IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC., Plaintiff(s), v. SAWAI PHARMACEUTICAL CO., LTD. and SAWAI USA, INC., Defendant(s).	)	C.A. No. 1:16-cv-00954-SLR **JURY TRIAL DEMANDED**

ANSWER AND COUNTERCLAIMS OF
SAWAI PHARMACEUTICAL CO., LTD. AND SAWAI USA, INC.

Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. (collectively, "Sawai"), by and through their undersigned counsel, hereby answer the complaint of Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs"). Sawai also alleges the following counterclaims.

RESPONSE TO "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.

ANSWER: Sawai lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 1 and therefore denies the same.

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.

ANSWER: Sawai lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 2 and therefore denies the same.

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.

ANSWER: Sawai lacks sufficient information to form a belief as to the truth of the allegations in Paragraph 3 and therefore denies the same.

4. On information and belief, Defendant Sawai USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Irvine, California. On information and belief, Sawai USA, 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.

ANSWER: Sawai admits the allegations of the first sentence of Paragraph 4. Sawai further admits that Sawai USA, Inc. is the owner of ANDA No. 209446. Sawai denies the remaining allegations set forth in Paragraph 4.

5. On information and belief, Defendant Sawai Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business in Osaka, Japan. On information and belief, Sawai Pharmaceutical Co., Ltd., 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.

ANSWER: Sawai admits the allegations of the first sentence of Paragraph 5. Sawai further admits that Sawai Pharmaceutical Co., Ltd. played a role in the development of the generic drug product for which approval is sought in ANDA No. 209446. Sawai denies the remaining allegations set forth in Paragraph 5.

6. On information and belief, Sawai USA, Inc. is a wholly-owned subsidiary of Sawai Pharmaceutical Co., Ltd.

ANSWER: Sawai admits the allegations of Paragraph 6.

7. On information and belief, Defendants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. have cooperated and assisted in the preparation and filing of Sawai's Abbreviated New Drug Application ("ANDA") No. 209446 and will be involved in the

manufacture, importation, marketing and sale of the drug that is the subject of ANDA No. 209446 if it is approved.

ANSWER: Sawai admits that Sawai Pharmaceutical Co., Ltd. participated in the preparation of ANDA No. 209446 and that Sawai USA, Inc. is the owner of ANDA No. 209446. Sawai denies the remaining allegations set forth in Paragraph 7.

RESPONSE TO "NATURE OF ACTION"

8. 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 Sawai's filing of ANDA No. 209446 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.

ANSWER: Sawai admits that Plaintiffs purport to bring this action under the United States Patent laws, Title 35, United States Code and is related to the '532, '117, '049, '474, and '872 patents. Sawai further admits that this action purports to relate to ANDA No. 209446, filed with FDA by Sawai USA, seeking FDA approval to market certain pharmaceutical products. Sawai denies that Plaintiffs are entitled to any relief under its claims. Sawai denies the remaining allegations set forth in Paragraph 8.

RESPONSE TO "JURISDICTION AND VENUE"

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

ANSWER: The allegations in Paragraph 9 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 9. For the purposes of this action only, Sawai does not contest subject matter jurisdiction under 28 U.S.C. §§1331, 1338(a), 2201, and 2202.

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

ANSWER: The allegations in Paragraph 10 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 10. For purposes of this action only, Sawai does not contest personal jurisdiction.

11. This Court has jurisdiction over Sawai Pharmaceutical Co., Ltd. On information and belief, Sawai Pharmaceutical Co., Ltd. is the parent corporation of Sawai USA, Inc.

ANSWER: Sawai admits that Sawai Pharmaceutical Co., Ltd. is the parent corporation of Sawai USA, Inc. The remaining allegations in Paragraph 11 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the remaining allegations set forth in Paragraph 11. For purposes of this action only, Sawai does not contest personal jurisdiction for Sawai Pharmaceutical Co., Ltd.

12. This Court has jurisdiction over Sawai USA, Inc. On information and belief, Sawai USA, Inc. is a Delaware company.

ANSWER: Sawai admits that Sawai USA, Inc. is a Delaware company. The remaining allegations in Paragraph 12 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the remaining allegations set forth in Paragraph 12. For purposes of this action only, Sawai does not contest personal jurisdiction for Sawai USA, Inc.

13. On information and belief, Sawai, 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, Sawai has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Sawai's generic drug products. On information and belief, Sawai has purposefully availed itself of the rights and benefits of the laws of the State of Delaware, having engaged in systematic and continuous contacts with the State of Delaware.

ANSWER: Sawai admits that Sawai Pharmaceutical Co., Ltd. played a role in the development and formulation, both of which occurred outside of the United States, in the product for which approval is sought in ANDA 209446. The remaining allegations in Paragraph 13 comprise conclusions of law to which no answer is required. To the extent that an answer is

required, Sawai denies the remaining allegations set forth in Paragraph 13. For purposes of this action only, Sawai does not contest personal jurisdiction for Sawai.

14. On information and belief, Sawai USA, Inc. and Sawai Pharmaceuticals Co., Ltd. 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 Sawai USA, Inc. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of Sawai Pharmaceuticals Co., Ltd.

ANSWER: Sawai denies the allegations set forth in Paragraph 14.

15. On information and belief, Sawai USA, Inc. 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.

ANSWER: Sawai admits that Sawai USA, Inc. owns ANDA No. 209446 seeking approval from the FDA to market and sell tablet pharmaceutical products containing mirabegron as the active ingredient, for the treatment of overactive bladder, prior to the expiration of the '532, '117, '049, '474, and '872 patents. Sawai denies the remaining allegations set forth in Paragraph 15.

16. This lawsuit arises in part from Sawai USA, Inc. sending Plaintiffs, one of which is a Delaware corporate entity, a letter dated September 12, 2016 purporting to be a "Notice of Certification Under 21 U.S.C. § 355(j)(2)(B)(ii) (§505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act) and 21 C.F.R. § 314.95" ("Notice Letter").

ANSWER: Sawai admits that Sawai USA, Inc. sent the Notice Letter dated September 12, 2016 to Astellas Pharma Inc., 3-11 Nihonbashi-Honcho 2-Chome, Chuo-Ku, Tokyo, Japan 103-8411 and Astellas Pharma Global Development, Inc., 1 Astellas Way, Northbrook, IL 60062-6111. Sawai lacks sufficient information to form a belief as to the truth of the remaining allegations in Paragraph 16 and therefore denies the same.

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

ANSWER: Sawai admits Sawai USA Inc. sent a Notice Letter. Sawai denies the remaining allegations in Paragraph 17.

18. Alternatively, assuming that the above facts do not establish personal jurisdiction over Sawai Pharmaceuticals Co., Ltd., this Court may exercise jurisdiction over Sawai Pharmaceuticals Co., Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law; (b) Sawai Pharmaceuticals Co., Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Sawai Pharmaceuticals Co., Ltd. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Sawai Pharmaceuticals Co., Ltd. satisfies due process.

ANSWER: The allegations in Paragraph 18 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 18. For purposes of this action only, Sawai does not contest personal jurisdiction for Sawai Pharmaceuticals Co., Ltd.

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

ANSWER: The allegations in Paragraph 19 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 19. For purposes of this action only, Sawai does not contest venue in this judicial district.

RESPONSE TO "FACTUAL BACKGROUND"

A. RESPONSE TO "The '532 Patent"

20. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 20 containing conclusions of law. Sawai admits that the PTO issued the '532 patent, titled "Amide Derivatives

or Salts Thereof," on February 12, 2002. Sawai further admits that the PTO issued a reexamination certificate after an ex parte reexamination proceeding regarding the '532 patent on February 24, 2015. Sawai admits that Exhibit A to Plaintiffs' complaint appears to include a copy of the '532 patent as originally issued, certificates of correction issued in connection with the '532 patent, and the ex parte reexamination certificate from the '532 patent. Sawai denies the remaining allegations set forth in Paragraph 20.

21. The '532 patent claims, *inter alia*, the compound mirabegron and compositions containing mirabegron.

ANSWER: The allegations in Paragraph 21 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 21.

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

ANSWER: The allegations in Paragraph 22 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 22.

23. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration date of the '532 patent as March 27, 2022.

ANSWER: Sawai admits that the Orange Book currently lists the expiration date of the '532 patent as March 27, 2022. Sawai otherwise denies the allegations set forth in Paragraph 23.

B. RESPONSE TO "The '117 Patent"

24. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 20 containing conclusions of law. Sawai admits that the PTO issued the '117 patent, titled "α-Form or β-Form

Crystal of Acetanilide Derivative," on March 11, 2008. Sawai further admits that Exhibit B to Plaintiffs' complaint appears to include a copy of the '117 patent and certificates of correction issued in connection with the '117 patent. Sawai denies the remaining allegations set forth in Paragraph 24.

25. The '117 patent claims, *inter alia*, crystal forms of mirabegron.

ANSWER: The allegations in Paragraph 25 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 25.

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

ANSWER: Sawai admits the Orange Book currently lists the expiration date of the '117 patent as November 4, 2023. Sawai denies the remaining allegations set forth in Paragraph 26.

C. RESPONSE TO "The '049 Patent"

27. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 20 containing conclusions of law. Sawai admits that the PTO issued the '049 patent, titled "α-Form or β-Form Crystal of Acetanilide Derivative," on July 19, 2011. Sawai further admits that Exhibit C to Plaintiffs' complaint appears to include a copy of the '049 patent and a certificate of correction issued in connection with the '049 patent. Sawai denies the remaining allegations set forth in Paragraph 27.

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

ANSWER: The allegations in Paragraph 28 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 28.

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

ANSWER: Sawai admits that the Orange Book currently lists the expiration date of the '049 patent as November 4, 2023. Sawai denies the remaining allegations set forth in Paragraph 29.

D. RESPONSE TO "The '474 Patent"

30. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 20 containing conclusions of law. Sawai admits that the PTO issued the '474 patent, titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," on September 16, 2014. Sawai further admits that Exhibit D to Plaintiffs' complaint appears to be a copy of the '474 patent. Sawai denies the remaining allegations set forth in Paragraph 30.

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

ANSWER: The allegations in Paragraph 31 comprise conclusions of law to which no answer is required. To the extent an answer is required, Sawai denies the allegations set forth in Paragraph 31.

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

ANSWER: Sawai admits the Orange Book currently lists the expiration date of the '474 patent as November 4, 2023. Sawai denies the remaining allegations set forth in Paragraph 32.

E. RESPONSE TO "The '872 Patent"

33. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 20 containing conclusions of law. Sawai admits that the PTO issued the '872 patent, titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient," on April 29, 2014. Sawai further admits that Exhibit E to Plaintiffs' complaint appears to be a copy of the '872 patent. Sawai denies the remaining allegations set forth in Paragraph 33.

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

ANSWER: The allegations in Paragraph 34 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 34.

35. 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.

ANSWER: The allegations in Paragraph 35 comprise conclusions of law to which no answer is required. To the extent that an answer is required, Sawai denies the allegations set forth in Paragraph 35.

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

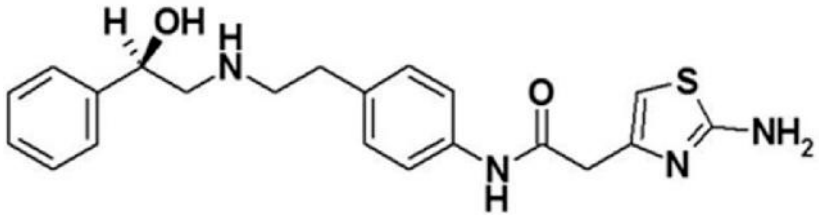
ANSWER: Sawai admits that the Orange Book currently lists the expiration date of the '872 patent as November 4, 2023. Sawai denies the remaining allegations set forth in Paragraph 36.

F. RESPONSE TO "Myrbetriq®"

37. 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.

ANSWER: Sawai admits that the Orange Book lists APGD as the NDA holder for NDA No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient mirabegron. Sawai admits that the Orange Book states that NDA No. 202611 was approved on June 28, 2012 for both the 25 mg and 50 mg dosages. The NDA speaks for itself. Sawai admits the allegations in the last sentence of Paragraph 37. Sawai lacks information to form a belief as to the truth of the remaining allegations set forth in Paragraph 37 and therefore denies the same.

38. 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:



ANSWER: Sawai 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. Sawai further admits that mirabegron can be depicted by the chemical formula in Paragraph 38.

Sawai lacks information to form a belief as to the truth of the remaining allegations set forth in Paragraph 38 and therefore denies the same.

39. 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.

ANSWER: Based upon the FDA-approved labeling for Myrbetriq®, Sawai believes that "MYRPETRIQ® is … indicated for the treatment of overactive bladder (OAB) with symptoms urinary incontinence, urgency, and urinary frequency …." Based on FDA website, Sawai believes that the FDA has approved Myrbetriq® as 25 mg and 50 mg extended-release tablets. Sawai lacks information to form a belief as to the truth of the remaining allegations set forth in Paragraph 39 and therefore denies the same.

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

ANSWER: Sawai provides no answer to the portions of Paragraph 40 containing conclusions of law. To the extent that an answer is required, Sawai admits that the USPTO Assignment Database lists Astellas Pharma Inc. as the assignee of '532,'117, '049, '474 and '872 patents. Sawai lacks information to form a belief as to the truth of the remaining allegations set forth in Paragraph 40 and therefore denies the same.

41. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 41 containing conclusions of law. To the extent that an answer is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 41 and therefore denies the same.

42. 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.

ANSWER: Sawai provides no answer to the portions of Paragraph 42 containing conclusions of law. To the extent that an answer is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 42 and therefore denies the same.

G. RESPONSE TO "Infringement by Sawai"

43. On information and belief, Sawai submitted to the FDA ANDA No. 209446 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 a 25 mg strength ("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. The Notice Letter does not provide notice that ANDA No. 209446 seeks FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic mirabegron extended-release tablets in a 50 mg strength. On information and belief, upon approval of ANDA No. 209446 Sawai will not engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic mirabegron extended-release tablets in a 50 mg strength.

ANSWER: Sawai admits that Sawai USA, Inc. submitted ANDA No. 209446 to the FDA under 21 U.S.C §355(j) seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of mirabegron extended-release tablets ("ANDA Product"), as a tablet 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. The Notice Letter speaks for itself. Sawai denies the remaining allegations set forth in Paragraph 43.

44. On information and belief, Sawai 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.

ANSWER: Sawai admits that Sawai USA, Inc. submitted ANDA No. 209446 to the FDA under 21 U.S.C §355(j) seeking FDA approval. Sawai denies the remaining allegations set forth in Paragraph 44.

45. The Notice Letter advised Plaintiffs that Sawai submitted ANDA No. 209446 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 Sawai's ANDA submission included a certification

under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Sawai's opinion, the claims of the '532, '117, '049, '474 and '872 patents are invalid, unenforceable and/or not infringed.

ANSWER: The Notice Letter Speaks for itself. Sawai denies the remaining allegations set forth in Paragraph 45.

46. The submission of ANDA No. 209446 to the FDA constituted an act of infringement by Sawai of the '532, '117, '049, '474 and '872 patents under 35 U.S.C. § 271(e)(2).

ANSWER: Sawai denies the allegations set forth in Paragraph 46.

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

ANSWER: Sawai admits that Plaintiffs filed this action on October 17, 2016, which was within 45 days of Plaintiffs' receiving the Notice Letter. Sawai denies the remaining allegations set forth in Paragraph 47.

RESPONSE TO "CLAIMS FOR RELIEF"

RESPONSE TO "COUNT I: DIRECT INFRINGEMENT OF THE '532 PATENT"

48. Plaintiffs incorporate by reference and reallege paragraphs 1 through 47 above as though fully restated herein.

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–47 as if fully set forth herein.

49. Pursuant to 35 U.S.C. § 271(e)(2), Sawai's submission of ANDA No. 209446 to the FDA seeking approval of the ANDA Product was an act of infringement by Sawai 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.

ANSWER: Paragraph 49 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai admits Sawai USA, Inc. submitted ANDA No. 209446 to the FDA seeking approval of the ANDA Product. Sawai denies the remaining allegations set forth in Paragraph 49.

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

ANSWER: The Notice Letter speaks for itself. Sawai denies the allegations of Paragraph 50 as the Notice Letter states, *inter alia*, that no valid and enforceable claim of the '532 patent is infringed by Sawai's ANDA Product.

51. 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.

ANSWER: Paragraph 51 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 51.

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

ANSWER: Paragraph 52 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 52 and therefore denies the same.

RESPONSE TO "COUNT II: DIRECT INFRINGEMENT OF THE '117 PATENT"

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

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–52 as if fully set forth herein.

54. Pursuant to 35 U.S.C. § 271(e)(2), Sawai's submission of ANDA No. 209446 to the FDA seeking approval of the ANDA Product was an act of infringement by Sawai of at least claim 1 of the '117 patent, which claims a crystal form of mirabegron that is contained in the ANDA Product.

ANSWER: Paragraph 54 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai admits Sawai USA, Inc. submitted ANDA No.

209446 to the FDA seeking approval of the ANDA Product. Sawai denies the remaining allegations set forth in Paragraph 54.

55. 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.

ANSWER: Paragraph 55 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 55.

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

ANSWER: Paragraph 56 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 56 and therefore denies the same.

RESPONSE TO "COUNT III: DIRECT INFRINGEMENT OF THE '049 PATENT"

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

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–56 as if fully set forth herein.

58. Pursuant to 35 U.S.C. § 271(e)(2), Sawai's submission of ANDA No. 209446 to the FDA seeking approval of the ANDA Product was an act of infringement by Sawai 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.

ANSWER: Paragraph 58 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai admits that Sawai USA, Inc. submitted ANDA No. 209446 to the FDA seeking approval of the ANDA Product. Sawai denies the remaining allegations set forth in Paragraph 58.

59. 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.

ANSWER: Paragraph 59 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 59.

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

ANSWER: Paragraph 60 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 60 and therefore denies the same.

RESPONSE TO "COUNT IV: DIRECT INFRINGEMENT OF THE '474 PATENT"

61. Plaintiffs incorporate by reference and reallege paragraphs 1 through 60 above as though fully restated herein.

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–60 as if fully set forth herein.

62. Pursuant to 35 U.S.C. § 271(e)(2), Sawai's submission of ANDA No. 209446 to the FDA seeking approval of the ANDA Product was an act of infringement by Sawai of at least claims 1, 3-4, 6-7, 9-10 and 12 of the '474 patent which cover the method of treating overactive bladder by administering mirabegron, the use for which Sawai seeks FDA approval in its ANDA.

ANSWER: Paragraph 62 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai admits Sawai USA, Inc. submitted ANDA No. 209446 to the FDA seeking approval of the ANDA Product. Sawai denies the remaining allegations set forth in Paragraph 62.

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

ANSWER: Paragraph 63 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 63 and therefore denies the same.

RESPONSE TO "COUNT V: INDUCEMENT TO INFRINGE THE '474 PATENT"

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

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–63 as if fully set forth herein.

65. Sawai has knowledge of the '474 patent.

ANSWER: Sawai admits that it currently has knowledge of the '474 patent. Sawai denies the remaining allegations of Paragraph 65.

66. If the ANDA Product is approved by the FDA and is sold by Sawai, 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.

ANSWER: Paragraph 66 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 66.

67. Sawai'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.

ANSWER: Paragraph 67 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 67.

68. 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 Sawai in its proposed label for the ANDA Product.

ANSWER: Sawai admits that its ANDA Product has a proposed label. Paragraph 68 contains conclusions of law regarding whether "any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers" to which no response is required.

To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 68 and therefore denies the same. Sawai denies the remaining allegations set forth in Paragraph 68.

69. If the ANDA Product is approved by the FDA, Sawai 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. Sawai has acted with knowledge that the induced acts would constitute infringement of the '474 patent.

ANSWER: Paragraph 69 contains conclusion of laws to which no response is required. To the extent that a response is required, Sawai denies that it has acted with knowledge that any acts would constitute infringement of the '474 patent. Sawai denies the remaining allegations set forth in Paragraph 69.

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

ANSWER: Paragraph 70 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies that it has specifically intended to cause any infringement of the '474 patent by others. Sawai denies the remaining allegations set forth in Paragraph 70.

71. If and when the FDA approves ANDA No. 209446, Sawai will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Sawai'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, Sawai 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 Sawai will affirmatively and specifically intend to cause direct infringement.

ANSWER: Paragraph 71 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 71.

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

ANSWER: Paragraph 72 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 72.

RESPONSE TO "COUNT VI: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT"

73. Plaintiffs incorporate by reference and reallege paragraphs 1 through 72 above as though fully restated herein.

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–72 as if fully set forth herein.

74. If ANDA No. 209446 is approved by the FDA, Sawai intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

ANSWER: Sawai admits that Sawai USA, Inc. submitted ANDA No. 209446 to the FDA under 21 U.S.C §355(j) seeking FDA approval. Sawai otherwise denies the allegations in set forth in Paragraph 74.

75. 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.

ANSWER: Paragraph 75 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 75.

76. On information and belief, Sawai 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.

ANSWER: Paragraph 76 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 76.

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

ANSWER: Paragraph 77 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 77.

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

ANSWER: Paragraph 78 contains conclusions of law to which no response is required. To the extent a response is required, Sawai denies the allegations set forth in Paragraph 78.

RESPONSE TO "COUNT VII: DIRECT INFRINGEMENT OF THE '872 PATENT"

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

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–79 as if fully set forth herein.

80. Pursuant to 35 U.S.C. § 271(e)(2), Sawai's submission of ANDA No. 209446 to the FDA seeking approval of the ANDA Product was an act of infringement by Sawai 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 Sawai seeks FDA approval in its ANDA.

ANSWER: Paragraph 80 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai admits Sawai USA, Inc. submitted ANDA No. 209446 to the FDA seeking approval of the ANDA Product. Sawai denies the remaining allegations set forth in Paragraph 80.

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

ANSWER: Paragraph 81 contains a conclusion of law to which no response is required. To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 81 and therefore denies the same.

RESPONSE TO "COUNT VIII: INDUCEMENT TO INFRINGE THE '872 PATENT"

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

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–82 as if fully set forth herein.

83. Sawai has knowledge of the '872 patent.

ANSWER: Sawai admits that it currently has knowledge of the '872 patent. Sawai denies the remaining allegations of Paragraph 83.

84. If the ANDA Product is approved by the FDA and is sold by Sawai, 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.

ANSWER: Paragraph 84 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 84.

85. Sawai'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.

ANSWER: Paragraph 85 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai admits that its ANDA Product has a proposed label. Sawai denies the allegations set forth in Paragraph 85.

86. 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 Sawai in its proposed label for the ANDA Product.

ANSWER: Sawai admits its ANDA Product has a proposed label. Paragraph 86 contains conclusions of law regarding whether "any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers" to which no response is required. To the extent that a response is required, Sawai lacks information to form a belief as to the truth of the allegations set forth in Paragraph 86 and therefore denies the same. Sawai denies the remaining allegations set forth in Paragraph 86.

87. If the ANDA Product is approved by the FDA, Sawai 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. Sawai has acted with knowledge that the induced acts would constitute infringement of the '872 patent.

ANSWER: Paragraph 87 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies that it has acted with knowledge that any acts would constitute infringement of the '872 patent. Sawai denies the remaining allegations set forth in Paragraph 87.

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

ANSWER: Paragraph 88 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies that it has specifically intended to cause any infringement of the '872 patent by others. Sawai denies the remaining allegations set forth in Paragraph 88.

89. If and when the FDA approves ANDA No. 209446, Sawai will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Sawai'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, Sawai 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 Sawai will affirmatively and specifically intend to cause direct infringement.

ANSWER: Paragraph 89 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 89.

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

ANSWER: Paragraph 90 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 90.

RESPONSE TO "COUNT IX: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT"

91. Plaintiffs incorporate by reference and reallege paragraphs 1 through 90 above as though fully restated herein.

ANSWER: Sawai reasserts its answers to each and every allegation contained in Paragraphs 1–91 as if fully set forth herein.

92. If ANDA No. 209446 is approved by the FDA, Sawai intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

ANSWER: Sawai admits that Sawai USA, Inc. submitted ANDA No. 209446 to the FDA under 21 U.S.C §355(j) seeking FDA approval. Sawai otherwise denies the allegations in set forth in Paragraph 92.

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

ANSWER: Paragraph 93 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 93.

94. On information and belief, Sawai 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.

ANSWER: Paragraph 94 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 94.

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

ANSWER: Paragraph 95 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 95.

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

ANSWER: Paragraph 96 contains conclusions of law to which no response is required. To the extent that a response is required, Sawai denies the allegations set forth in Paragraph 96.

RESPONSE TO "PRAYER FOR RELIEF"

Sawai denies that Plaintiffs are entitled to the judgment or any of the relief prayed for in paragraphs A-I under the heading "PRAYER FOR RELIEF" in the Complaint. Sawai demands judgment in its favor.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer, Sawai pleads the following affirmative defenses in response to Plaintiffs' allegations. Sawai reserves the right to allege any and all defenses not presently known or that are revealed during discovery or other analysis.

FIRST SEPARATE DEFENSE

97. Each purported claim in the Complaint, in whole or in part, is barred for failure to state a claim upon which relief can be granted.

SECOND SEPARATE DEFENSE

98. The claims of the patents-in-suit are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or based on other judicially created bases for invalidation.

THIRD SEPARATE DEFENSE

99. Sawai has not infringed, are not infringing, and will not infringe, literally or under the doctrine of equivalents, either directly or by contribution or inducement, any valid and enforceable claim of the patents-in-suit.

FOURTH SEPARATE DEFENSE

100. Plaintiffs' claims related to the '117 and '049 patents are barred by the doctrine of estoppel and are limited by amendment, by prior art, and/or by arguments and statements made during the prosecution of the '117 and '049 patents before the United States Patent and Trademark Office such that Plaintiffs are now estopped and precluded from

maintaining that such claims are of sufficient scope to cover Sawai's ANDA Products, either literally or under the doctrine of equivalents.

FIFTH SEPARATE DEFENSE

101. Sawai's actions do not constitute an exceptional case under 35 U.S.C. §285.

SIXTH SEPARATE DEFENSE

102. Plaintiffs may not seek injunctive relief against Sawai because Plaintiffs' alleged damages are not immediate or irreparable, and Plaintiffs therefore have an adequate remedy at law.

ADDITIONAL DEFENSES

103. Sawai reserves the right to allege additional affirmative defenses as they become known through the course of discovery.

WHEREFORE, Sawai prays this Court:

A. enter an order dismissing the Complaint, with prejudice, and denying Plaintiffs the relief requested in the Complaint and any relief whatsoever;

B. deny Plaintiffs any award of damages, costs, or fees;

C. declare this case exceptional under 35 U.S.C. §285 and award Sawai reasonable attorneys' fees;

D. award Sawai its costs; and

E. grant such other and further relief as this Court may deem just.

Sawai requests a trial by jury.

COUNTERCLAIMS

Without admitting any of the allegations of Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Astellas") other than those expressly admitted herein, and without prejudice to Defendant-Counterclaimants Sawai Pharmaceutical Co., Ltd. and Sawai USA, Inc. (collectively, "Sawai") to plead additional counterclaims as the facts of the matter warrant, Sawai assert the following counterclaims against Astellas Pharma Inc. ("API"):

NATURE OF THE ACTION

1. These Counterclaims arise under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202 and seek a declaratory judgment that Sawai's proposed products in ANDA 209446 do not and will not infringe any valid and enforceable claim 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") (collectively, the "Myrbetriq® Patents"), and that each and every claim of the Myrbetriq® Patents is invalid for failure to satisfy one or more provisions of Title 35 of the United States Code, including, but not limited to, 35 U.S.C. §§ 102, 103, and/or 112, and/or based on other judicially created bases for invalidation.

THE PARTIES

2. Defendant/Counterclaimant Sawai USA, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business in Irvine, California.

3. Defendant/Counterclaimant Sawai Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of Japan, having a principal place of business in Osaka, Japan.

4. Sawai USA, Inc. is a wholly-owned subsidiary of Sawai Pharmaceutical Co., Ltd.

5. On information and belief, and based on Astellas' allegations, Counterclaim Defendant API 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. On information and belief, API, by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202 based on an actual controversy among the parties, arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* This Court has original jurisdiction over the subject matter of these claims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 as well as 21 U.S.C. § 355(c)(3)(D).

7. This Court has personal jurisdiction over API based on, *inter alia,* its filing of this lawsuit in this jurisdiction.

8. Venue is proper in this judicial district based on 28 U.S.C. § 1400(a) and/or 28 U.S.C. § 1391(b), (c), and (d).

BACKGROUND

9. According to the United States Food & Drug Administration ("FDA") publication titled *Approved Drug Products and Therapeutic Equivalence Evaluations* ("the Orange Book"), APGD holds approved New Drug Application ("NDA") No. 202611 for mirabegron extended-release tablets, 25 mg and 50 mg, marketed under the trade name Myrbetriq®.

10. Under 21 U.S.C. §355(b)(1)(G), an NDA holder must provide to the FDA the patent numbers and expiration dates of any patent(s) that the NDA holder believes "claims the drug for

which the applicant submitted the [NDA] or which claims a method of using such drug." The FDA ministerially publishes these patents in the Orange Book.

11. Upon information and belief, and as stated in the Complaint in this matter, API is the owner and assignee of the '532,'117, '049, '474 and '872 patents.

12. Upon information and belief, API, itself or through its agents, caused the Myrbetriq® patents to be listed in the Orange Book as patents that claim Myrbetriq® or methods of using Myrbetriq®.

Certain Patents Listed in the Orange Book for Myrbetriq®

13. The '532 patent, on its face, is titled "Amide Derivatives or Salts Thereof," and states its date of issue as February 12, 2002.

14. The '117 patent, on its face, is titled "α-Form or β-Form Crystal of Acetanilide Derivative," and states its date of issue as March 11, 2008.

15. The '049 patent, on its face, is titled "α-Form or β-Form Crystal of Acetanilide Derivative," and states its date of issue as July 19, 2011.

16. The '474 patent, on its face, is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative as the Active Ingredient," and states its date of issue as September 16, 2014.

17. The '872 patent, on its face, is titled "Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative as the Active Ingredient," and states its date of reissue as April 29, 2014.

18. The '872 patent is the reissue patent of U.S. Patent No. 7,750,029, which issued on July 6, 2010.

Sawai's ANDA and Notice Letter

19. Sawai USA, Inc. has submitted ANDA No. 209446 to the FDA, seeking approval to engage in commercial manufacture, use, or sale of 25 mg mirabegron extended-release tablets (Sawai's ANDA Product) prior to the expiration of the Myrbetriq® patents.

20. ANDA No. 209446 contained Paragraph IV certifications under 21 U.S.C. §355(j)(2)(A)(vii)(IV) that the Myrbetriq® patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation into the United States of Sawai's ANDA Product.

21. On or about September 12, 2016, Sawai sent a notice letter providing notice of Sawai USA, Inc.'s submission of ANDA No. 209446 to the FDA ("the Notice Letter") to API and Astellas Pharma Global Development, Inc. The Notice Letter contained notifications of Sawai USA, Inc.'s Paragraph IV Certifications to the FDA that the Myrbetriq® patents are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of Sawai's ANDA Product.

22. On or around October 17, 2016, Astellas filed this lawsuit alleging that Sawai infringes the '532, '117, '049, '474, and '872 patents based on Sawai's filing of ANDA No. 209446.

23. Sawai denies that it infringes any valid claim of the patents-in-suit.

24. Unless enjoined, Astellas will continue to assert that Sawai infringes the Myrbetriq® patents and will continue to impair Sawai's ability to market its ANDA Product, causing irreparable harm to Sawai's business.

COUNT I

(Declaration of Invalidity of the '532 Patent)

25. Sawai incorporates by reference Paragraphs 1 through 24 as if fully set forth herein.

26. There is an actual, substantial, and continuing case or controversy between Sawai and API regarding, *inter alia*, the invalidity of the '532 patent.

27. One or more of the claims of the '532 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. §101 *et seq.*, including, *e.g.*, §§ 103 and 112, and/or other judicially-created bases for invalidation.

28. For example, one or more of the claims of the '532 patent are obvious at least in light of, *inter alia*, Blin *et al.*, Structural and Conformational Features Determining Selective Signal Transduction in the β3-Adrenergic Receptor, Molecular Pharmacology, Vol. 44, 1094-1104 (1993), U.S. Patent No. 6,011,048, U.S. Patent No. 5,451,677, U.S. Patent No. 5,541,197, U.S. Patent No. 5,223,614, U.S. Patent No. 5,321,036, WO 1995/029159, Silverman, The Organic Chemistry of Drug Design and Drug Action, Academic Press, Inc. 1992, pp. 19-23, and/or Thornber, "Isosterism and Molecular Modification in Drug Design" (1979), each taken alone or in combination with each other or additional prior art. A person of ordinary skill in the art would have been motivated to alter or combine one or more of these references and had a reasonable expectation of success in making mirabegron or its salts and that mirabegron or its salts would have a pharmaceutical utility. In the alternative, one or more of the claims of the '532 are invalid under 35 U.S.C. §112 at least because they lack enablement and/or adequate written description.

29. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. §355(j)(5)(c)(i)(II), 35 U.S.C. §271(e)(5), and 28 U.S.C. §§ 2201 *et seq.*, Sawai is entitled to a declaratory judgment that one or more claims of the '532 patent are invalid.

COUNT II

(Declaration of Noninfringement of the '532 Patent)

30. Sawai incorporates by reference Paragraphs 1 through 29 as if fully set forth herein.

31. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality

to warrant the issuance of a declaration of rights by the Court exists between Sawai and API concerning the infringement of the '532 patent.

32. The manufacture, use, sale, offer for sale, and/or importation into the United States of Sawai's ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '532 patent, either literally or under the doctrine of equivalents, at least because each of the claims of the '532 patent that API could assert against Sawai are invalid as set forth above in Count I of Sawai's counterclaims, and an invalid claim cannot be infringed.

33. A definite and concrete, real and substantial, justiciable controversy exists between Sawai and API concerning the alleged infringement by Sawai's ANDA Product of the '532 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

34. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. §355(j)(5)(c)(i)(II), 35 U.S.C. §271(e)(5), and 28 U.S.C. § 2201 *et seq.*, Sawai is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '532 patent, either literally or under the doctrine of equivalents.

COUNT III

(Declaration of Invalidity of the '117 Patent)

35. Sawai incorporates by reference Paragraphs 1 through 34 as if fully set forth herein.

36. There is an actual, substantial, and continuing case or controversy between Sawai and API regarding, *inter alia*, the invalidity of the '117 patent.

37. One or more of the claims of the '117 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 *et seq.*, including, *e.g.*, §§ 102, 103, and/or 112, and/or other judicially created bases for invalidation.

38. For example, one or more of the claims of the '117 Patent are invalid under § 102 at least because they are anticipated by PCT WO 99/20607 and/or the '532 patent. Also, one or more of the claims of the '117 patent are obvious at least in light of, *inter alia*, PCT WO 99/20607; the '532 patent; Bastin, *et al.*, "Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities," Org. Process Res. & Dev., Vol. 4, 427–35 (July 19, 2000) ("Bastin"); Bavin, M., "Polymorphism in Process Development," Chemistry & Industry, Vol. 21, 527–29 (August 21, 1989) ("Bavin"); Byrn *et al.*, "Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations," Pharmaceutical Research, Vol. 12, No. 7, 945–54, (1995) ("Byrn"); Caira, M.R., "Crystalline Polymorphism of Organic Compounds, in Design of Organic Solids," Topics in Current Chemistry, Vol. 198, 163–208 (1998) ("Caira"); Gold, D.H. & Byrn, S., "Product Quality Research Initiative and Bulk Actives Post Approval Change," Drug Information Journal, Vol. 33, 777-84 (1999) ("Gold & Byrn"); Guideline For Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) (February 1987) ("FDA Guidelines"); Guillory, J.K., "Ch. 5 – Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids" in Polymorphism in Pharmaceutical Sciences (H.G. Brittain ed., Marcel Dekker New York) (1999) ("Guillory"); Yu *et al.*, "Physical Characterization of Polymorphic Drugs: an Integrated Characterization Strategy," Pharmaceutical Science & Technology Today, Vol. 1, No. 3, 118–27 (June 1998) ("Yu"); Borka, L., Acta Pharm. Jugosl., 40:71–94 (1990) ("Borka"); Brittain, H., J. Pharm. Sci., 86:404–412 (1997) ("Brittain 1997"); Brittain, H., in Polymorphism in Pharmaceutical Solids, Brittain, H.G. ed., 227–278 (1999) ("Brittain 1999"); Canadian Patent Application Publication 2,305,802; Cardew, P.T. and Davey, R.J., Proc. R. Soc. Lond. A., 398:415-428 (1985) ("Cardew"); Fiese, E.F. and Hagen, T.A. in The Theory and Practice of

Industrial Pharmacy, Lachman, L. *et al*., eds., 171-196 (1986) ("Fiese"); Haleblian, J. and McCrone, W., J. Pharm. Sci., 58(8):911-29 (1969) ("Haleblian"); Remington; The Science and Practice of Pharmacy, Gennaro, A. *et al*. eds. (29th ed. 2000) ("Remington"); Sato, K., J. Phys. D.: Appl. Phys., 26:B77–B84 (1993) ("Sato"); Gould, Salt Selection for Basic Drugs, 33 Int. J. Pharm., 201–217 (1986) ("Gould"); Boatman *et. al*., A Four-Stage Approach to New Drug Development, 5 Pharm. Technol. 46–56 (1981) ("Boatman"); and/or M.J. Jozwiakowski, Alteration of the Solid State of the Drug Substance: Polymorphs, Solvates, and Amorphous Forms, in Water-Insoluble Drug Formation 525 (Rong Liu ed., 2000) ("Jozwiakowski"), each taken alone or in combination with each other or additional prior art. A person of ordinary skill in the art would have been motivated to alter or combine one or more of these references and had a reasonable expectation of success of obtaining the claimed polymorphs of mirabegron. In the alternative, one or more of the claims of the '117 patent are invalid under 35 U.S.C. § 112 at least because they lack enablement and/or adequate written description, and/or are indefinite.

39. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 et seq., Sawai is entitled to a declaratory judgment that one or more claims of the '117 patent are invalid.

COUNT IV

(Declaration of Noninfringement of the '117 Patent)

40. Sawai incorporates by reference Paragraphs 1 through 39 as if fully set forth herein.

41. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sawai and API concerning the infringement of the '117 patent.

42. The manufacture, use, sale, offer for sale, and/or importation into the United States of Sawai's ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents, at least because Sawai's Proposed ANDA Product does not and will not contain the crystal(s) of mirabegron claimed in the '117 patent and/or each of the claims of the '117 patent that API could assert against Sawai are invalid as set forth above in Count III of Sawai's counterclaims, and an invalid claim cannot be infringed.

43. A definite and concrete, real and substantial, justiciable controversy exists between Sawai and API concerning the alleged infringement by Sawai's ANDA Product of the '117 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

44. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 et seq., Sawai is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '117 patent, either literally or under the doctrine of equivalents.

COUNT V

(Declaration of Invalidity of the '049 Patent)

45. Sawai incorporates by reference Paragraphs 1 through 44 as if fully set forth herein.

46. There is an actual, substantial, and continuing case or controversy between Sawai and API regarding, *inter alia*, the invalidity of the '049 patent.

47. One or more of the claims of the '049 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 *et seq.*, including, *e.g.*, §§ 102, 103, and 112, and/or other judicially created bases for invalidation.

48. For example, one or more of the claims of the '049 Patent are invalid under § 102 at least because they are anticipated by PCT WO 99/20607 and/or the '532 patent. Also, one or more of

the claims of the '049 patent are obvious at least in light of at least PCT WO 99/20607; the '532 patent; Bastin *et al.*, "Salt Selection and Optimisation Procedures for Pharmaceutical New Chemical Entities," Org. Process Res. & Dev., Vol. 4, 427–35 (July 19, 2000) ("Bastin"); Bavin, M., "Polymorphism in Process Development," Chemistry & Industry, Vol. 21, 527–29 (August 21, 1989) ("Bavin"); Byrn *et al.*, "Pharmaceutical Solids: A Strategic Approach to Regulatory Considerations," Pharmaceutical Research, Vol. 12, No. 7, 945–54, (1995) ("Byrn"); Caira, M.R., "Crystalline Polymorphism of Organic Compounds, in Design of Organic Solids," Topics in Current Chemistry, Vol. 198, 163–208 (1998) ("Caira"); Gold, D.H. & Byrn, S., "Product Quality Research Initiative and Bulk Actives Post Approval Change," Drug Information Journal, Vol. 33, 777–84 (1999) ("Gold & Byrn"); Guideline For Submitting Supporting Documentation in Drug Applications for the Manufacture of Drug Substances, Center for Drug Evaluation and Research (CDER), Food and Drug Administration (FDA) (February 1987) ("FDA Guidelines"); Guillory, J.K., "Ch. 5 – Generation of Polymorphs, Hydrates, Solvates, and Amorphous Solids" in Polymorphism in Pharmaceutical Sciences (H.G. Brittain ed., Marcel Dekker New York) (1999) ("Guillory"); Yu et al., "Physical Characterization of Polymorphic Drug: an Integrated Characterization Strategy," Pharmaceutical Science & Technology Today, Vol. 1, No. 3, 118–27 (June 1998) ("Yu"); Borka, L., Acta Pharm. Jugosl., 40:71–94 (1990) ("Borka"); Brittain, H., J. Pharm. Sci., 86:404–412 (1997) ("Brittain 1997"); Brittain, H., in Polymorphism in Pharmaceutical Solids, Brittain, H.G. ed., 227–278 (1999) ("Brittain 1999"); Canadian Patent Application Publication 2,305,802; Cardew, P.T. and Davey, R.J., Proc. R. Soc. Lond. A., 398:415–428 (1985) ("Cardew"); Fiese, E.F. and Hagen, T.A. in The Theory and Practice of Industrial Pharmacy, Lachman, L. *et al*., eds., 171–196 (1986) ("Fiese"); Haleblian, J. and McCrone, W., J. Pharm. Sci., 58(8):911–29 (1969) ("Haleblian"); Remington: The Science and

Practice of Pharmacy, Gennaro, A. *et al*. eds. (29th ed. 2000) ("Remington"); Sato, K., J. Phys. D.: Appl. Phys., 26:B77–B84 (1993) ("Sato"); Gould, Salt Selection for Basic Drugs, 33 Int. J. Pharm., 201–217 (1986) ("Gould"); Boatman, *et. al*., A Four-Stage Approach to New Drug Development, 5 Pharm. Technol. 46–56 (1981) ("Boatman"); and/or M.J. Jozwiakowski, Alteration of the Solid State of the Drug Substance: Polymorphs, Solvates, and Amorphous Forms, in Water-Insoluble Drug Formation 525 (Rong Liu ed., 2000) ("Jozwiakowski"), each taken alone or in combination with each other or additional prior art. A person of ordinary skill in the art would have been motivated to alter or combine one or more of these references and had a reasonable expectation of success of obtaining the claimed polymorphs of mirabegron. In the alternative, one or more of the claims of the '049 Patent are invalid under 35 U.S.C. § 112 at least because they lack enablement and/or adequate written description, and/or are indefinite.

49. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 *et seq*., Sawai is entitled to a declaratory judgment that one or more claims of the '049 patent are invalid.

COUNT VI

(Declaration of Noninfringement of the '049 Patent)

50. Sawai incorporates by reference Paragraphs 1 through 49 as if fully set forth herein.

51. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sawai and API concerning the infringement of the '049 patent.

52. The manufacture, use, sale, offer for sale, and/or importation into the United States of Sawai's ANDA Product has not, does not, and will not infringe, induce infringement of, or

contribute to the infringement of any valid or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents at least because Sawai's Proposed ANDA Product does not and will not contain the crystal form(s) of mirabegron claimed in the '049 patent; the label for Sawai's Proposed ANDA Product does not and will not include an indication for treating diabetes; and/or each of the claims of the '049 patent that API could assert against Sawai are invalid as set forth above in Count V of Sawai's counterclaims, and an invalid claim cannot be infringed.

53. A definite and concrete, real and substantial, justiciable controversy exists between Sawai and API concerning the alleged infringement by Sawai's ANDA Product of the '049 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

54. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 et seq., Sawai is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '049 patent, either literally or under the doctrine of equivalents.

COUNT VII

(Declaration of Invalidity of the '474 Patent)

55. Sawai incorporates by reference Paragraphs 1 through 54 as if fully set forth herein.

56. There is an actual, substantial, and continuing case or controversy between Sawai and API regarding, *inter alia*, the invalidity of the '474 patent.

57. One or more of the claims of the '474 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 *et seq.*, including, *e.g.*, §§ 103 and 112, and/or other judicially-created bases for invalidation.

58. For example, one or more of the claims of the '474 patent are obvious in light of at least Blin *et al.*, Structural and Conformational Features Determining Selective Signal Transduction in the β3-Adrenergic Receptor, Molecular Pharmacol., Vol. 44, 1094–1104 (1993) ("Blin"); Igawa

et al., "Functional and Molecular Biological Evidence of β 3-Adrenoceptors in the Human Detrusor," J. Urol., Vol. 157, No. 4, 175 (April 1997) ("Igawa 1997a"); Park *et al.*, "Existence of β3-Adrenoceptor and its Functional Roll [sic] in the Human Ureter," J. Urol., Vol. 157, No. 4, 77 (April 1997) ("Park"); Igawa *et al.*, "Possible β3-adrenoceptor-mediated relaxation of the human detrusor," Acta Physiol. Scand., Vol. 164, 117–118 (1998) ("Igawa 1998"); Fujimura *et al.*, Expression and Possible Functional Role of the β3-Adrenoceptor in Human and Rat Detrusor Muscle, J. Urol., Vol. 161, 680–85 (February 1999) ("Fujimura 1999"); Takeda *et al.*, "Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β_3-Adrenoceptor Agonist, CL316, 243, and Various Smooth Muscle Relaxants," J. Pharmacol. & Exper. Therapeutics, Vol. 293(3), 939–45 (2000) ("Takeda"); Igawa *et al.*, "Functional Investigation of Beta-Adrenoceptors in Isolated Human Detrusor – Using the Novel Selective β_3-Adrenoceptor Agonist, KUC-7322," 32nd Annual Meeting of International Continence Society, Heidelberg, Germany, August 28–30, 2002 ("Igawa 2002"); the '532 Patent, WO 99/20607, U.S. Patent No. 6,291,491 ("the '491 Patent"); WO 1998/007445, EP 0958835, Canadian Patent Publication 2,305,802; Igawa *et al*., Functional and Molecular Biological Evidence for a Possible β_3-Adrenoceptor in the Human Detrusor Muscle, 126 Brit. J. Pharmacol. 819 (1999) ("Igawa 1999"); Takeda *et al*., Effects of β_3-Adrenoceptor Stimulation on Prostaglandin E_2-Induced Bladder Hyperactivity and on the Cardiovascular System in Conscious Rats, 21 Neurourol. & Urodynamics 558 (2002); Takeda *et al*., Evidence for β_3-Adrenoceptor Subtypes in Relaxation of the Human Urinary Bladder Detrusor: Analysis by Molecular Biological and Pharmacological Methods, 288 J. Pharmacol. & Exper. Therapeutics 1367 (1999); Takeda *et al*., Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β3-Adrenoceptor Agonist, CL316,243, and Various Smooth Muscle Relaxants, 293 J. Pharmacol. & Exper.

Therapeutics 939 (2000); H.M. Dallosso *et al*., The Association of Diet and Other Lifestyle Factors with Overactive Bladder and Stress Incontinence: A Longitudinal Study in Women, 92 BJU Int'l 69 (2003); Brown *et al*., Urinary Incontinence in Older Women: Who Is at Risk?, 87 Obstetrics & Gynecology 715 (1996); Mommsen et al., Body Mass Index and Adult Female Urinary Incontinence, 12 World J. Urol. 319 (1994); 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, Publication Date (2001) (Web, April 3, 2001) ("Tanaka"); Yano *et al*., "The Reason Why Prostatic Hyperplasia Causes Lower Urinary Tract Symptoms," Asian Med. J. 44, 2 Feb. 2001 ("Yano"); 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"); Canadian Patent Application Publication No. 2,305,802; Canadian Patent Application Publication No. 2,398,199; Igawa, Y. *et al*., Proc. 1997 ICS Annual Meeting, Abstract 14, Neurourol. Urodynamics, 16:363–365 ("Igawa 1997b"); Igawa, Y. *et al*., Brit J. Pharmacol., 126:819–825 (1999) ("Igawa 1999"); Woods. M. *et al.*, J. Urology, 166:1142–47 ("Woods"); Canadian Patent Application Publication No. 2,263,659; Sellers, *et al.*, Potential therapeutic targets for treatment of the overactive bladder, 19 World. J. Urol. 307–311 (2001) ("Sellers"); Yamaguchi, β3-Adrenoreceptors in Human Detrusor Muscle, J. Urol., 59 (Suppl. 5A), 25–29 (2002) ("Yamaguchi"); Michel *et al*., Effect of Diabetes on Lower Urinary Tract Symptoms in Patients With Benign Prostatic Hyperplasia, 163 J. Urol. 1725–1729 (2000) ("Michel"); Knutson et al., BPH with Coexisting Overactive Bladder Dysfunction – An Everyday Urological Dilemma, Neurourol. & Urodynamics 20:237-247 (2001) ("Knutson"); WO02/000622; and/or U.S. Patent No. 6,699,860, each taken alone or in combination with each other or additional prior art. A person

of ordinary skill in the art would have been motivated to alter or combine one or more of these references and had a reasonable expectation of success of in treating OAB with mirabegron free base form or as a salt. Also, one or more of the claims of the '474 Patent are invalid under 35 U.S.C. § 112 at least because they lack enablement and/or adequate written description, and/or are indefinite.

59. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 *et seq*., Sawai is entitled to a declaratory judgment that one or more claims of the '474 patent are invalid.

COUNT VIII

(Declaration of Noninfringement of the '474 Patent)

60. Sawai incorporates by reference Paragraphs 1 through 59 as if fully set forth herein.

61. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sawai and API concerning the infringement of the '474 patent.

62. The manufacture, use, sale, offer for sale, and/or importation into the United States of Sawai's ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '474 patent, either literally or under the doctrine of equivalents at least because the proposed label of Sawai's ANDA Product does not and will not include an indication for treating overactive bladder that is a result of benign prostatic hyperplasia or pollakiuria and/or each of the claims of the '474 patent that API could assert against Sawai are invalid as set forth above in Count VII of Sawai's counterclaims, and an invalid claim cannot be infringed.

63. A definite and concrete, real and substantial, justiciable controversy exists between Sawai and API concerning the alleged infringement by Sawai's ANDA Product of the '474 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

64. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 *et seq*., Sawai is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '474 patent, either literally or under the doctrine of equivalents.

COUNT IX

(Declaration of Invalidity of the '872 Patent)

65. Sawai incorporates by reference Paragraphs 1 through 64 as if fully set forth herein.

66. There is an actual, substantial, and continuing case or controversy between Sawai and API regarding, *inter alia*, the invalidity of the '872 patent.

67. One or more of the claims of the '872 patent are invalid for failure to comply with one or more of the requirements set forth in 35 U.S.C. § 101 *et seq.*, including, *e.g.*, §§ 103 and 112, and/or other judicially-created bases for invalidation.

68. For example, one or more of the claims of the '872 patent are obvious in light of at least Blin *et al.*, Structural and Conformational Features Determining Selective Signal Transduction in the β_3-Adrenergic Receptor, Molecular Pharmacol., Vol. 44, 1094–1104 (1993) ("Blin"); Igawa *et al.*, "Functional and Molecular Biological Evidence of β_3-Adrenoceptors in the Human Detrusor," J. Urol., Vol. 157, No. 4, 175 (April 1997) ("Igawa 1997a"); Park *et al.*, "Existence of β_3-Adrenoceptor and its Functional Roll [sic] in the Human Ureter," J. Urol., Vol. 157, No. 4, 77 (April 1997) ("Park"); Igawa *et al.*, "Possible β3-adrenoceptor-mediated relaxation of the human detrusor," Acta Physiol. Scand., Vol. 164, 117–118 (1998) ("Igawa 1998"); Fujimura *et al.*, Expression and Possible Functional Role of the β3-Adrenoceptor in Human and Rat Detrusor

Muscle, J. Urol., Vol. 161, 680–85 (February 1999) ("Fujimura 1999"); Takeda *et al.*, "Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β_3-Adrenoceptor Agonist, CL316, 243, and Various Smooth Muscle Relaxants," J. Pharmacol. & Exper. Therapeutics, Vol. 293(3), 939–45 (2000) ("Takeda"); Igawa *et al.*, "Functional Investigation of Beta-Adrenoceptors in Isolated Human Detrusor – Using the Novel Selective β_3-Adrenoceptor Agonist, KUC-7322," 32nd Annual Meeting of International Continence Society, Heidelberg, Germany, August 28–30, 2002 ("Igawa 2002"); the '532 Patent, WO 99/20607, U.S. Patent No. 6,291,491 ("the '491 Patent"); WO 1998/007445, EP 0958835, Canadian Patent Publication 2,305,802; Igawa *et al*., Functional and Molecular Biological Evidence for a Possible β_3-Adrenoceptor in the Human Detrusor Muscle, 126 Brit. J. Pharmacol. 819 (1999) ("Igawa 1999"); Takeda *et al*., Effects of β_3-Adrenoceptor Stimulation on Prostaglandin E_2-Induced Bladder Hyperactivity and on the Cardiovascular System in Conscious Rats, 21 Neurourol. & Urodynamics 558 (2002); Takeda *et al*., Evidence for β_3-Adrenoceptor Subtypes in Relaxation of the Human Urinary Bladder Detrusor: Analysis by Molecular Biological and Pharmacological Methods, 288 J. Pharmacol. & Exper. Therapeutics 1367 (1999); Takeda *et al*., Role of the β_3-Adrenoceptor in Urine Storage in the Rat: Comparison Between the Selective β_3-Adrenoceptor Agonist, CL316,243, and Various Smooth Muscle Relaxants, 293 J. Pharmacol. & Exper. Therapeutics 939 (2000); H.M. Dallosso *et al*., The Association of Diet and Other Lifestyle Factors with Overactive Bladder and Stress Incontinence: A Longitudinal Study in Women, 92 BJU Int'l 69 (2003); Brown *et al*., Urinary Incontinence in Older Women: Who Is at Risk?, 87 Obstetrics & Gynecology 715 (1996); Mommsen *et al*., Body Mass Index and Adult Female Urinary Incontinence, 12 World J. Urol. 319 (1994) ; 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, Publication Date (2001) (Web, April 3, 2001) ("Tanaka"); Yano *et al*., "The Reason Why Prostatic Hyperplasia Causes Lower Urinary Tract Symptoms," Asian Med. J. 44, 2 Feb. 2001 ("Yano"); 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"); Canadian Patent Application Publication No. 2,305,802; Canadian Patent Application Publication No. 2,398,199; Igawa, Y. *et al*., Proc. 1997 ICS Annual Meeting, Abstract 14, Neurourol. Urodynamics, 16:363–365 ("Igawa 1997b"); Igawa, Y. *et al*., Brit J. Pharmacol., 126:819–825 (1999) ("Igawa 1999"); Woods. M. *et al*., J. Urology, 166:1142–47 ("Woods"); Canadian Patent Application Publication No. 2,263,659; Sellers, *et al.*, Potential therapeutic targets for treatment of the overactive bladder, 19 World. J. Urol. 307–311 (2001) ("Sellers"); Yamaguchi, β_3-Adrenoreceptors in Human Detrusor Muscle, J. Urol., 59 (Suppl. 5A), 25–29 (2002) ("Yamaguchi"); Michel *et al*., Effect of Diabetes on Lower Urinary Tract Symptoms in Patients With Benign Prostatic Hyperplasia, 163 J. Urol. 1725–1729 (2000) ("Michel"); Knutson et al., BPH with Coexisting Overactive Bladder Dysfunction – An Everyday Urological Dilemma, Neurourol. & Urodynamics 20:237-247 (2001) ("Knutson");f WO02/000622; and/or U.S. Patent No. 6,699,860, each taken alone or in combination with each other or additional prior art. A person of ordinary skill in the art would have been motivated to alter or combine one or more of these references and had a reasonable expectation of success of in treating OAB with mirabegron free base form or as a salt. In the alternative, one or more of the claims of the '872 Patent are invalid under 35 U.S.C. §112 at least because they lack enablement and/or adequate written description, and/or are indefinite..

69. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 et seq., Sawai is entitled to a declaratory judgment that one or more claims of the '872 patent are invalid.

COUNT X

(Declaration of Noninfringement of the '872 Patent)

70. Sawai incorporates by reference Paragraphs 1 through 69 as if fully set forth herein.

71. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Sawai and API concerning the infringement of the '872 patent.

72. The manufacture, use, sale, offer for sale, and/or importation into the United States of Sawai's ANDA Product has not, does not, and will not infringe, induce infringement of, or contribute to the infringement of any valid or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents at least because the proposed label of Sawai's ANDA Product does not and will not include an indication for treating overactive bladder (a) that is a result of benign prostatic hyperplasia or pollakiuria; (b) in patients not suffering from diabetes; and/or (c) in patients that are not adults and/or each of the claims of the '474 patent that API could assert against Sawai are invalid as set forth above in Count IX of Sawai's counterclaims, and an invalid claim cannot be infringed.

73. A definite and concrete, real and substantial, justiciable controversy exists between Sawai and API concerning the alleged infringement by Sawai's ANDA Product of the '872 patent, which is of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.

74. Pursuant to Federal Rule of Civil Procedure 57, 21 U.S.C. § 355(j)(5)(c)(i)(II), 35 U.S.C. § 271(e)(5), and 28 U.S.C. §§ 2201 et seq., Sawai is entitled to a declaratory judgment that it has not, does not, and will not infringe, either directly or indirectly, any valid or enforceable claim of the '872 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Sawai respectfully requests this Court enter judgment in its favor granting the following relief:

A. dismissing Plaintiffs' Complaint with prejudice and denying each request for relief made by Plaintiffs;

B. declaring that all claims of the '532 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Sawai Product;

C. declaring all claims of the '532 patent invalid;

D. declaring that all claims of the '117 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Sawai Product;

E. declaring all claims of the '117 patent invalid;

F. declaring that all claims of the '049 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Sawai Product;

G. declaring all claims of the '049 patent invalid;

H. declaring that all claims of the '474 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Sawai Product;

I. declaring all claims of the '474 patent invalid;

J. declaring that all claims of the '872 patent are not infringed and will not be infringed by the manufacture, use, sale, offer for sale, marketing, or importation into the United States of the Sawai Product;

K. declaring all claims of the '872 patent invalid;

L. declaring that Sawai has a lawful right to obtain FDA approval for the product as described in ANDA No. 209446, and that Sawai has a lawful right to manufacture, import, use, sell, and/or offer to sell the product as described in ANDA No. 209446;

M. declaring that this is an exceptional case under 35 U.S.C. § 285;

N. awarding Sawai its fees, costs and expenses in this action pursuant to 35 U.S.C. § 285 and 28 U.S.C. § 1920, or any other applicable statute; and

O. awarding Sawai such other and further relief as the Court deems just and proper.

OF COUNSEL:

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