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. MSN PHARMACEUTICALS INC. and MSN LABORATORIES PRIVATE LIMITED, *Defendants*.	C.A. No. 23-cv-689-JFB-CJB

DEFENDANTS MSN PHARMACEUTICALS INC. AND MSN LABORATORIES PRIVATE LIMITED'S ANSWER AND DEFENSES

Defendants MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals") and MSN Laboratories Private Limited ("MSN Labs" and together with MSN Pharmaceuticals, "MSN"), by and through their undersigned counsel, hereby submit the following Answer and Defenses ("Answer") in response to the Complaint ("Complaint") filed by Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc. (collectively, "Astellas" or "Plaintiffs").

Pursuant to Federal Rule of Civil Procedure 8(b)(3), MSN denies all allegations in the Complaint, whether express or implied, that are not specifically admitted below. Any factual allegation below is admitted only as to the specific admitted facts, not as to any purported conclusions, characterizations, implications, or speculations that arguably follow from the admitted facts. MSN denies that Plaintiffs are entitled to the relief requested or any other relief. MSN responds to the Complaint as follows:

RESPONSE TO "THE PARTIES" [1]

A. Response to "Astellas Pharma Inc., Astellas Ireland Co., Ltd. and Astellas Pharma Global Development, Inc."

1. Plaintiff Astellas Pharma Inc. ("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. API was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

ANSWER: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 1 and therefore denies those allegations.

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 API.

ANSWER: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 2 and therefore denies those allegations.

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 API.

ANSWER: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 3 and therefore denies those allegations.

B. Response to "MSN Pharmaceuticals Inc. and MSN Laboratories Pvt. Ltd. (collectively, "MSN" or "Defendants")"

4. On information and belief, MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 20 Duke Rd., Piscataway, NJ, 08854.

ANSWER: MSN admits the allegations of paragraph 4.

5. On information and belief, MSN Laboratories Pvt. Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at MSN House, Plot No. C-24, Sanathnagar Industrial Estate, Hyderabad, Telangana, 500018, India.

[1] Plaintiffs' headings are reprinted here with the same language as used in Plaintiffs' Complaint for ease of reference, and do not constitute an admission by Defendants.

ANSWER: MSN admits that MSN Labs is a private limited company organized and existing under the laws of India having a place of business at MSN House, Plot No. C-24, Sanathnagar Industrial Estate, Hyderabad, Telangana, 500018, India. MSN denies the remaining allegations of paragraph 5.

6. On information and belief, MSN is in the business of, *inter alia*, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in this judicial district.

ANSWER: MSN admits that MSN Pharmaceuticals is in the business of, among other things, development and manufacture of generic pharmaceutical products. MSN further admits that MSN Labs is in the business of, among other things, the development, manufacture, sale, marketing, and distribution of generic drugs. MSN denies the remaining allegations of paragraph 6.

7. By a letter dated May 18, 2023 ("MSN's Notice Letter"), MSN notified Plaintiffs that MSN had submitted to the United States Food and Drug Administration ("FDA") Abbreviated New Drug Application ("ANDA") No. 218543 for mirabegron extended-release tablets, 25 mg and 50 mg ("MSN ANDA"), a drug product that is a generic version of Myrbetriq® extended-release tablets, in the 25 and 50 mg strengths ("MSN's ANDA Product"). On information and belief, the purpose of MSN's submission of the MSN ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of MSN's ANDA Product Prior to March 28, 2030.

ANSWER: MSN admits that it submitted a Notice Letter dated May 18, 2023 notifying Plaintiffs that MSN had submitted to the United States Food and Drug Administration ANDA No. 218543 for mirabegron extended-release tablets, 25 mg and 50 mg, which ANDA lists Myrbetriq® (mirabegron) extended-release tablets as the reference-listed drug. MSN further admits the purpose of MSN's submission of ANDA No. 218543 was to obtain approval under the Federal Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use,

or sale of MSN's proposed ANDA Product prior to March 28, 2030. MSN denies the remaining allegations of paragraph 7.

8. In MSN's Notice Letter, MSN notified Plaintiffs that as part of the MSN ANDA, MSN had filed a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification"), with respect to one of the then listed patents in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"), asserting that it is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of MSN's ANDA Product.

ANSWER: Admitted.

RESPONSE TO "NATURE OF ACTION"

9. This is an action for patent infringement of United States Patent No. 10,842,780 ("the '780 Patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to the ANDA submitted by MSN under Section 505(j) of the FDCA, 21 U.S.C. § 355(j), seeking FDA approval to market generic pharmaceutical products.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN admits that the Complaint purports to be an action for patent infringement of the '780 patent arising out of the filing of the ANDA submitted by MSN. MSN denies any such infringement. MSN admits that MSN Labs submitted ANDA No. 218543 to FDA seeking approval to sell its ANDA Product. MSN otherwise denies the remaining allegations in paragraph 9.

RESPONSE TO "JURISDICTION AND VENUE"

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

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN does not contest that this Court has subject matter jurisdiction over the suit based on the facts alleged by Plaintiffs.

11. This Court has personal jurisdiction over MSN because, *inter alia*, MSN has committed, or aided, abetted, contributed to, or participated in the commission of, tortious acts of patent infringement in filing ANDA No. 218534 that has led to foreseeable harm and injury to

Plaintiffs, and will imminently commit, or aid, abet, contribute to, or participate in the commission of, a tortious act of patent infringement by selling its ANDA Product throughout the United States and in this judicial district, which will lead to foreseeable harm and injury to Plaintiffs.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent that a response is required, MSN does not contest that this Court has personal jurisdiction over MSN for purposes of this litigation only. MSN denies the remaining allegations of paragraph 11.

12. This Court also has personal jurisdiction over MSN Pharmaceuticals Inc. because its affiliations with the State of Delaware, including by virtue of its incorporation in Delaware, are so continuous and systematic as to render MSN Pharmaceuticals Inc. essentially at home in this forum.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent that a response is required, MSN admits that MSN Pharmaceuticals is a corporation incorporated in Delaware. Further, MSN does not contest that this Court has personal jurisdiction over MSN for purposes of this litigation, only. MSN denies the remaining allegations of paragraph 12.

13. The Court also has personal jurisdiction over MSN Laboratories Pvt. Ltd. under Fed. R. Civ. P. 4(k)(2) because (a) Astellas's claims arise under federal law; (b) as a foreign defendant, MSN Laboratories Pvt. Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction; and (c) MSN Laboratories Pvt. Ltd. has sufficient contacts within 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 MSN Laboratories Pvt. Ltd. satisfies due process.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent that a response is required, MSN does not contest that this Court has personal jurisdiction over MSN for purposes of this litigation, only. MSN admits that MSN Labs prepared and submitted an ANDA to the FDA for the purpose of seeking approval to engage in the

commercial sale of MSN's ANDA Product in the United States. MSN denies the remaining allegations of paragraph 13.

14. The Court also has personal jurisdiction over MSN because, *inter alia*, this action arises from actions of MSN directed toward Delaware, and because MSN has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, MSN regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware, either on its own or through its affiliates. Upon information and belief, MSN derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business in Delaware.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent that a response is required, MSN does not contest that this Court has personal jurisdiction over MSN for the purposes of this litigation, only. MSN denies the remaining allegations of paragraph 14.

15. This Court also has personal jurisdiction over MSN because it has frequently availed itself of the legal protections of the State of Delaware, by, among other things, admitting jurisdiction and asserting counterclaims in lawsuits filed in the United States District Court for the District of Delaware. *See, e.g., Taiho Pharmaceutical Co., Ltd. et al. v. MSN Laboratories Private Ltd. et al.,* 23-00008 (D. Del.).

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN admits that it has asserted counterclaims in the action captioned *Taiho Pharmaceutical Co., Ltd. et al. v. MSN Laboratories Private Ltd. et al.*, 23-00008 (D. Del.). MSN does not contest that this Court has personal jurisdiction over MSN for purposes of this litigation only. MSN denies the remaining allegations of paragraph 15.

16. For these reasons, and for other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN does not contest that this Court has personal

jurisdiction over MSN for purposes of this litigation only. MSN denies the remaining allegations of paragraph 16.

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

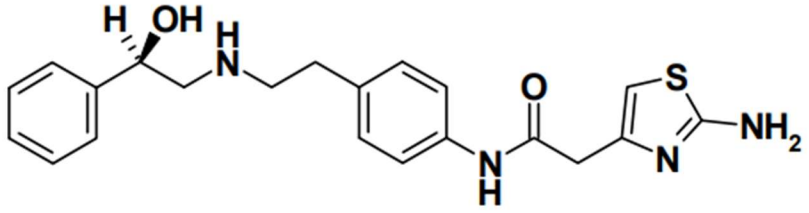
ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent that a response is required, MSN does not contest that venue is proper in this Court for purposes of this litigation only. MSN denies any remaining allegation of paragraph 17.

RESPONSE TO "MYRBETRIQ® TABLETS"

18. 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.

ANSWER: Upon information and belief, and based upon Plaintiffs' allegations, MSN admits that Astellas Pharma Global Development, Inc. is listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") as the Applicant Holder of NDA No. 202611 of the drug by the brand name of Myrbetriq, extended release oral tablets, 25 mg and 50 mg. Upon information and belief, and based upon Plaintiffs' allegations, MSN admits that Myrbetriq® contains the active ingredient mirabegron. MSN further admits, upon information and belief, that the Orange Book lists the approval date of NDA No. 202611 as June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets.

19. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetic acid anilide, (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: MSN admits, upon information and belief, that mirabegron has been referred to chemically as 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. MSN further admits, upon information and belief, that mirabegron can be depicted as the formula shown above. MSN is without sufficient information to admit or deny the remaining allegations of paragraph 19, and thus denies them.

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

ANSWER: Upon information and belief and based upon Plaintiffs' allegations, MSN admits that Myrbetriq® extended-release tablets, containing 25 mg or 50 mg of mirabegron, are indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

21. Myrbetriq® Tablets comprise a sustained release hydrogel-forming formulation containing, *inter alia*, a means for forming a hydrogel and a means for ensuring penetration of water into the tablets.

ANSWER: MSN is without sufficient information to admit or deny the allegations of paragraph 21, and thus denies them.

22. For quality control purposes in the U.S. market, Myrbetriq® Tablets are subjected to dissolution testing using the United States Pharmacopeia ("USP") Apparatus I. A dissolution test evaluates the rate and extent that a compound forms a solution under carefully controlled conditions. Within the context of regulatory approval, the USP dissolution test helps safeguard against the release of drug products that do not perform acceptably. USP Apparatus I (basket) and II (paddle) provide a platform to evaluate the *in vitro* performance of dosage forms using standardized conditions. These two apparatus, and associated procedures, have become widely used and accepted.

ANSWER: MSN is without sufficient information to admit or deny the allegations of paragraph 22, and thus denies them.

23. When measured in accordance with the United States Pharmacopeia ("USP") dissolution apparatus II, using 900 mL of USP buffer and having a pH of 6.8 at a paddle rotation

speed of 200 rpm ("USP II Method"), the Myrbetriq® Tablets release 39% or less of mirabegron after 1.5 hours, and at least 75% mirabegron after 7 hours.

ANSWER: MSN is without sufficient information to admit or deny the allegations of paragraph 23, and thus denies them.

24. The '780 Patent is listed in the Orange Book in connection with NDA 202611 as covering Myrbetriq®.

ANSWER: Upon information and belief, and based upon Plaintiffs' allegations, MSN admits that U.S. Patent No. 10,842,780 is listed in the Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 202611. MSN denies the remaining allegations of paragraph 24.

RESPONSE TO "THE PATENT-IN-SUIT"

25. The United States Patent & Trademark Office ("PTO") duly and legally issued the '780 Patent, entitled "Pharmaceutical Composition for Modified Release," on November 24, 2020. A true and correct copy of the '780 Patent is attached as **Exhibit A**.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN admits that the patent attached as Exhibit A purports to be the '780 patent. MSN admits that the patent attached is entitled "Pharmaceutical Composition for Modified Release" and that it states it was issued on November 24, 2020. To the extent paragraph 25 contains any additional allegations, MSN denies them.

26. API is the record owner and assignee of the '780 Patent.

ANSWER: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 26 and therefore denies those allegations.

27. The '780 Patent will expire no earlier than September 28, 2029.

ANSWER: Upon information and belief, MSN admits that the Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book") lists U.S. Patent No.

10,842,780 as expiring on September 28, 2029. To the extent paragraph 27 contains any additional allegations, MSN denies them.

28. The '780 Patent's pediatric exclusivity extends to March 28, 2030.

ANSWER: Upon information and belief, MSN admits that the Orange Book lists the '780 Patent as having pediatric exclusivity until March 28, 2030. To the extent paragraph 28 contains any additional allegations, MSN denies them.

29. AICL is the exclusive licensee of the '780 Patent 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: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 29 and therefore denies those allegations.

30. APGD has contracted with AICL to, *inter alia*, clinically develop mirabegron, prepare and submit NDA No. 202611 for marketing approval of Myrbetriq® Tablets in the United States.

ANSWER: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 30 and therefore denies those allegations.

31. AICL has contracted with Astellas Pharma US, Inc., a subsidiary of API to, *inter alia*, market and sell Myrbetriq® Tablets, in the United States on its behalf.

ANSWER: MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 31 and therefore denies those allegations.

32. Myrbetriq® Tablets are covered by one or more claims of the '780 Patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 32 and therefore denies those allegations.

33. On June 9, 2023, the Court in *Astellas Pharma Inc., et al. v. Sandoz Inc., et al.*, CA 20-1589 (D. Del.) issued a judgment (D.I. 572) ("June 9, 2023 Decision"), declaring that the '780 patent was invalid.

ANSWER: Admitted.

34. Astellas appealed the June 9, 2023 Decision to the Court of Appeals for the Federal Circuit on June 12, 2023.

ANSWER: Admitted.

35. Notwithstanding the June 9, 2023 Decision, Astellas believes the '780 patent is valid, and that the June 9, 2023 Decision will be reversed on appeal.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN is without sufficient knowledge or information to form a belief as to the allegations of paragraph 35 and therefore denies those allegations.

RESPONSE TO "MIRABEGRON ANDA FILERS"

36. In June 2013, FDA issued a notice in the Federal Register (78 Fed. Reg. 37230 at 31 (June 20, 2013)) regarding bioequivalence guidance to be published on its website for mirabegron ANDAs. On its website, FDA lists the following dissolution requirements for mirabegron ANDA filers in order to establish bioequivalence with Myrbetriq® Tablets ("Mirabegron Bioequivalence Guidance"):

Drug Name	Dosage Form	USP Apparatus	Speed (RPMs)	Medium	Volume (mL)	Recommended Sampling Times (minutes)	Date Updated
Mirabegron	Tablet (Extended Release)	I (Basket)	100	Phosphate Buffer, pH 6.8	900	1, 3, 5, 7, 8.5, 10 and 12 hours	05/09/2013

ANSWER: MSN admits that FDA issued a notice in the Federal Register (78 Fed. Reg. 37230 at 31 (June 20, 2013)) regarding bioequivalence guidance to be published on its website for mirabegron ANDAs, and FDA dissolution requirements for mirabegron ANDA filers on its website. To the extent paragraph 36 contains any additional allegations, MSN denies them.

37. On information and belief, each mirabegron ANDA filer will be required to meet this dissolution method, or an equivalent dissolution method, to meet its bioequivalence requirements for its proposed ANDA product using Myrbetriq® Tablets as the reference

standard. On information and belief, a proposed mirabegron ANDA product will have equivalent dissolution properties to Myrbetriq® Tablets as measured by USP Apparatus I and II.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN is without sufficient information to admit or deny the allegations of paragraph 37, and thus denies them.

RESPONSE TO "CLAIMS FOR RELIEF"

RESPONSE TO "COUNT I: INFRINGEMENT OF THE '780 PATENT BY DEFENDANTS UNDER 35 U.S.C. § 271(e)(2)(A) AND 35 U.S.C. § 271(a)"

38. Plaintiffs incorporate by reference and reallege paragraphs 1 through 37 above as though fully restated herein.

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent a response is required, MSN incorporates by references its response to each preceding paragraph as if fully set forth herein.

39. MSN, by filing ANDA No. 218543, has necessarily represented to the FDA that, upon approval, MSN's ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets.

ANSWER: MSN admits that MSN's proposed ANDA Product will have the same active ingredient, method of administration, dosage form, and dosage amount as Myrbetriq® Tablets, and will be bioequivalent to Myrbetriq® Tablets. MSN denies the remaining allegations of paragraph 39.

40. MSN, via its Notice Letter, has indicated its intent to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of MSN's ANDA Product prior to the expiration of the '780 Patent's patent term and pediatric exclusivity period.

ANSWER: MSN admits that it submitted MSN's ANDA to obtain approval to engage in the commercial manufacture, use, offer or sale of MSN's proposed ANDA Product prior to the

expiration of the '780 Patent's patent term and pediatric exclusivity period. MSN otherwise denies the allegations of paragraph 40.

41. In MSN's Notice Letter, MSN does not deny that MSN's ANDA Product is covered by one or more claims of the '780 Patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN avers that the '780 patent is invalid and MSN's ANDA Product cannot be covered by an invalid claim. MSN denies any remaining allegations of paragraph 41.

42. MSN's submission of ANDA No. 218534 seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of MSN's ANDA Product, prior to the expiration of the '780 Patent, constitutes infringement of one or more of the claims of the '780 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 42.

43. On information and belief, MSN intends to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of MSN's ANDA Product upon final approval of ANDA No. 218534 and prior to the expiration of the pediatric exclusivity associated with the '780 Patent.

ANSWER: MSN admits that it submitted MSN's ANDA No. 218543 to obtain approval to engage in the commercial manufacture, use, or sale of MSN's proposed ANDA Product upon final approval of ANDA No. 218543 and prior to the expiration of the pediatric exclusivity associated with the '780 patent. MSN otherwise denies the allegations of paragraph 43.

44. Astellas has not received from MSN notice of its filing of a Paragraph IV certification for its ANDA Product as to any other patent listed in the Orange Book for Myrbetriq® other than the '780 Patent. On information and belief, MSN has filed certifications of the type described in Section 505(j)(2)(A)(vii)(III) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(III) ("Paragraph III certification"), with respect to the other Orange Book listed patents for Myrbetriq®, including United States Patent Nos.: 7,342,117; 7,982,049; 8,835,474; and RE44,872.

ANSWER: MSN admits that it has not submitted a Paragraph IV certification for its proposed ANDA Product for any other patent presently listed in the Orange Book for Myrbetriq® other than the '780 Patent. To the extent this paragraph contains any additional allegations, MSN denies those allegations.

45. MSN's ANDA Product contains either 25 mg or 50 mg of mirabegron in extended-release tablets. MSN's ANDA Product will also be bioequivalent to Myrbetriq® Tablets.

ANSWER: MSN admits that MSN's proposed ANDA Product contains either 25 mg or 50 mg of mirabegron in extended-release tablets. MSN further admits that MSN's proposed ANDA Product will be bioequivalent to Myrbetriq® Tablets.

46. On information and belief, and as required by the Mirabegron Bioequivalence Guidance, MSN uses the dissolution method (or its equivalent) to establish MSN's ANDA Product is bioequivalent to Myrbetriq® Tablets. On information and belief, MSN's ANDA Product will have equivalent dissolution properties, as measured by USP Apparatus I and II, to Myrbetriq® Tablets, which use a hydrogel formulation. On information and belief, because of the dissolution requirements contained within the Mirabegron Bioequivalence Guidance, including the use of Myrbetriq® Tablets as the reference standard, MSN's ANDA Product uses a hydrogel formulation, the same as or equivalent to the Myrbetriq® Tablets formulation, that is covered by one or more claims of the '780 Patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 46. MSN denies the remaining allegations of paragraph 46.

47. On information and belief, MSN's ANDA Product contains a hydrogel-forming polymer and an additive that meet the claim limitations of one or more claims of the '780 Patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 47.

48. On information and belief, and based on the representations in MSN's Notice Letter, MSN's ANDA Product is a sustained release hydrogel forming formulation of mirabegron having either 25 mg or 50 mg mirabegron, containing, *inter alia*, a hydrogel-forming polymer and an additive that are covered by one or more claims of the '780 Patent and having a dissolution profile meeting the dissolution rate element of the claims.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 48.

49. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of MSN's ANDA Product would infringe one or more claims of the '780 Patent, or their equivalents, under 35 U.S.C. § 271(a).

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 49.

50. Unless MSN is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by MSN's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 50.

RESPONSE TO "COUNT II: CONTRIBUTORY INFRINGEMENT OF THE '780 PATENT BY DEFENDANTS UNDER 35 U.S.C. § 271(c)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent a response is required, MSN incorporates by references its response to each preceding paragraph as if fully set forth herein.

52. On information and belief, if ANDA No. 218543 is approved by the FDA, MSN will manufacture MSN's ANDA Product, and will, without authority, induce or cause others to import MSN's ANDA Product into the United States, or will offer to sell or sell MSN's ANDA Product within the United States.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 52.

53. MSN's ANDA Product constitutes a material part of the inventions covered by the claims of the '780 Patent and has no substantial non-infringing uses.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 53.

54. On information and belief, MSN has had, and continues to have, knowledge that there is no substantial non-infringing use for MSN's ANDA Product.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 54.

55. MSN's actions will constitute contributory infringement of the '780 Patent pursuant to 35 U.S.C. § 271(c).

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 55.

56. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN as to the liability of MSN's infringement of the '780 Patent. MSN's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from MSN's threatened imminent actions.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 56.

57. Unless MSN is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by MSN's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 57.

RESPONSE TO "COUNT III: INDUCED INFRINGEMENT OF THE '780 PATENT BY DEFENDANTS UNDER 35 U.S.C. § 271(b)"

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

ANSWER: No response is required to the general re-allegation and incorporation by reference of each preceding paragraph. To the extent a response is required, MSN incorporates by references its response to each preceding paragraph as if fully set forth herein.

59. On information and belief, if ANDA No. 218543 is approved by the FDA, MSN will manufacture MSN's ANDA Product, and will, without authority, induce or cause others to import MSN's ANDA Product into the United States, offer for sale or sell MSN's ANDA Product in the United States, or use MSN's ANDA Product in the United States.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 59.

60. MSN's ANDA Product and the use thereof would directly infringe the '780 Patent under 35 U.S.C. § 271(a).

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 60.

61. On information and belief, MSN has had, and continues to have, knowledge of the '780 Patent.

ANSWER: Admitted.

62. On information and belief, MSN has had, and continues to have, knowledge that MSN's ANDA Product and the use thereof would directly infringe the '780 Patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 62.

63. MSN's inducement of others to import MSN's ANDA Product into the United States, offer for sale or sell MSN's ANDA Product in the United States, or use MSN's ANDA Product in the United States will aid and abet the direct infringement of the '780 Patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 63.

64. On information and belief, MSN specifically intends to induce infringement of the '780 patent.

ANSWER: This paragraph alleges legal conclusions to which no response is required.

To the extent a response is required, MSN denies the allegations of paragraph 64.

65. MSN's actions will constitute inducement of infringement of the '780 Patent pursuant to 35 U.S.C. § 271(b).

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 65.

66. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Plaintiffs and MSN as to the liability of MSN's infringement of the '780 Patent. MSN's actions have created in Plaintiffs a reasonable apprehension of irreparable harm and loss resulting from MSN's threatened imminent actions.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 66.

67. Unless MSN is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by MSN's infringement of the '780 Patent. Plaintiffs do not have an adequate remedy at law.

ANSWER: This paragraph alleges legal conclusions to which no response is required. To the extent a response is required, MSN denies the allegations of paragraph 67.

RESPONSE TO "PRAYER FOR RELIEF"

With respect to Plaintiffs' request for relief, MSN denies that Plaintiffs are entitled to any relief for the allegations and claims made in the Complaint, including the relief requested in paragraphs A-G.

SEPARATE DEFENSES

Without prejudice to the denials set forth in this Answer, MSN further responds to the Complaint with the defenses set forth below. MSN expressly reserves the right to supplement this Answer, including the right to assert additional defenses as more information is learned through discovery and further factual investigation in this case. MSN does not intend to hereby assume the burden of proof with respect to those matters as to which, pursuant to law, Plaintiffs bear the burden of proof.

FIRST AFFIRMATIVE DEFENSE
(Non-Infringement of the '780 Patent)

MSN has not and will not infringe, either directly or indirectly, literally or under the doctrine of equivalents, any valid and enforceable claim of the '780 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of the '780 Patent)

The claims of the '780 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, 112, and/or 116, double patenting, the defenses recognized in 35 U.S.C. § 282(b), or under other judicially-created bases for invalidation or unenforceability.

THIRD AFFIRMATIVE DEFENSE
(Equitable Defenses)

Any claim of relief by Plaintiffs is barred, in whole or in part, by the equitable doctrines of unclean hands, estoppel, or patent misuse.

FOURTH AFFIRMATIVE DEFENSE
(Not An Exceptional Case)

MSN's actions in defending this case do not constitute an exceptional case under 35 U.S.C. § 285.

FIFTH AFFIRMATIVE DEFENSE
(No Willful Infringement)

MSN has not willfully infringed, and will not willfully infringe, any claim of the patents-in-suit.

SIXTH AFFIRMATIVE DEFENSE
(No Injunctive Relief)

Plaintiffs are not entitled to any injunction relief because, *inter alia*, any alleged injury to Plaintiffs is not immediate or irreparable, Plaintiffs have an adequate remedy at law, or public policy concerns weigh against any award of injunctive relief.

SEVENTH AFFIRMATIVE DEFENSE
(Failure to State a Claim)

Plaintiffs' complaint fails to state a claim upon which relief may be granted.

EIGHTH AFFIRMATIVE DEFENSE
(Issue Preclusion/Collateral Estoppel)

Plaintiffs are precluded from asserting all claims of the '780 patent by the Court's prior adjudication in *Astellas Pharma Inc., et al. v. Sandoz Inc., et al.*, CA 20-1589 (D. Del.) holding that claims 5, 20, and 25 are invalid. There is no material difference between invalidated claims 5, 20, and 25 of the '780 patent and the remaining claims of the '780 patent.

NINTH AFFIRMATIVE DEFENSE
(No Costs)

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

TENTH AFFIRMATIVE DEFENSE
(Plaintiffs' Actions Are Exceptional)

Plaintiffs' actions in litigating this case constitute an exceptional case under 35 U.S.C. § 285. All claims of the '780 patent are invalid under *Astellas Pharma Inc., et al. v. Sandoz Inc. et al.*, CA 20-1589 (D. Del.).

Reservation of Additional Defenses

MSN reserves the right to assert additional separate defenses that may be developed through discovery, or otherwise, in this action, such as claims of inequitable conduct during the prosecution of the patent-in-suit.

DATED: October 30, 2023

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