactured, used, and sold in the United States. Further answering, Actavis does not contest personal jurisdiction for purposes of this case only. Actavis denies the remaining allegations in this paragraph.

17. This paragraph contains conclusions of law for which no response is required. This paragraph further contains allegations directed to Actavis, Inc., which is no longer a party to this action. To the extent a response is required, Actavis admits that Actavis Elizabeth LLC and Actavis LLC are sister entities. Actavis denies that Actavis LLC or Actavis, Inc. had any involvement in the development of the product that is the subject of ANDA No. 209368 or the filing of ANDA No. 209368. Actavis denies the remaining allegations in this paragraph.

18. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 209368 to the FDA seeking approval to manufacture, use, and sell the products described in ANDA No. 209368, containing the compound mirabegron as active ingredient, according to the proposed label included with the ANDA submission. Actavis further admits that ANDA No. 209368 contains a Paragraph IV certification as to 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(k)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act. Actavis denies the remaining allegations in this paragraph.

19. Actavis admits that Actavis Elizabeth LLC sent a letter dated August 24, 2016 to Plaintiffs titled "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(k)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act." Actavis further admits that the Notice Letter is on Actavis stationary and is signed by Actavis Elizabeth LLC's Director, Regulatory Affairs. Actavis further

admits that the Notice Letter refers to in-house legal personnel of Actavis. Actavis denies the remaining allegations in this paragraph.

20. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis denies the allegations in this paragraph.

21. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis does not contest that venue is proper in this Court for purposes of this case only. Actavis denies the remaining allegations of this paragraph.

FACTUAL BACKGROUND

A. The ’532 Patent

22. Actavis admits that Exhibit A to the Complaint appears to be a copy of United States Patent No. 6,346,532 (“the ’532 patent”), which indicates on its face an issue date of February 12, 2002. Actavis further admits that the ’532 patent is titled “Amide Derivatives or Salts Thereof.” Actavis further admits that included in Exhibit A to the Complaint is a document which appears to be a copy of an ex parte reexamination certificate, which indicates on its face that the PTO issued a reexamination certificate regarding the ’532 patent on February 24, 2015. Actavis denies that the ’532 patent was duly and legally issued. Actavis denies that the reexamination certificate as to the ’532 patent was duly and legally issued. Actavis denies the remaining allegations in this paragraph.

23. Actavis admits that the ’532 patent purports to claim the compound mirabegron and compositions containing mirabegron, but denies that the claims are valid. Actavis denies the remaining allegations in this paragraph.

24. Actavis admits that the ’532 patent purports to claim a pharmaceutical composition containing mirabegron in an amount effective for treatment, but denies that the claims are valid. Actavis denies the remaining allegations in this paragraph.

25. Actavis admits that the FDA’s publication the “Approved Drug Products with Therapeutic Equivalence Evaluations” (“the Orange Book”) lists the expiration date of the ’532 patent as March 27, 2022. Actavis denies the remaining allegations in this paragraph.

B. The ’117 Patent

26. Actavis admits that Exhibit B to the Complaint appears to be a copy of United States Patent No. 7,342,117 (“the ’117 patent”), which indicates on its face an issue date of March 11, 2008. Actavis further admits that the ’117 patent is titled “α-Form or β-Form Crystal of Acetanilide Derivative.” Actavis denies that the ’117 patent was duly and legally issued. Actavis denies the remaining allegations in this paragraph.

27. Actavis admits that the ’117 patent purports to claim crystal forms of mirabegron, but denies that the claims are valid. Actavis denies the remaining allegations in this paragraph.

28. Actavis admits that the Orange Book lists the expiration date of the ’117 patent as November 4, 2023. Actavis denies the remaining allegations in this paragraph.

C. The ’049 Patent

29. Actavis admits that Exhibit C to the Complaint appears to be a copy of United States Patent No. 7,982,049 (“the ’049 patent”), which indicates on its face an issue date of July 19, 2011. Actavis further admits that the ’049 patent is titled “α-Form or β-Form Crystal of Acetanilide Derivative.” Actavis denies that the ’049 patent was duly and legally issued. Actavis denies the remaining allegations in this paragraph.

30. Actavis admits that the ’049 patent purports to claim pharmaceutical compositions comprising crystal forms of mirabegron and a pharmaceutically acceptable carrier, but denies that the claims are valid. Actavis denies the remaining allegations in this paragraph.

31. Actavis admits that the Orange Book lists the expiration date of the ’049 patent as November 4, 2023. Actavis denies the remaining allegations in this paragraph.

D. The ’474 Patent

32. Actavis admits that Exhibit D to the Complaint appears to be a copy of United States Patent No. 8,835,474 (“the ’474 patent”), which indicates on its face an issue date of September 16, 2014. Actavis further admits that the patent is titled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient.” Actavis denies that the ’474 patent was duly and legally issued. Actavis denies the remaining allegations in this paragraph.

33. Actavis admits that the ’474 patent purports to claim methods of treating overactive bladder by administering mirabergron, but denies that the claims are valid. Actavis denies the remaining allegations in this paragraph.

34. Actavis admits that the Orange Book lists the expiration date of the ’474 patent as November 4, 2023. Actavis denies the remaining allegations in this paragraph.

E. The ’872 Patent

35. Actavis admits that Exhibit E to the Complaint appears to be a copy of United States Patent No. RE44,872 (“the ’872 patent”), which indicates on its face an issue date of April 29, 2014. Actavis further admits that the patent is titled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient.” Actavis denies that the ’872 patent

was duly and legally issued or re-issued. Actavis denies the remaining allegations in this paragraph.

36. Actavis admits that the ’872 patent purports to claim methods of treating overactive bladder by administering mirabegron to “a subject in need thereof”, but denies that the claims are valid. Actavis denies the remaining allegations in this paragraph.

37. Actavis admits that the ’872 patent purports to claim methods of treating overactive bladder by administering mirabegron to non-adult subjects that are not suffering from diabetes, but denies that these claims are valid. Actavis denies the remaining allegations in this paragraph.

38. Actavis admits that the Orange Book lists the expiration date of the ’872 patent as November 4, 2023. Actavis denies the remaining allegations in this paragraph.

F. Myrbetriq®

39. Actavis admits that the Orange Book lists Astellas Pharma Global Development, Inc. (“APGD”) as the holder of approved New Drug Application (“NDA”) No. 202611 in connection with 25 mg and 50 mg extended-release Myrbetriq® tablets, which contain mirabegron as the active ingredient. Actavis admits that the Orange Book lists the approval date for NDA No. 202611 as June 28, 2012. Actavis admits that the ’532, ’117, ’049, ’474, and ’872 patents are listed in the Orange Book with respect to NDA No. 202611. Actavis denies the remaining allegations in this paragraph.

40. Actavis admits that mirabegron has been referred to chemically as (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.

Actavis further admits that mirabegron can be depicted with the structural formula appearing in paragraph 40 of the Complaint. Actavis denies the remaining allegations in this paragraph.

41. Actavis admits that the package insert for Myrbetriq® states that Mybetriq® 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. Actavis denies the remaining allegations in this paragraph.

42. Actavis admits that the USPTO Patent Application Information Retrieval website and/or the face of the patent indicates that Astellas Pharma Inc. is the assignee and record owner of the '532, '117, '049, '474, and '872 patents. Actavis denies the remaining allegations in this paragraph.

43. Actavis is without knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph and therefore denies the same.

44. Actavis admits that the package insert for Myrbetriq® states that the product is "Marketed and Distributed by: Astellas Pharma US, Inc." Actavis is without knowledge or information sufficient to form a belief about the truth of the remaining allegations in this paragraph and therefore denies the same.

G. Infringement by Actavis

45. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 209368, pertaining to mirabegron extended-release tablets in 25 mg and 50 mg strengths, to the FDA, under 21 U.S.C. § 355(j). Actavis further admits that ANDA No. 209368 contains Paragraph IV certifications with respect to the '532, '117, '049, '474, and '872 patents. Actavis denies the remaining allegations in this paragraph.

46. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 209368 to the FDA, pursuant to applicable laws and regulations, to obtain approval to engage in the commercial manufacture, use or sale of extended-release tablets of mirabegron in 25 mg and 50 mg strengths. Actavis denies the remaining allegations in this paragraph.

47. Actavis admits that Actavis Elizabeth LLC sent a Notice Letter to Plaintiffs regarding ANDA No. 209368, and disclosing that ANDA No. 209368 contains Paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of Mirabegron Extended-Release Tablets, 25 mg and 50 mg, before the expiration of the '532, '117, '049, '474, and '872 patents. Actavis denies the remaining allegations in this paragraph.

48. Denied.

49. Admitted.

CLAIMS FOR RELIEF

COUNT I: DIRECT INFRINGEMENT OF THE '532 PATENT

50. Actavis repeats and incorporates by reference its answers to paragraphs 1-49 as if fully set forth herein.

51. Denied.

52. Denied.

53. Denied.

54. Denied.

COUNT II: DIRECT INFRINGEMENT OF THE '117 PATENT

55. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 54 as if fully set forth herein.

56. Denied.

57. Denied.

58. Denied.

COUNT III: DIRECT INFRINGEMENT OF THE ’049 PATENT

59. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 58 as if fully set forth herein.

60. Denied.

61. Denied.

62. Denied.

COUNT IV: DIRECT INFRINGEMENT OF THE ’474 PATENT

63. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 62 as if fully set forth herein.

64. Denied.

65. Denied.

COUNT V: INDUCEMENT TO INFRINGE THE ’474 PATENT

66. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 65 as if fully set forth herein.

67. Actavis admits that Actavis Elizabeth LLC filed ANDA No. 209368 with a paragraph IV certification as to the ’474 patent. Actavis denies the remaining allegations in this paragraph.

68. Denied.

69. Denied.

70. Denied.

71. Denied.

72. Denied.

73. Denied.

74. Denied.

COUNT VI: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

75. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 74 as if fully set forth herein.

76. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 209368 under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product in the United States. Actavis denies the remaining allegations in this paragraph.

77. This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Actavis denies the allegations in this paragraph.

78. Denied.

79. Denied.

80. Denied.

COUNT VII: DIRECT INFRINGEMENT OF THE '872 PATENT

81. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 80 as if fully set forth herein.

82. Denied.

83. Denied.

COUNT VIII: INDUCEMENT TO INFRINGE THE '872 PATENT

84. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 83 as if fully set forth herein.

85. Actavis admits that Actavis Elizabeth LLC filed ANDA No. 209368 with a paragraph IV certification as to the '872 patent. Actavis denies the remaining allegations in this paragraph.

86. Denied.

87. Denied.

88. Denied.

89. Denied.

90. Denied.

91. Denied.

92. Denied.

COUNT IX: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

93. Actavis repeats and incorporates by reference its answers to paragraphs 1 through 92 as if fully set forth herein.

94. Actavis admits that Actavis Elizabeth LLC submitted ANDA No. 209368 under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, and sale of the ANDA Product in the United States. Actavis denies the remaining allegations in this paragraph.

95. Denied.

96. Denied.

97. Denied.

98. Denied.

PRAYER FOR RELIEF

Actavis denies that Plaintiffs are entitled to any of the relief requested in their Prayer for Relief or any relief whatsoever.

ACTAVIS'S AFFIRMATIVE DEFENSES

Further answering the Complaint, Actavis asserts the following defenses in response to the allegations of the Complaint, undertaking the burden of proof only as to those defenses required by law, regardless of how such defenses are denominated below. Actavis reserves the right to

amend this Answer with additional defenses as further information is obtained. Actavis asserts the following defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted.

FIRST DEFENSE
(Invalidity)

The '532, '117, '049, '474 and '872 patents and each of the claims thereof are invalid for failure to comply with one or more conditions for patentability set forth in one or more provisions of 35 U.S.C. §§ 101, 102, 103 and/or 112, or under other judicially-created bases for invalidation, such as double patenting.

SECOND DEFENSE
(No Direct Infringement)

Actavis has not, does not, and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '532, '117, '049, '474 and '872 patents.

THIRD DEFENSE
(No Indirect Infringement)

Actavis has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '532, '117, '049, '474 and '872 patents.

FOURTH DEFENSE

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this suit.

FIFTH DEFENSE

The Complaint fails to state a claim for relief against Actavis.

SIXTH DEFENSE

The Complaint fails to state a claim for relief against Actavis for exceptional case under 35 U.S.C. § 285.

SEVENTH DEFENSE

Any additional defenses that discovery may reveal.

WHEREFORE, Actavis respectfully requests that Plaintiffs take nothing by way of their Complaint, that judgment be entered in favor of Actavis, and that Actavis be awarded its attorneys' fees and costs, and all other just and proper relief.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Defendant and Counterclaim Plaintiff Actavis Elizabeth LLC for its counterclaims against Counterclaim Defendants and Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. ("AICL"), and Astellas Pharma Global Development, Inc. ("APGD") (collectively "Counterclaim Defendants" or "Astellas") allege as follows:

1. Actavis Elizabeth LLC repeats and realleges by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint.

2. This is an action for declaratory judgment of noninfringement and invalidity of one or more claim of U.S. Patent No. 6,346,532 ("the '532 patent") under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

3. This is an action for declaratory judgment of noninfringement and invalidity of one or more claim of U.S. Patent No. 7,342,117 ("the '117 patent") under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

4. This is an action for declaratory judgment of noninfringement and invalidity of one or more claim of U.S. Patent No. 7,982,049 ("the '049 patent") under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

5. This is an action for declaratory judgment of noninfringement and invalidity of one or more claim of U.S. Patent No. 8,835,474 ("the '474 patent") under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

6. This is an action for declaratory judgment of noninfringement and invalidity of one or more claim of U.S. Patent No. RE44,872 ("the '872 patent") under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*.

Parties and Acts Leading to These Counterclaims

7. Actavis Elizabeth LLC is a limited liability company organized under the laws of the State of Delaware. Actavis Elizabeth LLC's principal place of business is at 200 Elmora Avenue, Elizabeth, New Jersey 07202.

8. On information and belief, Counterclaim Defendant 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.

9. On information and belief, Counterclaim Defendant 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. On information and belief, AICL is a subsidiary of Astellas Pharma Inc.

10. On information and belief, Counterclaim Defendant 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. On information and belief, APGD is a subsidiary of Astellas Pharma Inc.

11. On February 12, 2002, the U.S. Patent and Trademark Office ("PTO") issued the '532 patent entitled, "Amide Derivatives or Salts Thereof," listing on its face Souichirou Kawazoe,

Kenichirou Sakamoto, Yuji Awamura, Tatsuya Maruyama, Takayuki Suzuki, Kenichi Onda, and Toshiyuki Takasu as inventors. According to the Food and Drug Administration ("FDA") publication entitled "*Approved Drug Product with Therapeutics Equivalence Evaluations*" (known as "the Orange Book"), the '532 patent will expire on March 27, 2022.

12. On March 11, 2008, the PTO issued the '117 patent entitled, "α-Form or β-Form Crystal of Acetanilide Derivative," listing on its face Souichirou Kawazoe, Kenichirou Sakamoto, Yuji Awamura, Tatsuya Maruyama, Takayuki Suzuki, Kenichi Onda, and Toshiyuki Takasu as inventors. According to the Orange Book, the '117 patent will expire on November 4, 2023.

13. On July 19, 2011, the PTO issued the '049 patent entitled, "α-Form or β-Form Crystal of Acetanilide Derivative," listing on its face Souichirou Kawazoe, Kenichirou Sakamoto, Yuji Awamura, Tatsuya Maruyama, Takayuki Suzuki, Kenichi Onda, and Toshiyuki Takasu as inventors. According to the Orange Book, the '049 patent will expire on November 4, 2023.

14. On September 16, 2014, the PTO issued the '474 patent entitled, "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative as the Active Ingredient," listing on its face Toshiyuki Takasu, Shuichi Sato, Masashi Ukai, Tatsuya Maruyama, and Masayuki Shibasaki as inventors. According to the Orange Book, the '474 patent will expire on November 4, 2023.

15. On April 29, 2014, the PTO issued the '872 patent entitled, "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative as the Active Ingredient," listing on its face Toshiyuki Takasu, Shuichi Sato, Masashi Ukai, Tatsuya Maruyama, and Masayuki Shibasaki as inventors. According to the Orange Book, the '872 patent will expire on November 4, 2023.

16. APGD alleges that it is the holder of approved New Drug Application ("NDA") No. 202611 for Myrbetriq® (mirabegron) extended-release tablets in 25 mg and 50 mg dosage forms.

17. Astellas Pharma Inc. alleges that it is the assignee and record owner of the '532, '117, '049, '474, and '872 patents.

18. AICL alleges that it is the exclusive licensee of the '532, '117, '049, '474, and '872 patents.

19. Actavis Elizabeth LLC holds Abbreviated New Drug Application ("ANDA") No. 209368 for mirabegron extended-release tablets in 25 and 50 mg dosage forms ("the Actavis ANDA Product").

20. Actavis LLC had no involvement in the development of the Actavis ANDA Product or the filing of ANDA No. 209368, and Actavis LLC has no role with regard to the Actavis ANDA or the Actavis ANDA Product today.

21. On August 24, 2016, Actavis Elizabeth LLC sent Counterclaim Defendants Astellas Pharma Global Development Inc. and Astellas Pharma, Inc. a letter ("Actavis's Notice Letter") pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act and 21 C.F.R. § 314.95. This letter advised Counterclaim Defendants of the filing of ANDA No. 209368 for Mirabegron Extended-Release Tablets, 25 mg and 50 mg, and contained Paragraph IV certifications for the '532, '117, '049, '474, and '872 patents.

22. Counterclaim Defendants have alleged in the present action that Actavis Elizabeth LLC has infringed and will infringe the '532, '117, '049, '474, and '872 patents by filing ANDA No. 209368 with the FDA and/or by manufacturing, using, offering for sale, selling or importing the products described in the ANDA.

23. As a consequence of the foregoing, there is an actual and justiciable controversy between Actavis Elizabeth LLC and Counterclaim Defendants as to whether the claims of the '532, '117, '049, '474, and '872 patents are invalid and/or unenforceable, and whether those claims are being infringed or will be infringed by Actavis's ANDA No. 209368.

Jurisdiction and Venue

24. This court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202 based on an actual controversy between Actavis Elizabeth LLC, on one hand, and Counterclaim Defendants, on the other hand, arising under the Patent Laws of the United States, Title 35, United States Code.

25. This court has personal jurisdiction over Counterclaim Defendant Astellas Pharma Inc. based, *inter alia*, on the filing by Counterclaim Defendant Astellas Pharma Inc. of this lawsuit in this jurisdiction and because Counterclaim Defendant Astellas Pharma Inc. is doing business in this jurisdiction.

26. This court has personal jurisdiction over Counterclaim Defendant AICL based, *inter alia*, on the filing by Counterclaim Defendant AICL of this lawsuit in this jurisdiction and because Counterclaim Defendant AICL is doing business in this jurisdiction.

27. This court has personal jurisdiction over Counterclaim Defendant APGD based, *inter alia*, on the filing by Counterclaim Defendant APGD of this lawsuit in this jurisdiction and because Counterclaim Defendant APGD is doing business in this jurisdiction.

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

Exceptional Case

29. This case is an exceptional one, and Actavis Elizabeth LLC is entitled to an award of its reasonable attorneys' fees and costs under 35 U.S.C. § 285.

FIRST COUNT
(Declaratory Judgment of Noninfringement of the '532 Patent)

30. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

31. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the infringement of the claims of the '532 patent.

32. Counterclaim Defendants allege ownership of, title to, and/or interest in the '532 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe at least claims 1, 4, 5, 11, and 15 of the '532 patent.

33. Actavis Elizabeth LLC has not and will not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the '532 patent at least because the claims of the '532 patent are invalid, as set forth below in the Second Count of Actavis Elizabeth LLC's counterclaims, and an invalid claim cannot be infringed. *See Richdel, Inc. v. Sunspool Corp.*, 714 F.2d 1573, 1580 (Fed. Cir. 1983) ("It is axiomatic that one cannot infringe an invalid patent.").

34. Further, Counterclaim Defendants bear the burden of proving by preponderant evidence that every limitation set forth in each asserted claim is found in the accused product, either literally or under the doctrine of equivalents. To date, Counterclaim Defendants have not

set forth any evidence attempting to prove infringement of claims 1, 4, 5, 11, or 15 of the ’532 patent or any other claim of the ’532 patent.

35. Actavis Elizabeth LLC reserves the right to provide additional bases for noninfringement of the ’532 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

36. A present, genuine, and justiciable controversy exists between Actavis Elizabeth LLC, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the Actavis ANDA Product would infringe any valid or enforceable claim of the ’532 patent.

37. Actavis Elizabeth LLC is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Actavis ANDA Product described in ANDA No. 209368 does not and will not infringe any valid claim of the ’532 patent.

SECOND COUNT
(Declaratory Judgment of Invalidity of the ’532 Patent)

38. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis’s Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

39. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the validity of the claims of the ’532 patent.

40. Counterclaim Defendants allege ownership of, title to, and/or interest in the '532 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe at least claims 1, 4, 5, 11, and 15 of the '532 patent.

41. Actavis Elizabeth LLC asserts that the manufacture, use, offer for sale, or sale of the Actavis ANDA Product does not and will not infringe, either directly or indirectly, any valid claim of the '532 patent and that the claims of the '532 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

42. By way of example and not limitation, the claims of the '532 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102 and/or 103. For example, the claims of the '532 patent are invalid under 35 U.S.C. §§ 102 and/or 103 at least in view of Fisher et al., WO 1995/029159, Substituted Sulfonamides as Selective β_3 Agonists for the Treatment of Diabetes and Obesity ("Fisher '159"), alone or in combination with other prior art; Blin et al., *Structural and Conformational Features Determining Selective Signal Transduction in the β_3-Adrenergic Receptor*, Molecular Pharmacology 44: 1094-1104, 1993 ("Blin"), alone or in combination with other prior art; Schromm et al., U.S. Patent No. 5,223,614, New Quaternary Ammonium Compounds, Their Preparation and Use ("Schromm"), alone or in combination with other prior art; Sher, U.S. Patent No. 5,321,036, Thiazole and Oxazole-based β_3 Adrenergic Receptor Agonists ("Sher"), alone or in combination with other prior art; Silverman, The Organic Chemistry of Drug Design and Drug Action, Academic Press, Inc. 1992, pages 19-23 ("Silverman"), alone or in combination with other prior art; Thornber, *Isosterism and Molecular Modification in Drug Design*, Chem. Soc. Rev. 8, 563-580, 1979 ("Thornber"), alone or in combination with other prior art; and in view of the general knowledge in the art.

43. Further, the specification of the ’532 patent fails to sufficiently describe the subject matter recited in the claims and fails to show that the named inventors actually invented the claimed amide derivative compounds or their salts. Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of the ’532 patent, that the named inventors were in possession of any claimed invention(s) and demonstrate that by what is actually disclosed in the patent specification, one or more claims of the ’532 patent are invalid under 35 U.S.C. § 112.

44. The ’532 patent also fails to disclose sufficient information to enable or teach a person skilled in the art, at the time the patent application was filed, how to make and use the full scope of the amide derivative compounds or their salts recited in the patent claims, without undue experimentation, and therefore one or more claims of the ’532 patent are invalid under 35 U.S.C. § 112.

45. Additionally, the claims of the ’532 patent, read in light of the corresponding specification and prosecution history, fail to inform, with reasonable certainty, those skilled in the art of the full scope of the claims regarding amide derivative compounds or their salts, and therefore one or more claims of the ’532 patent are invalid under 35 U.S.C. § 112.

46. Actavis Elizabeth LLC reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

47. Actavis Elizabeth LLC is entitled to a declaration that the claims of the ’532 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

THIRD COUNT
(Declaratory Judgment of Noninfringement of the ’117 Patent)

48. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

49. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the infringement of the claims of the '117 patent.

50. Counterclaim Defendants allege ownership of, title to, and/or interest in the '117 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe at least claim 1 of the '117 patent.

51. Actavis Elizabeth LLC has not and will not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the '117 patent at least because the claims of the '117 patent are invalid, as set forth below in the Fourth Couth of Actavis Elizabeth LLC's counterclaims, and an invalid claim cannot be infringed. *See Richdel*, 714 F.2d at 1580.

52. Further, Counterclaim-Defendants bear the burden of proving by preponderant evidence that every limitation set forth in each asserted claim is found in the accused product, either literally or under the doctrine of equivalents. To date, Counterclaim Defendants have not set forth any evidence attempting to prove infringement of claim 1 of the '117 patent or any other claim of the '117 patent.

53. A present, genuine, and justiciable controversy exists between Actavis Elizabeth LLC, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the

issue of whether the manufacture, use, or sale of the Actavis ANDA Product would infringe any valid or enforceable claim of the ’117 patent.

54. Actavis Elizabeth LLC reserves the right to provide additional bases for noninfringement of the ’117 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

55. Actavis Elizabeth LLC is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Actavis ANDA Product described in ANDA No. 209368 does not and will not infringe any valid claim of the ’117 patent.

FOURTH COUNT
(Declaratory Judgment of Invalidity of the ’117 Patent)

56. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis’s Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

57. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the validity of the claims of the ’117 patent.

58. Counterclaim Defendants allege ownership of, title to, and/or interest in the ’117 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe at least claim 1 of the ’117 patent.

59. Actavis Elizabeth LLC asserts that the manufacture, use, offer for sale, or sale of the Actavis ANDA Product does not and will not infringe, either directly or indirectly, any valid

claim of the '117 patent and that the claims of the '117 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

60. By way of example and not limitation, the claims of the '117 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102 and/or 103. For example, the claims of the '117 patent are invalid under 35 U.S.C. §§ 102 and/or 103 at least in view of Maruyama et al, WO 1999/20607 ("Maruyama"), the English language equivalent of which is the '532 patent, alone or in combination with other prior art; Akahane, *et. al.,* PCT Application Publication No. WO 1998/007445, published February 26, 1998 (also published in English as European Patent Application Publication No. EP0958835 on November 24, 1999) ("Akahane") alone or in combination with other prior art; Philip L. Gould, *Salt selection for basic drugs*, Int. J. Pharm., 33:201-217 (1986) ("Gould"), alone or in combination with other prior art; J.A. Boatman, et. al., *A four-stage approach to new-drug development*, Pharm. Technol., 5:46-56 (1981) ("Boatman"), alone or in combination with other prior art; and in view of the general knowledge in the art.

61. Further, the specification of the '117 patent fails to sufficiently describe the subject matter recited in the claims and fails to show that the named inventors actually invented the α-form or β-form crystals of mirabegron that are claimed. Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of the '117 patent, that the named inventors were in possession of any claimed invention(s) and demonstrate that by what is actually disclosed in the patent specification, one or more claims of the '117 patent are invalid under 35 U.S.C. § 112.

62. The ’117 patent also fails to disclose sufficient information to enable or teach a person skilled in the art, at the time the patent application was filed, how to make and use the full scope of the α-form or β-form crystals of mirabegron recited in the ’117 patent, without undue experimentation, and therefore one or more claims of the ’117 patent are invalid under 35 U.S.C. § 112.

63. Additionally, the claims of the ’117 patent, read in light of their corresponding specifications and prosecution histories, fail to inform, with reasonable certainty, those skilled in the art of the full scope of the claims regarding α-form or β-form crystals of mirabegron, and therefore one or more claims of the ’117 patent are invalid under 35 U.S.C. § 112.

64. Actavis Elizabeth LLC reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

65. Actavis Elizabeth LLC is entitled to a declaration that the claims of the ’117 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

FIFTH COUNT
(Declaratory Judgment of Noninfringement of the ’049 Patent)

66. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis’s Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

67. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists

between Actavis Elizabeth LLC and Counterclaim Defendants concerning the infringement of the claims of the ’049 patent.

68. Counterclaim Defendants allege ownership of, title to, and/or interest in the ’049 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe at least claims 1, 5, 9, and 13 of the ’049 patent.

69. Actavis Elizabeth LLC has not and will not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the ’049 patent at least because the claims of the ’049 patent are invalid, as set forth below in the Sixth Count of Actavis Elizabeth LLC’s counterclaims, and an invalid claim cannot be infringed. *See Richdel*, 714 F.2d at 1580.

70. Further, Counterclaim Defendants bear the burden of proving by preponderant evidence that every limitation set forth in each asserted claim is found in the accused product, either literally or under the doctrine of equivalents. To date, Counterclaim Defendants have not set forth any evidence attempting to prove infringement of claims 1, 5, 9, or 13 of the ’049 patent or any other claim of the ’049 patent.

71. A present, genuine, and justiciable controversy exists between Actavis Elizabeth LLC, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the Actavis ANDA Product would infringe any valid or enforceable claim of the ’049 patent.

72. Actavis Elizabeth LLC reserves the right to provide additional bases for noninfringement of the ’049 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

73. Actavis Elizabeth LLC is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Actavis ANDA Product described in ANDA No. 209368 does not and will not infringe any valid claim of the '049 patent.

SIXTH COUNT
(Declaratory Judgment of Invalidity of the '049 Patent)

74. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

75. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the validity of the claims of the '049 patent.

76. Counterclaim Defendants allege ownership of, title to, and/or interest in the '049 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe at least claims 1, 5, 9, and 13 of the '049 patent.

77. Actavis Elizabeth LLC asserts that the manufacture, use, offer for sale, or sale of the Actavis ANDA Product does not and will not infringe, either directly or indirectly, any valid claim of the '049 patent and that the claims of the '049 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

78. By way of example and not limitation, the claims of the '049 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102 and/or 103. For example, the

claims of the ’049 patent are invalid under 35 U.S.C. §§ 102 and/or 103 at least in view of Maruyama, the English language equivalent of which is the ’532 patent, alone or in combination with other prior art; Akahane, alone or in combination with other prior art; Gould, alone or in combination with other prior art; Boatman, alone or in combination with other prior art; and in view of the general knowledge in the art.

79. Further, the specification of the ’049 patent fails to sufficiently describe the subject matter recited in the claims and fails to show that the named inventors actually invented a pharmaceutical composition containing the α-form or β-form crystals of mirabegron that are claimed. Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of the ’049 patent, that the named inventors were in possession of any claimed invention(s) and demonstrate that by what is actually disclosed in the patent specification, one or more claims of the ’049 patent are invalid under 35 U.S.C. § 112.

80. The ’049 patent also fails to disclose sufficient information to enable or teach a person skilled in the art, at the time the patent application was filed, how to make and use the full scope of the pharmaceutical composition containing the α-form or β-form crystals of mirabegron recited in the ’049 patent, without undue experimentation, and therefore one or more claims of the ’049 patent are invalid under 35 U.S.C. § 112.

81. Additionally, the claims of the ’049 patent, read in light of their corresponding specifications and prosecution histories, fail to inform, with reasonable certainty, those skilled in the art of the full scope of the claims regarding pharmaceutical compositions containing the α-form or β-form crystals of mirabegron, and therefore one or more claims of the ’049 patent are invalid under 35 U.S.C. § 112.

82. Actavis Elizabeth LLC reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

83. Actavis Elizabeth LLC is entitled to a declaration that the claims of the ’049 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

SEVENTH COUNT
(Declaratory Judgment of Noninfringement of the ’474 Patent)

84. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis’s Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

85. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the infringement of the claims of the ’474 patent.

86. Counterclaim Defendants allege ownership of, title to, and/or interest in the ’474 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe, contribute to the infringement of, and/or induce the infringement of at least claims 1, 3-4, 6-7, 9-10, and 12 of the ’474 patent.

87. Actavis Elizabeth LLC has not and will not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the ’474 patent at least because

the claims of the ’474 patent are invalid, as set forth below in the Eighth Count of Actavis Elizabeth LLC’s counterclaims, and an invalid claim cannot be infringed. *See Richdel*, 714 F.2d at 1580.

88. Further, Counterclaim Defendants bear the burden of proving by preponderant evidence that every limitation set forth in each asserted claim is found in the accused product, either literally or under the doctrine of equivalents. To date, Counterclaim Defendants have not set forth any evidence attempting to prove infringement of claims 1, 3-4, 6-7, 9-10, and 12 of the ’474 patent or any other claim of the ’474 patent.

89. A present, genuine, and justiciable controversy exists between Actavis Elizabeth LLC, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the Actavis ANDA Product would infringe any valid or enforceable claim of the ’474 patent.

90. Actavis Elizabeth LLC reserves the right to provide additional bases for noninfringement of the ’474 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

91. Actavis Elizabeth LLC is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Actavis ANDA Product described in ANDA No. 209368 does not and will not infringe any valid claim of the ’474 patent.

EIGHTH COUNT
(Declaratory Judgment of Invalidity of the ’474 Patent)

92. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis’s Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

93. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual,

substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the validity of the claims of the '474 patent.

94. Counterclaim Defendants allege ownership of, title to, and/or interest in the '474 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe, contribute to the infringement of, and/or induce the infringement of at least claims 1, 3-4, 6-7, 9-10, and 12 of the '474 patent.

95. Actavis Elizabeth LLC asserts that the manufacture, use, offer for sale, or sale of the Actavis ANDA Product does not and will not infringe, either directly or indirectly, any valid claim of the '474 patent and that the claims of the '474 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

96. By way of example and not limitation, the claims of the '474 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102 and/or 103. For example, the claims of the '474 patent are invalid under 35 U.S.C. §§ 102 and/or 103 at least in view of Maruyama, the English language equivalent of which is the '532 patent, alone or in combination with other prior art; Akahane, alone or in combination with other prior art; Tanaka et al., *Discovery of Novel N-Phenylglycine Derivatives as Potent and Selective β_3-Adrenoceptor Agonists for the Treatment of Frequent Urination and Urinary Incontinence*, J. Med. Chem., 44(9):1436-1445 (2001) ("Tanaka"), alone or in combination with other prior art; Yano et al., *The Reason Why Prostatic Hyperplasia Causes Lower Urinary Tract Symptoms*, Asian Med. J. 44, 2 Feb. 2001

("Yano"), alone or in combination with other prior art; and in view of the general knowledge in the art.

97. Further, the specification of the '474 patent fails to sufficiently describe the subject matter recited in the claims and fails to show that the named inventors actually invented the use of mirabegron or its salt as a remedy for overactive bladder that is claimed. Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of the '474 patent, that the named inventors were in possession of any claimed invention(s) and demonstrate that by what is actually disclosed in the patent specification, one or more claims of the '474 patent are invalid under 35 U.S.C. § 112.

98. The '474 patent also fails to disclose sufficient information to enable or teach a person skilled in the art, at the time the patent application was filed, how to make and use the full scope of the use of mirabegron or its salt as a remedy for overactive bladder recited in the '474 patent, without undue experimentation, and therefore one or more claims of the '474 patent are invalid under 35 U.S.C. § 112.

99. Additionally, the claims of the '474 patent, read in light of their corresponding specifications and prosecution histories, fail to inform, with reasonable certainty, those skilled in the art of the full scope of the claims regarding use of mirabegron or its salt as a remedy for overactive bladder, and therefore one or more claims of the '474 patent are invalid under 35 U.S.C. § 112.

100. Actavis Elizabeth LLC reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

101. Actavis Elizabeth LLC is entitled to a declaration that the claims of the '474 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

NINTH COUNT
(Declaratory Judgment of Noninfringement of the '872 Patent)

102. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

103. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the infringement of the claims of the '872 patent.

104. Counterclaim Defendants allege ownership of, title to, and/or interest in the '872 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe, contribute to the infringement of, and/or induce the infringement of at least claims 1, 3-4, 6, 8-9, and 11-14 of the '872 patent.

105. Actavis Elizabeth LLC has not and will not infringe, contribute to the infringement of, or induce infringement of any valid and enforceable claim of the '872 patent at least because the claims of the '872 patent are invalid, as set forth below in the Tenth Count of Actavis Elizabeth LLC's counterclaims, and an invalid claim cannot be infringed. *See Richdel*, 714 F.2d at 1580.

106. Further, Counterclaim Defendants bear the burden of proving by preponderant evidence that every limitation set forth in each asserted claim is found in the accused product,

either literally or under the doctrine of equivalents. To date, Counterclaim Defendants have not set forth any evidence attempting to prove infringement of claims 1, 3-4, 6, 8-9, and 11-14 of the '872 patent or any other claim of the '872 patent.

107. A present, genuine, and justiciable controversy exists between Actavis Elizabeth LLC, on the one hand, and Counterclaim Defendants, on the other hand, regarding, *inter alia*, the issue of whether the manufacture, use, or sale of the Actavis ANDA Product would infringe any valid or enforceable claim of the '872 patent.

108. Actavis Elizabeth LLC reserves the right to provide additional bases for noninfringement of the '872 patent in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

109. Actavis Elizabeth LLC is entitled to a declaration that the manufacture, use, offer for sale, and sale of the Actavis ANDA Product described in ANDA No. 209368 does not and will not infringe any valid claim of the '872 patent.

TENTH COUNT
(Declaratory Judgment of Invalidity of the '872 Patent)

110. Actavis Elizabeth LLC repeats and incorporates by reference each of the foregoing paragraphs of Actavis's Answer and Affirmative Defenses to the Complaint and of these Counterclaims.

111. This counterclaim arises under the Patent Laws of the United States, Title 35, United States Code, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*. A case of actual, substantial, and continuing justiciable controversy having adverse legal interests of sufficient immediacy and reality to warrant the issuance of a declaration of rights by this Court exists between Actavis Elizabeth LLC and Counterclaim Defendants concerning the validity of the claims of the '872 patent.

112. Counterclaim Defendants allege ownership of, title to, and/or interest in the '872 patent and assert that the commercial manufacture, use, sale and/or offer for sale of the Actavis ANDA Product would infringe, contribute to the infringement of, and/or induce the infringement of at least claims 1, 3-4, 6, 8-9, and 11-14 of the '872 patent.

113. Actavis Elizabeth LLC asserts that the manufacture, use, offer for sale, or sale of the Actavis ANDA Product does not and will not infringe, either directly or indirectly, any valid claim of the '872 patent, and that the claims of the '872 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

114. By way of example and not limitation, the claims of the '872 patent are invalid for failure to comply with one or more of the conditions for patentability set forth in Title 35 of the United States Code, including but not limited to, 35 U.S.C. §§ 102 and/or 103. For example, the claims of the '872 patent are invalid under 35 U.S.C. §§ 102 and/or 103 at least in view of Maruyama, the English language equivalent of which is the '532 patent, alone or in combination with other prior art; Akahane, alone or in combination with other prior art; Igawa et al., *Relaxant Effects of Isoproterenol and Selective β_3-adrenoceptor Agonists on Normal, Low Compliant and Hyperreflexic Human Bladders*, J. Urol. Vol. 165, 240-244, January 2001 ("Igawa 2001"), alone or in combination with other prior art; Tanaka, alone or in combination with other prior art; Yano, alone or in combination with other prior art; and in view of the general knowledge in the art.

115. Further, the specification of the '872 patent fails to sufficiently describe the subject matter recited in the claims and fails to show that the named inventors actually invented the use of mirabegron or its salt as a remedy for overactive bladder that is claimed. Because the named inventors failed to convey with reasonable clarity to those skilled in the art, as of the filing date of the '872 patent, that the named inventors were in possession of any claimed invention(s) and

demonstrate that by what is actually disclosed in the patent specification, one or more claims of the ’872 patent are invalid under 35 U.S.C. § 112.

116. The ’872 patent also fails to disclose sufficient information to enable or teach a person skilled in the art, at the time the patent application was filed, how to make and use the full scope of the use of mirabegron or its salt as a remedy for overactive bladder recited in the ’872 patent, without undue experimentation, and therefore one or more claims of the ’872 patent are invalid under 35 U.S.C. § 112.

117. Additionally, the claims of the ’872 patent, read in light of their corresponding specifications and prosecution histories, fail to inform, with reasonable certainty, those skilled in the art of the full scope of the claims regarding the use of mirabegron or its salt as a remedy for overactive bladder, and therefore one or more claims of the ’872 patent are invalid under 35 U.S.C. § 112.

118. Actavis Elizabeth LLC reserves the right to provide additional prior art and bases for invalidity in its contentions, responses to discovery requests, expert reports, and/or pleadings filed and/or served later in this action.

119. Actavis Elizabeth LLC is entitled to a declaration that the claims of the ’872 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, or 112, or other judicially-created bases for invalidation.

PRAYER FOR RELIEF

WHEREFORE, Actavis Elizabeth LLC prays that the Court enter a judgment in its favor and against Counterclaim Defendants as follows:

(a) declaring that Actavis Elizabeth LLC has not infringed any valid and enforceable claim of U.S. Patent No. 6,346,532;

(b) declaring that the claims of U.S. Patent No. 6,346,532 are invalid;

(c) declaring that Actavis Elizabeth LLC has not infringed any valid and enforceable claim of U.S. Patent No. 7,342,117;

(d) declaring that the claims of U.S. Patent No. 7,342,117 are invalid;

(e) declaring that Actavis Elizabeth LLC has not infringed any valid and enforceable claim of U.S. Patent No. 7,982,049;

(f) declaring that the claims of U.S. Patent No. 7,982,049 are invalid;

(g) declaring that Actavis Elizabeth LLC has not infringed any valid and enforceable claim of U.S. Patent No. 8,835,474;

(h) declaring that the claims of U.S. Patent No. 8,835,474 are invalid;

(i) declaring that Actavis Elizabeth LLC has not infringed any valid and enforceable claim of U.S. Patent No. RE44,872;

(j) declaring that the claims of U.S. Patent No. RE44,872 are invalid;

(k) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Actavis Elizabeth LLC its attorneys' fees, costs, and expenses in this action; and

(l) awarding Actavis Elizabeth LLC any further and additional relief as the Court deems just and proper.

Respectfully submitted,

/s/ Nathan R. Hoeschen

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