IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALKERMES PHARMA IRELAND LIMITED, ALKERMES CONTROLLED THERAPEUTICS, INC., JANSSEN PHARMACEUTICALS, INC.	)	
Plaintiffs,	)	C.A. No.: _____
v.	)	
LUYE PHARMA GROUP LTD., LUYE PHARMA (USA) LTD., NANJING LUYE PHARMACEUTICAL CO., LTD., SHANDONG LUYE PHARMACEUTICAL CO., LTD.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Alkermes Pharma Ireland Limited, Alkermes Controlled Therapeutics, Inc., and Janssen Pharmaceuticals, Inc. (collectively, "Plaintiffs"), for their Complaint against Defendants Luye Pharma Group Ltd., Luye Pharma (USA) Ltd., Nanjing Luye Pharmaceutical Co., Ltd., and Shandong Luye Pharmaceutical Co., Ltd., (collectively, "Defendants"), hereby allege as follows:

THE PARTIES

1. Plaintiff Alkermes Pharma Ireland Limited is a corporation organized and existing under the laws of Ireland having its principal place of business at Connaught House, 1 Burlington Road, Dublin 4, Ireland.

2. Plaintiff Alkermes Controlled Therapeutics, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania having its principal place of business at 852 Winter St. Waltham, Massachusetts 02451.

3. Plaintiff Janssen Pharmaceuticals, Inc. 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.

4. On information and belief, Defendant Luye Pharma Group Ltd. is a corporation organized and existing under the laws of Bermuda having its principal place of business at No. 15 Chuangye Road, High-tech Industrial Development Zone, Yantai, Shandong 264003, People's Republic of China.

5. On information and belief, Luye Pharma Group Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

6. On information and belief, Defendant Luye Pharma (USA) Ltd. is a corporation organized and existing under the laws of the State of Delaware having its principal place of business at 502 Carnegie Center, Suite 103, Princeton, New Jersey 08540.

7. On information and belief, Luye Pharma (USA) Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

8. On information and belief, Defendant Nanjing Luye Pharmaceutical Co., Ltd. is a corporation organized and existing under the laws of China having its principal place of

business at No. 15 Chuangye Road, High-tech Industrial Development Zone, Yantai, Shandong 264003, People's Republic of China.

9. On information and belief, Nanjing Luye Pharmaceutical Co., Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

10. On information and belief, Defendant Shandong Luye Pharmaceutical Co. Ltd. is a corporation organized and existing under the laws of China having its principal place of business at No. 15 Chuangye Road, Hightech District, Yantai, 264670, People's Republic of China.

11. On information and belief, Shandong Luye Pharmaceutical Co. Ltd., by itself and/or through its affiliates and agents, is in the business of among other things, manufacturing, marketing, importing, preparing, and selling pharmaceutical products that it distributes in the State of Delaware and throughout the United States.

12. On information and belief, Luye Pharma (USA) Ltd. is a wholly-owned subsidiary of Luye Pharma Group Ltd.

13. On information and belief, Shandong Luye Pharmaceutical Co., Ltd. is an indirect, wholly-owned subsidiary of Luye Pharma Group Ltd.

14. On information and belief, Nanjing Luye Pharmaceutical Co., Ltd. is an indirect, wholly-owned subsidiary of Luye Pharma Group Ltd.

15. On information and belief, Defendants are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical drug products.

16. On information and belief, the acts of Defendants complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of, each other.

17. On information and belief, Defendants have cooperated and assisted in the preparation and filing of Defendants' New Drug Application ("NDA") No. 212849 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of NDA No. 212849 if it is approved.

NATURE OF THE ACTION

18. This is a civil action for the infringement of United States Patent No. 6,667,061 ("the '061 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Defendants' filing of an NDA with the United States Food and Drug Administration ("FDA") seeking approval to market Defendants' extended release risperidone injections ("Defendants' Risperidone Product") before the expiration of Plaintiffs' patent protecting Risperdal Consta®.

JURISDICTION AND VENUE

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

20. This Court has personal jurisdiction over Defendants by virtue of the fact that, *inter alia*, Defendants have committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs in the State of Delaware, and throughout the United States.

21. This Court also has personal jurisdiction over Defendants because Defendants are at home in Delaware as reflected by the fact that, on information and belief, they

regularly do or solicit business in Delaware, engage in other persistent courses of conduct in Delaware, and/or derive substantial revenue from services or things used or consumed in Delaware, including by selling their pharmaceutical products in Delaware and, therefore, can reasonably expect to be subject to jurisdiction in the Delaware courts. Among other things, on information and belief, Defendants conduct marketing and sales activities in the State of Delaware, including, but not limited to, distribution, marketing, and sales of pharmaceutical products to Delaware residents that are continuous and systematic. On information and belief, if Defendants' NDA No. 212849 is approved, they will market and sell Defendants' Risperidone Product in Delaware.

22. This Court has personal jurisdiction over Defendant Luye Pharma (USA) Ltd. On information and belief, Defendant Luye Pharma (USA) Ltd. is a Delaware company.

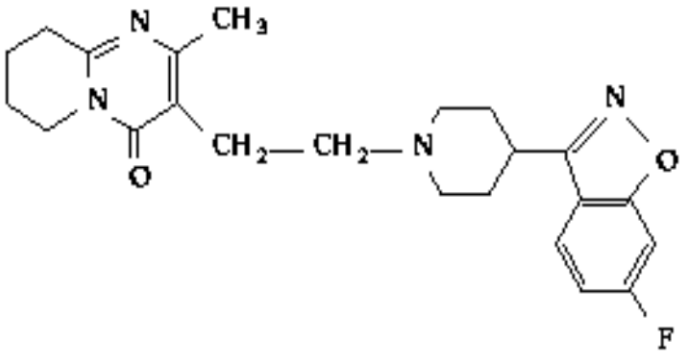
23. Alternatively, this Court may exercise jurisdiction over Luye Pharma Group Ltd., Nanjing Luye Pharmaceutical Co., Ltd., and Shandong Luye Pharmaceutical Co., Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Luye Pharma Group Ltd., Nanjing Luye Pharmaceutical Co., Ltd., and Shandong Luye Pharmaceutical Co., Ltd. are foreign defendants not subject to general personal jurisdiction in the courts of any state; and (c) Luye Pharma Group Ltd., Nanjing Luye Pharmaceutical Co., Ltd., and Shandong Luye Pharmaceutical Co., Ltd. have sufficient contacts with the United States as a whole, including but not limited to manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Luye Pharma Group Ltd., Nanjing Luye Pharmaceutical Co., Ltd., and Shandong Luye Pharmaceutical Co., Ltd. satisfies due process.

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

THE RISPERDAL CONSTA® NDA

25. Janssen Pharmaceuticals, Inc. holds NDA No. 21346 for Risperdal Consta® (risperidone) Long-Acting Injection. The FDA approved NDA No. 21346 for Risperdal Consta® Long-Acting Injection on October 29, 2003 for the treatment of schizophrenia. On May 15, 2009, the FDA approved an expanded indication for treatment as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder.

26. Risperdal Consta® contains risperidone, which can be referred to by the chemical name 3-[2-[4-(6-fluoro-1,2-benzisoxazol-3-yl)-1-piperidinyl]ethyl]-6,7,8,9-tetrahydro-2-methyl-4H-pyrido[1,2-a]pyrimidin4-one. The structural formula is:



THE PATENT-IN-SUIT

27. On December 23, 2003, the ’061 patent, entitled “Preparation of Injectable Suspensions Having Improved Injectability,” was duly and legally issued to Alkermes Controlled Therapeutics, Inc. A true and correct copy of the ’061 patent is attached hereto as Exhibit A.

28. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the ’061 patent is listed in the FDA’s Approved Drug Products with Therapeutic Equivalence

Evaluations (also known as the "Orange Book") for Risperdal Consta® 25 mg, 37.5 mg, and 50 mg.

29. Effective September 15, 2011 Alkermes Controlled Therapeutics, Inc. assigned one half interest in the '061 patent to Alkermes Pharma Ireland Limited with the confirmatory assignment being filed with the patent office at Reel 027366, Frame 0141.

30. Janssen Pharmaceuticals, Inc. holds an exclusive license under the '061 patent.

CLAIMS FOR RELIEF – PATENT INFRINGEMENT

31. By a letter dated June 4, 2019 ("Defendants' Notice Letter"), Shandong Luye Pharmaceutical Co., Ltd., advised Janssen Pharmaceuticals, Inc. c/o Johnson & Johnson Pharmaceutical Research and Development LLC, Alkermes Pharma Ireland Limited, Alkermes Controlled Therapeutics, Inc., Janssen Pharmaceuticals, Alkermes, Inc., and Covington & Burling LLP that it had submitted NDA No. 212849 to the FDA seeking approval to manufacture, use, or sell Defendants' Risperidone Product 12.5 mg, 25 mg, 37.5 mg and 50 mg prior to the expiration of the '061 patent.

32. On information and belief, Defendants submitted NDA No. 212849 to the FDA under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Defendants' Risperidone Product and citing to the NDA for Risperdal Consta®.

33. On information and belief, Defendants' NDA No. 212849 includes a Paragraph IV certification with respect to the '061 patent.

34. On information and belief, NDA No. 212849 seeks FDA approval of Defendants' Risperidone Product as an atypical antipsychotic indicated for the treatment of

schizophrenia and/or as monotherapy or as adjunctive therapy to lithium or valproate for the maintenance treatment of Bipolar I Disorder.

35. On information and belief, Defendants are in the business of manufacturing, marketing, importing, distributing, and/or selling pharmaceutical drug products, including generic drug products, either directly or through affiliates, agents, and/or alter egos, throughout the United States and this judicial district.

36. On information and belief, Defendants know and intend that Defendants' Risperidone Product will be distributed and sold in Delaware and will thereby displace sales of Risperdal Consta®, causing injury to Plaintiffs.

37. In Defendants' Notice Letter, Defendants purported to offer confidential access to Defendants' NDA No. 212849.

38. Since receiving Defendants' Notice Letter, Plaintiffs negotiated in good faith with Defendants to procure a copy of Defendants' NDA No. 212849 and samples of Defendants' Risperidone Product under restrictions that would protect Defendants' confidential information and materials. The negotiations have been unsuccessful. To date, Plaintiffs have not received either Defendants' NDA No. 212849 or samples of Defendants' Risperidone Product.

39. Defendants' Notice Letter also advised Plaintiffs that Defendants' NDA submission included certifications under 21 C.F.R. § 314.52(c)(5) that, in Defendants' opinion, certain claims of the '061 patent are invalid, unenforceable, and/or not infringed.

40. Defendants' Notice Letter does not allege invalidity or unenforceability of any claims of the '061 patent.

41. By not identifying invalidity or unenforceability defenses for the claims of the ’061 patent in Defendants’ Notice Letter, Defendants admit the claims of the ’061 patent are valid and are enforceable.

42. Defendants have previously challenged the validity of the claims of the ’061 patent. Those prior challenges have been rejected.

43. On May 31, 2016, Defendants filed two petitions requesting *inter partes* review of claims 1-13 and 17-23 of the ’061 patent (IPR2016-01095 and IPR2016-01096).

44. On November 20, 2016, the United States Patent Trial and Appeal Board (“Board”) issued two decisions. In one decision, the Board denied institution in IPR2016-01095 and in the second decision, the Board granted institution in IPR2016-01096.

45. On November 28, 2017, the Board issued a final written decision finding that Defendants had failed to demonstrate that claims 1-13 and 17-23 are unpatentable in IPR2016-01096.

46. There is an actual, real, immediate, and justiciable controversy between Plaintiffs and Defendants regarding the infringement of the ’061 patent.

47. Plaintiffs are commencing this action within 45 days of receiving Defendants’ Notice Letter pursuant to 21 U.S.C. § 355(c)(3)(C).

CLAIM FOR RELIEF
(Infringement of The ’061 Patent)

48. Plaintiffs incorporate each of the preceding paragraphs 1 to 47 as if fully set forth herein.

49. By submitting NDA No. 212849, with a Paragraph IV certification, to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants’ Risperidone Product

throughout the United States, including Delaware, prior to expiration of the '061 patent, Defendants committed an act of infringement of the '061 patent under 35 U.S.C. § 271(e)(2)(A).

50. The '061 patent claims, *inter alia*, injectable compositions having improved injectability.

51. On information and belief, Defendants' Risperidone Product, if approved by the FDA, will contain an injectable composition of risperidone which will infringe one or more claims of the '061 patent either literally or under the doctrine of equivalents.

52. On information and belief, Defendants' manufacture, use, sale, offer for sale, and/or importation into the United States of Defendants' Risperidone Product prior to the expiration of the '061 patent, including any applicable exclusivities or extensions, will infringe one or more claims of the '061 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, and/or Defendants will induce the infringement of and/or contribute to the infringement of one or more claims of the '061 patent under 35 U.S.C. § 271(b) and/or (c).

53. On information and belief, Defendants' Risperidone Product will infringe at least claim 1 of the '061 patent which recites "[a] composition suitable for injection through a needle into a host, comprising: microparticles comprising a polymeric binder; and an injection vehicle, wherein said microparticles are suspended in said injection vehicle at a concentration of greater than about 30 mg/ml to form a suspension, wherein a fluid phase of said suspension has a viscosity greater than about 20 cp and less than about 600 cp at 20° C., wherein the viscosity of said fluid phase of said suspension provides injectability of the composition through a needle ranging in diameter from 18-22 gauge." On information and belief, Defendants' Risperidone Product will infringe claim 1 of the '061 patent because Defendants' Risperidone Product will contain a composition containing risperidone meeting the elements of claim 1.

54. Prior to filing their NDA, Defendants had actual notice of the '061 patent and its listing in the Orange Book as demonstrated by Defendants' reference to the '061 patent in Defendants' Notice Letter and Defendants' filing of petitions for *inter partes* review of the '061 patent.

55. On information and belief, Defendants were aware that filing of the NDA with a Paragraph IV certification prior to the expiry of the '061 patent, inclusive of any extensions and periods of exclusivity, would constitute an act of infringement.

56. Defendants were also aware that the claims of the '061 patent are valid and enforceable. Indeed, their multiple challenges to the validity of the '061 patent all failed, and were rejected by the Board.

57. On information and belief, Defendants know or should know that their commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Risperidone Product prior to patent expiry, inclusive of any extensions and periods of exclusivity, will infringe one or more claims of the '061 patent.

58. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law, and considering the balance of hardships between Plaintiffs and Defendants, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction prior to the expiration of the '061 patent, inclusive of any extensions and periods of exclusivity.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Defendants have infringed one or more claims of United States Patent No. 6,667,061 by submitting NDA No. 212849 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Defendants' Risperidone Product before the expiration of United States Patent No. 6,667,061 including any extensions and additional periods of exclusivity under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Defendants' commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Defendants' Risperidone Product will infringe one or more claims of United States Patent No. 6,667,061 under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Defendants, their officers, agents, servants, employees, parents, affiliates, and subsidiaries, and those persons and entities acting in concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Defendants' Risperidone Product until the day after the expiration of United States Patent No. 6,667,061, inclusive of any extensions or additional periods of exclusivity, and from otherwise infringing the claims of United States Patent No. 6,667,061;

D. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of NDA No. 212849 under Section 505(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)) shall be a date that is not earlier than the day after the expiration of United States Patent No. 6,667,061, inclusive of any extensions or additional periods of exclusivity;

E. An award of damages or other relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C), if Defendants engage in the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Defendants' Risperidone Product, or any product that infringes United States

Patent No. 6,667,061, or induces or contributes to such conduct, prior to the expiration of United States Patent No. 6,667,061, inclusive of any extensions or additional periods of exclusivity;

F. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

G. An award of costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

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/s/ Karen Jacobs

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