IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV, *Plaintiffs*, v. PHARMASCIENCE INC., MALLINCKRODT PLC, and SPECGX LLC *Defendants*.	Civil Action No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV ("JPN") (collectively "Plaintiffs" or "Janssen"), for their Complaint against Defendants Pharmascience Inc. ("Pharmascience Inc."), Mallinckrodt plc ("Mallinckrodt"), and SpecGx LLC ("SpecGx") (collectively "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

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

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 for Defendants to market a generic version of JPI's Invega Sustenna® brand products in the United States prior to the expiration of the '906 Patent.

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.

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.

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.

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.

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.

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 Delaware and throughout the United States.

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 Delaware and throughout the United States.

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.

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.

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

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

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 Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. 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 Delaware, prior to the expiration of the '906 Patent.

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 Delaware.

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

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 Delaware and throughout the United States.

18. This Court also has personal jurisdiction over Pharmascience Inc. because, *inter alia*, this action arises from the actions of Pharmascience Inc. directed toward Delaware. For example, Pharmascience Inc.'s counsel sent a letter dated November 7, 2019 to JPI 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 Delaware and other states, either directly or through its affiliates and/or agents Mallinckrodt and/or SpecGx, causing injury to Plaintiffs in Delaware.

19. 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.

Mallinckrodt

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

21. 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 Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. 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 Delaware, prior to the expiration of the '906 Patent.

22. 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 Delaware.

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

24. This Court also has personal jurisdiction over Mallinckrodt because, *inter alia*, this action arises from the actions of Mallinckrodt directed toward Delaware, either directly or through Pharmascience Inc. and/or SpecGx. For example, Pharmascience Inc.'s counsel sent a letter dated November 7, 2019 to JPI 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 Delaware and other states, either directly or through its affiliates and/or agents SpecGx and/or Pharmascience Inc., causing injury to Plaintiffs in Delaware.

25. 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.

SpecGx

26. 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 Delaware and throughout the United States.

27. 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 Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs in Delaware. 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 Delaware, prior to the expiration of the '906 Patent.

28. 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 Delaware.

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

30. On information and belief, SpecGx has substantial, continuous and systematic contacts with Delaware, is a limited liability company organized and existing under the laws of Delaware, is registered to do business in Delaware, has appointed a registered agent in Delaware for receipt of service of process, and is registered as a drug manufacturer and wholesaler in Delaware.

31. This Court also has personal jurisdiction over SpecGx because, *inter alia*, this action arises from the actions of SpecGx directed toward Delaware, either directly or through Pharmascience Inc. and/or Mallinckrodt. For example, Pharmascience Inc.'s counsel sent a letter dated November 7, 2019 to JPI 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 Delaware and other states, either directly or through its affiliates Pharmascience Inc. and/or SpecGx, causing injury to Plaintiffs in Delaware.

32. SpecGx has conceded that venue is proper over SpecGx in patent cases in this Judicial District in at least the following District of Delaware action: *Shire Development LLC, et al., v. SpecGx LLC.*, C.A. No. 18-800-RGA.

33. SpecGx has consented to or did not contest the jurisdiction of this Court in at least the following District of Delaware action: *Shire Development LLC, et al., v. SpecGx LLC.*, C.A. No. 18-800-RGA.

Defendants Collectively

34. 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 Delaware and throughout the United States.

35. On information and belief, at least 45 subsidiaries of Mallinckrodt—including SpecGx—are organized or incorporated under the laws of Delaware.

36. 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.

37. 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.

38. 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.

39. 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 in Delaware.

THE PATENT-IN-SUIT

40. 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.

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

42. 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.

43. 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.

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

44. Plaintiffs re-allege paragraphs 1-43 as if fully set forth herein.

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

46. 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 Delaware, 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.

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

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

49. 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.

50. 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.

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

52. On information and belief, Defendants' generic products, 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).

53. 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 Defendants' generic products 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).

54. 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 Defendants' generic products upon approval.

55. On information and belief, upon approval, Defendants will take active steps to encourage the use of Defendants' generic products by physicians and/or patients with the knowledge and intent that Defendants' generic products 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 their 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.

56. 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 Defendants' generic products are a material part of the claimed invention, wherein Defendants know that physicians will prescribe and patients will use Defendants' 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 Defendants' generic paliperidone palmitate extended-release injectable suspension products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Defendants' 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.

57. 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.

58. 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.

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

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the '906 Patent through Defendants' submission of ANDA No. 210397 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Defendants' proposed generic versions of JPI's Invega Sustenna® brand product identified in this Complaint in the United States before the expiration of the '906 Patent;

B. Enter judgment under 35 U.S.C. § 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States of Defendants' proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, prior to the expiration of the '906 Patent, constitutes infringement of one or more claims of the '906 Patent under 35 U.S.C. § 271(a), (b), or (c);

C. Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of ANDA No. 210397 be a date that is not earlier than the expiration date of the '906 Patent, or such later date as the Court may determine;

D. Order that Defendants, their affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Defendants, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Defendants' proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint, and any other product that infringes or contributes to the infringement of the '906 Patent, prior to the expiration of the '906 Patent, or such later date as the Court may determine;

E. If Defendants engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the proposed generic versions of JPI's Invega Sustenna® brand products identified in this Complaint prior to the expiration of the '906 Patent, a Judgment awarding damages to Plaintiffs resulting from such infringement with interest;

F. Declare this to be an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and award Plaintiffs their costs, expenses, and disbursements in this action, including reasonable attorneys' fees; and

G. Award such further and other relief that the Court deems proper and just.

ASHBY & GEDDES

/s/ Steven J. Balick

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Dated: December 20, 2019