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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV, Plaintiffs/Counterclaim-Defendants, v. PHARMASCIENCE INC., MALLINCKRODT PLC, and SPECGX LLC Defendants/Counterclaim-Plaintiffs.	Civil Action No. 2:19-cv-21590 (CCC-MF) **DEFENDANTS PHARMASCIENCE INC., MALLINCKRODT PLC AND SPECGX LLC'S ANSWER AND DEFENSES TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT AND DEFENDANTS' COUNTERCLAIMS** *Filed Electronically*

Defendants Pharmascience Inc. ("Pharmascience"), Mallinckrodt plc ("Mallinckrodt"), and SpecGx LLC ("SpecGx") (collectively, "Defendants"), by and through their undersigned attorneys, answer the Complaint for Patent Infringement of Plaintiffs Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica NV (collectively, "Plaintiffs") with the following answers, affirmative defenses, and counterclaims. Defendants deny all allegations not expressly admitted herein.

NATURE OF THE ACTION

1. This is a civil action for patent infringement of United States Patent No. 9,439,906 (the "'906 Patent").

ANSWER:

Defendants admit the complaint purports to state claims for infringement of United States Patent No. 9,439,906 (the "'906 Patent"). Defendants deny any remaining allegations of this paragraph.

2. This action relates to the submission of an Abbreviated New Drug Application ("ANDA") by Pharmascience Inc. to the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of JPI's Invega Sustenna® brand products in the United States prior to the expiration of the '906 Patent.

ANSWER:

Defendants admit the Complaint relates to the submission of an Abbreviated New Drug Application ("ANDA") by Pharmascience to the United States Food and Drug Administration ("FDA"). Defendants further admit Pharmascience filed ANDA No. 210397 seeking regulatory approval of its proposed generic paliperidone palmitate extended-release injectable suspension products. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny all remaining allegations of this paragraph.

THE PARTIES

3. JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore deny the same.

4. JPN is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations of this paragraph, and therefore deny the same.

5. On information and belief, Pharmascience Inc. is a corporation organized and existing under the laws of Canada, having a place of business at 6111 Royalmount Avenue, Suite 100, Montréal, Quebec H4P 2T4, Canada.

ANSWER:

Defendants admit Pharmascience is a corporation organized and existing under the laws of Canada, having a place of business at 6111 Royalmount Avenue, Suite 100, Montréal, Quebec H4P 2T4, Canada. Defendants deny any remaining allegations of this paragraph.

6. On information and belief, Mallinckrodt plc ("Mallinckrodt") is a corporation organized and existing under the laws of Ireland, having a corporate headquarters at 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey TW18 3AG, United Kingdom. Upon information and belief, Mallinckrodt Pharmaceuticals is a registered business name of Mallinckrodt plc.

ANSWER:

Defendants admit Mallinckrodt is a corporation organized and existing under the laws of Ireland, having a place of business at 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey TW18 3AG, United Kingdom. Defendants deny all remaining allegations of this paragraph.

7. On information and belief, SpecGx LLC ("SpecGx") is a limited liability company organized and existing under the laws of Delaware, having a place of business at 385 Marshall Avenue, St. Louis, Missouri 63119. On information and belief, SpecGx is a wholly owned subsidiary of Mallinckrodt.

ANSWER:

Defendants admit SpecGx is a limited-liability company organized and existing under the laws of Delaware, having a place of business at 385 Marshall Avenue, St. Louis, Missouri 63119. Defendants deny all remaining allegations in this paragraph.

8. On information and belief, Pharmascience Inc., Mallinckrodt, and SpecGx are pharmaceutical companies that develop, manufacture, market, and distribute pharmaceutical products, including generic pharmaceutical products, for sale in the State of New Jersey and throughout the United States.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

9. On information and belief, Pharmascience Inc., Mallinckrodt, and SpecGx are acting in concert to develop, manufacture, market, and/or distribute generic pharmaceutical products, including the proposed generic version of Invega Sustenna described in ANDA No. 210397, for sale in the State of New Jersey and throughout the United States.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

10. On information and belief, Pharmascience Inc. is acting on behalf of itself and on behalf of Mallinckrodt and SpecGx with respect to ANDA No. 210397.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or

otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

JURISDICTION AND VENUE

11. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02.

ANSWER:

Defendants admit the complaint purports to state claims for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 271(e)(2), including an action seeking declaratory judgment pursuant to the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. Defendants deny that Plaintiffs have sufficiently stated a claim. Defendants deny any remaining allegations of this paragraph.

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

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants admit this Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) only over claims asserted under 35 U.S.C. § 271(e)(2)(A). Defendants deny any remaining allegations of this paragraph.

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

ANSWER:

This paragraph contains conclusions of law for which no response is required. To the extent an answer is required, Defendants do not contest venue for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

Pharmascience Inc.

14. This Court has personal jurisdiction over Pharmascience Inc. because, *inter alia*, Pharmascience Inc. has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 210397, Pharmascience Inc. will, directly or through its affiliates and/or agents Mallinckrodt and/or SpecGx, make, use, import, sell, and/or offer for sale its proposed generic versions of JPI's Invega Sustenna® brand products in the United States, including in New Jersey, prior to the expiration of the '906 Patent.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

15. Exercising personal jurisdiction over Pharmascience Inc. in this district would not be unreasonable given Pharmascience Inc.'s contacts with this district and this district's interest in resolving disputes related to products to be sold in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

16. This Court also has personal jurisdiction over Pharmascience Inc. because Pharmascience Inc. has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Pharmascience Inc. regularly and continuously transacts business within New Jersey, either directly or through its affiliates and/or agents—including Mallinckrodt and SpecGx— including by selling pharmaceutical products in New Jersey. On information and belief, Pharmascience Inc.

derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

17. On information and belief, Pharmascience Inc., either directly or indirectly through Mallinckrodt or SpecGx, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

ANSWER:

Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

18. This Court also has personal jurisdiction over Pharmascience Inc. because, *inter alia*, this action arises from the actions of Pharmascience Inc. directed toward New Jersey. For example, Pharmascience Inc.'s counsel sent a letter dated November 7, 2019 to JPI, a corporation with its principal place of business in this Judicial District, stating that Pharmascience Inc. had submitted ANDA No. 210397 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. If Pharmascience Inc. succeeds in obtaining FDA approval, it will sell its proposed generic versions of JPI's Invega Sustenna® brand products in New Jersey and other states, either directly or through its affiliates and/or agents Mallinckrodt and/or SpecGx, causing injury to Plaintiffs in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

19. Pharmascience Inc. has conceded that venue is proper over Pharmascience Inc. in patent cases in this Judicial District in at least the following District of New Jersey action: *Celgene Corp. v. Pharmascience Inc.*, No. 3:18-cv-11545.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest venue for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

20. Pharmascience Inc. has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Celgene Corp. v. Pharmascience Inc.*, No. 3:18-cv-11545.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

21. In the alternative, this Court has personal jurisdiction over Pharmascience Inc. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

Mallinckrodt

22. On information and belief, Mallinckrodt is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

ANSWER:

Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

23. This Court has personal jurisdiction over Mallinckrodt because, *inter alia*, Mallinckrodt has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 210397, Mallinckrodt will, directly or through its affiliates and/or agents including SpecGx, distribute the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397 in the United States, including in New Jersey, prior to the expiration of the '906 Patent.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

24. Exercising personal jurisdiction over Mallinckrodt in this district would not be unreasonable given Mallinckrodt's contacts with this district and this district's interest in resolving disputes related to products to be sold in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

25. This Court also has personal jurisdiction over Mallinckrodt because Mallinckrodt has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, Mallinckrodt regularly and continuously transacts business within New Jersey, either directly or through its affiliates and/or agents—including Pharmascience Inc. and SpecGx— including by selling pharmaceutical products in New Jersey. On information and belief, Mallinckrodt derives

substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

26. On information and belief, Mallinckrodt has substantial, continuous, and systematic contacts with New Jersey, including, but not limited to, the direction of operation and management of SpecGx and the maintenance of an office at 1405 US-206, Bedminster, New Jersey, 07921.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further admit that Mallinckrodt has a place of business at 1405 US-206, Bedminster, New Jersey, 07921. Defendants deny any remaining allegations of this paragraph.

27. This Court also has personal jurisdiction over Mallinckrodt because, *inter alia*, this action arises from the actions of Mallinckrodt directed toward New Jersey, either directly or through Pharmascience Inc. and/or SpecGx. For example, Pharmascience Inc.'s counsel sent a letter dated November 7, 2019 to JPI, a corporation with its principal place of business in this Judicial District, stating that Pharmascience Inc. had submitted ANDA No. 210397 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. Upon information and belief, Mallinckrodt is listed as the distributor of the proposed generic version of JPI's Invega Sustenna® described in ANDA No. 210397. If Pharmascience Inc. succeeds in obtaining FDA approval, Mallinckrodt will sell its proposed generic versions of JPI's Invega Sustenna® brand products in New Jersey and other states, either directly or through its affiliates and/or agents SpecGx and/or Pharmascience Inc., causing injury to Plaintiffs in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself,

and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

28. In the alternative, this Court has personal jurisdiction over Mallinckrodt because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

SpecGx

29. On information and belief, SpecGx, either directly or indirectly through Pharmascience Inc. or Mallinckrodt, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

ANSWER:

Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

30. This Court has personal jurisdiction over SpecGx because, *inter alia*, SpecGx has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in New Jersey. For example, on information and belief, following approval of ANDA No. 210397, SpecGx will, directly or through its affiliates including Mallinckrodt distribute the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397 in the United States, including in New Jersey, prior to the expiration of the '906 Patent.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself,

and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

31. Exercising personal jurisdiction over SpecGx in this district would not be unreasonable given SpecGx's contacts with this district and this district's interest in resolving disputes related to products to be sold in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

32. This Court also has personal jurisdiction over SpecGx because SpecGx has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contacts with the State of New Jersey. On information and belief, SpecGx regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Mallinckrodt and Pharmascience Inc.—including by selling pharmaceutical products in New Jersey. On information and belief, SpecGx derives substantial revenue from the sale of those products in New Jersey and has availed itself of the privilege of conducting business within New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

33. On information and belief, SpecGx has substantial, continuous and systematic contacts with New Jersey, is registered to do business in New Jersey, has appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug manufacturer and wholesaler in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

34. This Court also has personal jurisdiction over SpecGx because, *inter alia*, this action arises from the actions of SpecGx directed toward New Jersey, either directly or through Pharmascience Inc. and/or Mallinckrodt. For example, Pharmascience Inc.'s counsel sent a letter dated November 7, 2019 to JPI, a corporation with its principal place of business in this Judicial District, stating that Pharmascience Inc. had submitted ANDA No. 210397 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import its proposed generic versions of JPI's Invega Sustenna® brand products prior to the expiration of the '906 Patent. The proposed label for the proposed generic version of Invega Sustenna® described in ANDA No. 210397 lists SpecGx as the distributor. If Pharmascience Inc. succeeds in obtaining FDA approval, SpecGx will sell its proposed generic versions of JPI's Invega Sustenna® brand products in New Jersey and other states, either directly or through its affiliates Pharmascience Inc. and/or SpecGx, causing injury to Plaintiffs in New Jersey.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

Defendants Collectively

35. On information and belief, Mallinckrodt and SpecGx, along with other subsidiaries of Mallinckrodt, hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants deny any remaining allegations of this paragraph.

36. On information and belief, Mallinckrodt and SpecGx employ people and maintain a regular and established office in New Jersey, including at least at 1405 US-206, Bedminster, New Jersey, 07921.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further admit that Mallinckrodt has a place of business at 1405 US-206, Bedminster, New Jersey, 07921. Defendants deny any remaining allegations of this paragraph.

37. On information and belief, Pharmascience Inc., Mallinckrodt, and SpecGx are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 210397.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

38. On information and belief, Pharmascience Inc., Mallinckrodt, and SpecGx are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States and will do the same with respect to the product for which they have sought approval from the FDA in ANDA No. 210397.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants further state that ANDA No. 210397 speaks for itself,

and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

39. On information and belief, Mallinckrodt and SpecGx, together with their affiliate and/or agent Pharmascience Inc., filed the Pharmascience ANDA No. 210397 with the FDA that is at issue in this patent infringement suit.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants admit Pharmascience filed ANDA No. 210397 seeking regulatory approval of its proposed generic paliperidone palmitate extended-release injectable suspension products. Defendants further state that ANDA No. 210397 speaks for itself, and denies any remaining allegations of this paragraph to the extent that they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

40. On information and belief, Pharmascience Inc., Mallinckrodt, and SpecGx, alone and/or together with each other as affiliates and/or agents, have committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including JPI, which is a New Jersey company, in New Jersey.

ANSWER:

Defendants deny the allegations of this paragraph.

THE PATENT-IN-SUIT

41. On September 13, 2016, the '906 Patent, titled "Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters" was duly and legally issued to JPN as assignee. A copy of the '906 Patent is attached as Exhibit A.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants state that the '906 patent speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the '906 patent. Defendants further admit a copy of what is purported to be the '906 patent is attached to the complaint as Exhibit A. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning the ownership of the '906 patent, and therefore deny the same. Defendants deny the '906 patent was duly and legally issued and otherwise deny any remaining allegations of this paragraph.

42. JPI holds approved NDA No. 022264 for paliperidone palmitate extended release injectable suspension, which is prescribed and sold under the trademark Invega Sustenna®.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning ownership of the New Drug Application ("NDA") No. 022264, and therefore deny the same. Defendants admit that the FDA website indicates that JPI is the holder of NDA No. 022264 which is approved for paliperidone palmitate extended release injectable suspension with the proprietary name Invega Sustenna®. Defendants deny any remaining allegations of this paragraph.

43. Pursuant to 21 U.S.C. § 355(b)(1), the '906 Patent is listed in the United States FDA publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (also

known as the "Orange Book") as covering JPI's Invega Sustenna® brand paliperidone palmitate extended release suspension products.

ANSWER:

Defendants state that the FDA's publication, "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") speaks for itself and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Orange Book. Defendants deny the remaining allegations in this paragraph.

44. Invega Sustenna® is indicated for treatment of schizophrenia in adults and treatment of schizoaffective disorder in adults as a monotherapy and as an adjunct to mood stabilizers or antidepressants.

ANSWER:

Defendants state that the FDA-approved labeling for Invega Sustenna® speaks for itself, including as to approved indications of the product, and Defendants deny the allegations in this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the FDA-approved label or approved indications. Defendants deny the remaining allegations in this paragraph.

COUNT I: INFRINGEMENT OF THE '906 PATENT BY PHARMASCIENCE'S ANDA FOR INVEGA SUSTENNA®

45. Plaintiffs re-allege paragraphs 1-44 as if fully set forth herein.

ANSWER:

Defendants repeat and incorporate by reference its responses to paragraphs 1-44 as if fully stated herein.

46. An actual controversy exists between the parties as to whether Defendants' proposed sale of their generic paliperidone palmitate extended-release injectable suspension products infringes at least one claim, including claim 1, of the '906 Patent.

ANSWER:

Defendants deny the allegations of this paragraph.

47. By letter dated November 7, 2019 ("Pharmascience Notice Letter"), Pharmascience Inc. notified Plaintiffs that it had submitted ANDA No. 210397 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). The Notice Letter stated that ANDA No. 210397 seeks the FDA approval necessary to engage in the commercial manufacture, use, sale, offer for sale in, and/or importation into the United States, including the State of New Jersey, of generic paliperidone palmitate extended-release injectable suspension products prior to the expiration of certain of JPN's Orange Book listed patents. ANDA No. 210397 specifically seeks FDA approval to market generic versions of JPI's Invega Sustenna® brand paliperidone palmitate extended-release injectable suspension products in 39 mg, 78 mg, 117 mg, 156 mg, and 234 mg doses prior to the expiration of the '906 Patent.

ANSWER:

Defendants admit that Pharmascience sent a letter to Plaintiffs dated November 7, 2019 (the "Pharmascience Notice Letter"). Defendants further state that the Pharmascience Notice Letter speaks for itself, and deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Pharmascience Notice letter. Defendants deny any remaining allegations of this paragraph.

48. ANDA No. 210397 includes a Paragraph IV Certification that the claims of the '906 Patent are invalid, unenforceable, and/or not infringed.

ANSWER:

Defendants state that ANDA No. 210397 speaks for itself, and deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe ANDA No. 210397. Defendants deny any remaining allegations of this paragraph.

49. Upon information and belief, the Pharmascience Notice Letter was sent to Plaintiffs via overnight mail no earlier than November 7, 2019.

ANSWER:

Defendants admit that Pharmascience sent Plaintiffs the Pharmascience Notice Letter on November 7, 2019. Defendants deny any remaining allegations of this paragraph.

50. The Pharmascience Notice Letter was subsequently received by Plaintiffs, and Plaintiffs commenced this action within 45 days of the date of receipt of the Pharmascience Notice Letter.

ANSWER:

This paragraph states legal conclusions to which no response is required. To the extent an answer is required, Defendants admit this action was commenced within 45 days of the receipt of the Pharmascience Notice Letter by Plaintiffs. Defendants deny any remaining allegations of this paragraph.

51. The Pharmascience Notice Letter purports to include a Notice of Certification for ANDA No. 210397 under 37 C.F.R. § 314.95(c)(6) as to the '906 Patent. The Pharmascience Notice Letter did not include a detailed statement of allegations of non-infringement as to at least one claim of the '906 Patent.

ANSWER:

Defendants admit that Pharmascience sent Plaintiffs the Pharmascience Notice Letter. Defendants further state that the Pharmascience Notice Letter speaks for itself, and deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Pharmascience Notice letter. Defendants deny any remaining allegations of this paragraph.

52. Defendants have actual knowledge of the '906 Patent, as shown by the Pharmascience Notice Letter.

ANSWER:

Defendants admit they have actual knowledge of the '906 patent at least as early as the service of this Complaint. Defendants deny any remaining allegations of this paragraph.

53. On information and belief, the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '906 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER:

Defendants deny the allegations of this paragraph.

54. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Defendants have infringed at least one claim, including at least claim 1, of the '906 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 210397 seeking approval to manufacture, use, import, offer to sell or sell the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397 before the expiration date of the '906 Patent. Upon information and belief, the products described in ANDA No. 210397 would infringe, either literally or under the doctrine of equivalents, at least one claim, including at least claim 1 of the '906 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER:

Defendants deny the allegations of this paragraph.

55. On information and belief, physicians and/or patients will directly infringe at least one claim, including at least claim 1, of the '906 Patent by use of the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397 upon approval.

ANSWER:

Defendants deny the allegations of this paragraph.

56. On information and belief, upon approval, Defendants will take active steps to encourage the use of the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397 by physicians and/or patients with the knowledge and intent that the proposed generic versions of JPI's Invega Sustenna® brand products described in ANDA No. 210397 will be used by physicians and/or patients in a manner that infringes at least one claim, including at least claim 1, of the '906 Patent for the pecuniary benefit of Defendants. Pursuant to 21 C.F.R. § 314.94, Defendants are required to copy the FDA-approved Invega Sustenna® labeling. Defendants specifically intend the generic paliperidone palmitate products to be used according to their proposed labeling in a manner that infringes at least one claim, including at least claim 1, of the '906 Patent. Upon information and belief, Defendants will thus induce the infringement of at least one claim, including at least claim 1 of the '906 Patent.

ANSWER:

Defendants deny the allegations of this paragraph.

57. On information and belief, if the FDA approves ANDA No. 210397, Defendants will sell or offer to sell their generic products specifically labeled for use in practicing at least one claim, including at least claim 1 of the '906 Patent, wherein the generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use the generic products in accordance with the instructions and/or label provided by Defendants in practicing at least one claim, including at least claim 1 of the '906 Patent, and wherein the generic paliperidone palmitate extended-release injectable suspension products are not staple articles or commodities of commerce suitable for substantial non-infringing use. The generic paliperidone palmitate extended-release injectable suspension products are specifically designed for use in a manner that infringes at least one claim, including at least claim 1, of the '906 Patent. On information and belief, Defendants will thus contribute to the infringement of at least one claim, including at least claim 1 of the '906 Patent.

ANSWER:

Defendants deny the allegations of this paragraph.

58. On information and belief, the actions described in this Complaint relating to Pharmascience's ANDA No. 210397 were done by and for the benefit of Defendants.

ANSWER:

Defendants deny the allegations of this paragraph.

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

ANSWER:

Defendants deny the allegations of this paragraph.

60. This is an exceptional case, and Plaintiffs are entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

ANSWER:

Defendants deny the allegations of this paragraph.

PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief requested in their prayer for relief, or any relief whatsoever.

AFFIRMATIVE DEFENSES

Defendants deny all allegations not expressly admitted above. Without prejudice to the responses and denials set forth in Defendants' Answer to the Complaint, and without admitting any allegations of the Complaint not otherwise admitted, Defendants assert the following defenses:

FIRST AFFIRMATIVE DEFENSE

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of United States Patent No. 9,439,906 (the "'906 Patent") either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the '906 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 116, and/or 120 thereof.

THIRD AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '906 patent, Plaintiffs are estopped from maintaining that Defendants infringe any valid claim of the '906 patent.

FOURTH AFFIRMATIVE DEFENSE

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

FIFTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

SIXTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over portions of the claims asserted against defendant, in particular, any infringement claims Plaintiffs assert under 35 U.S.C. § 271(a), (b), and/or (c).

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' Complaint, including but not limited to supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

COUNTERCLAIMS

Pharmascience Inc. ("Pharmascience"), Mallinckrodt plc ("Mallinckrodt"), and SpecGx LLC ("SpecGx"), (collectively, "Counterclaim-Plaintiffs"), for their counterclaims against Janssen Pharmaceuticals, Inc., and Janssen Pharmaceutica NV (collectively, "Counterclaim-Defendants"), allege as follows:

1. These counterclaim actions are for declaratory judgment of invalidity and/or noninfringement of United States Patent No. 9,439,906 (the "'906 Patent").

THE PARTIES

2. Pharmascience is a corporation organized and existing under the laws of Canada, having a place of business at 6111 Royalmount Avenue, Suite 100, Montréal, Quebec H4P 2T4, Canada.

3. Mallinckrodt is a corporation organized and existing under the laws of Ireland, having a place of business at 3 Lotus Park, The Causeway, Staines-Upon-Thames, Surrey TW18 3AG, United Kingdom.

4. SpecGx is a limited-liability company organized and existing under the laws of Delaware, having a place of business at 385 Marshall Avenue, St. Louis, Missouri 63119.

5. On information and belief, Janssen Pharmaceuticals, Inc. ("JPI") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

6. On information and belief, Janssen Pharmaceutica NV ("JPN") is a corporation organized and existing under the laws of Belgium, having its principal place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these counterclaim actions for declaratory judgments pursuant to 35 U.S.C. § 271(e)(5); 28 U.S.C. §§ 1331, 1338, 2201, and 2202; and/or 21 U.S.C. § 355(j), based on an actual controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants arising under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*

8. The Court has personal jurisdiction over Counterclaim-Defendants based on the filing of this lawsuit in this jurisdiction and because, on information and belief, Counterclaim-Defendants are doing business in this jurisdiction, and on information and belief, because Counterclaim-Defendant JPI is incorporated in the state of New Jersey.

9. Venue is proper in this District under 28 U.S.C. §§ 1391(b) and (c), 28 U.S.C. § 1400(b), and 21 U.S.C. § 355(j)(5)(C)(i)(II).

FACTS RELEVANT TO COUNTERCLAIMS
PATENT-IN-SUIT

10. On information and belief, on September 13, 2016, the USPTO issued the '906 patent, entitled "Dosing Regimen Associated with Long Acting Injectable Paliperidone Esters." According to the information on the face of the patent, the '906 patent was assigned to JPN.

11. On information and belief, JPI is the holder of New Drug Application ("NDA") No. 022264, directed to Invega Sustenna®.

12. On information and belief, Counterclaims-Defendants caused the Food and Drug Administration ("FDA") to list the '906 patent in the FDA's publication "Approved Drug Products with Therapeutic Equivalence Evaluations" ("the Orange Book") in connection with NDA No. 022264.

13. By maintaining the listing of the counterclaim patent-in-suit in the Orange Book, Counterclaim-Defendants represent that a claim of patent infringement of the counterclaim patent-in-suit "could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1)(G).

PHARMASCIENCE'S ABBREVIATED NEW DRUG APPLICATION

14. Pharmascience filed Abbreviated New Drug Application ("ANDA") No. 210397 (the "Pharmascience ANDA") seeking regulatory approval of Pharmascience's proposed generic paliperidone palmitate suspension, extended-release products (39mg/0.25ml, 78mg/0.5ml, 117mg/0.75ml, 156mg/ml, 234mg/1.5ml) (the "Pharmascience ANDA Product"). In the Pharmascience ANDA, Pharmascience certified to the FDA that the '906 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacturer, use, or sale of the Pharmascience ANDA Product.

15. By letter dated November 7, 2019, Pharmascience sent Counterclaim-Defendants a notice letter providing Pharmascience's submission of ANDA No. 210397 to the FDA (the "Pharmascience Notice Letter"). The Pharmascience Notice Letter contained notifications of Pharmascience's Paragraph IV Certifications to the FDA that the '906 patent is invalid, unenforceable and/or will not be infringed by the commercial manufacturer, use, or sale of the Pharmascience ANDA Product.

16. The Pharmascience Notice Letter included an Offer of Confidential Access ("OCA") pursuant to 21 U.S.C. § 355(j)(5)(C).

17. On December 19, 2019, Counterclaim-Defendants filed an infringement action against Counterclaim-Plaintiffs alleging infringement of the '906 patent.

18. On information and belief, Counterclaim-Defendants have not caused the FDA to remove the '906 patent from the Orange Book in connection with NDA No. 022264.

19. In light of all the circumstances, there has been and is now an actual, substantial, and justiciable controversy having sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court between Counterclaim-Plaintiffs and Counterclaim-Defendants as to whether the Pharmascience ANDA Product infringes any or all of the claims of the '906 patent and whether any valid or enforceable claim of the '906 patent exists.

COUNT I
Declaratory Judgement of Invalidity of the '906 Patent

20. Counterclaim-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of its counterclaims

21. The claims of the '906 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of patentability specified in Title 35 of the United States Code, including but not limited to 35 U.S.C. §§ 101, 102, 103, 112, 116 and/or 120, and/or based on other judicially-created bases for invalidation.

22. The alleged invention of the '906 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for the patent.

23. The alleged invention of the ’906 patent was patented or described in a printed publication in this or a foreign country more than one year prior to the date of the application for patent in the United States.

24. The ’906 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty, but only the obvious judgment, knowledge and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

25. The alleged invention of the ’906 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the ’906 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ’906 patent and would have had a reasonable expectation of success in doing so.

26. The subject matter claimed in the ’906 patent fails to comply with 35 U.S.C. §§ 102 and/or 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

27. The ’906 patent does not contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention purported to be covered thereby.

28. The claims of the ’906 patent are invalid and void because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not

particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

29. An actual and justiciable case or controversy exists between Counterclaim-Plaintiffs and Counterclaim-Defendants as to whether the ’906 patent is invalid.

30. Counterclaim-Plaintiffs are entitled to and seek a declaration that the claims of the ’906 patent are invalid.

COUNT II
Declaratory Judgement of Non-infringement of the ’906 Patent

31. Counterclaim-Plaintiffs repeat and incorporate by reference each of the foregoing paragraphs of its counterclaims.

32. Counterclaim-Defendants have accused Counterclaim-Plaintiffs of infringing claims of the ’906 patent in connection with the Pharmascience ANDA.

33. Counterclaim-Plaintiffs deny infringement of any valid, properly construed claim of the ’906 patent, and allege that the manufacture, use, sale, offer for sale or importation of the products that are the subject of the Pharmascience ANDA have not infringed, do not infringe and would not, if manufactured, used, sold, offered for sale or imported, infringe any valid, properly construed claim of the ’906 patent, either directly, indirectly, contributorily, by inducement, or in any other manner.

34. There is an actual, substantial, and continuing justiciable case or controversy between Counterclaim-Plaintiffs and Counterclaim-Defendants regarding infringement of the ’906 patent in connection with the Pharmascience ANDA.

35. Counterclaim-Plaintiffs are entitled to and seek a judicial declaration that the manufacture, use, sale, offer for sale and/or importation of the products that are the subject of the Pharmascience ANDA have not infringed, do not infringe and would not, if manufactured, used,

sold, offered for sale or imported, infringe any valid, properly construed claim of the '906 patent either directly or indirectly.

EXCEPTIONAL CASE

36. This case is an exceptional one, and Counterclaim-Plaintiffs are entitled to and seek an award of their reasonable attorneys' fees and costs under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiffs pray that the Court enter judgement in its favor and against Counterclaim-Defendants as follows:

(a) Dismissing the Complaint with prejudice and denying each request for relief made by Plaintiffs therein;

(b) Declaring the claims of the counterclaim patent-in-suit invalid;

(c) Declaring that the filing of ANDA No. 210397 has not infringed and does not infringe any valid claim, if any, of the counterclaim patent-in-suit, either directly or indirectly, either literally or under the doctrine of equivalents;

(d) Granting Defendants judgment in their favor on Plaintiffs' claims;

(e) Granting Counterclaim-Plaintiffs judgement in their favor on their counterclaims;

(f) Declaring this case exceptional in favor of Counterclaim-Plaintiffs pursuant to 35 U.S.C. § 285;

(g) Declaring that Counterclaim-Plaintiffs are the prevailing parties and awarding Counterclaim-Plaintiffs their costs and attorneys' fees to them; and

(h) Awarding Counterclaim-Plaintiffs such other and further relief as the Court deems just and proper.

Dated: February 10, 2020

/s/ Rebekah Conroy
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding, except for the prior matters *Janssen Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals USA*, Inc., Civil Action No. 2:18-cv-00734 (CCC) (MF), and *Janssen Pharmaceuticals, Inc., et al. v. Mylan Laboratories Ltd*., Civil Action No. 2:19-cv-16484 (CCC) (MF), in this Judicial District, which involve the same plaintiffs and the same patent.

Dated: February 10, 2020

/s/ Rebekah Conroy
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Attorney for Defendants Pharmascience Inc., Mallinckrodt plc, and SpecGx LLC

CERTIFICATION PURSUANT TO LOCAL RULE 201.1

Pursuant to Local Rule 201.1, Defendants Pharmascience Inc., Mallinckrodt plc, and SpecGx LLC, by their undersigned counsel, herby certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: February 10, 2020

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