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

JANSSEN PHARMACEUTICALS, INC. and JANSSEN PHARMACEUTICA NV, *Plaintiffs*, *v.* QILU PHARMACEUTICAL CO., LTD. and QILU PHARMA INC., *Defendants*.	Civil Action No. 2:24-cv-07094

DEFENDANTS QILU PHARMACEUTICAL CO., LTD AND QILU PHARMA INC.'S ANSWER AND COUNTERCLAIMS

Defendants Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd.") and Qilu Pharma, Inc. ("Qilu Pharma"), (collectively, "Qilu" or "Defendants"), by their undersigned attorneys, for their Answer to the Complaint for Patent Infringement filed by Plaintiffs Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV, LLC ("JPN") (collectively "Janssen" or "Plaintiffs"), state as follows. Pursuant to

Fed. R. Civ. P. 8(b)(3), Qilu denies all allegations in Plaintiffs' Complaint except those expressly admitted below.

NATURE OF THE ACTION

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

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits Plaintiffs purport to bring this civil action for infringement of United States Patent No. 9,439,906 ("the '906 Patent" or "the Patent-In-Suit"). Qilu denies any and all remaining allegations contained in this paragraph.

2. This action relates to the submission of Abbreviated New Drug Application ("ANDA") No. 217889 by Qilu to the United States Food and Drug Administration ("FDA") seeking approval to market a proposed generic version of JPI's Invega Sustenna® brand products ("Qilu's Proposed Generic Products") prior to the expiration of the '906 Patent.

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed Abbreviated New Drug Application ("ANDA") No. 217889 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of generic versions of paliperidone palmitate, (the "Qilu ANDA Products"), which are generic versions of INVEGA SUSTENNA®, prior to

expiration of the '906 Patent. Qilu denies any and all remaining allegations contained in this paragraph.

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: Paragraph 3 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief as to the truth of the allegations in this Paragraph, and therefore denies 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: Paragraph 4 contains legal conclusions and allegations to which no answer is required. Qilu lacks knowledge or information sufficient to form a belief about the truth of the allegations in this paragraph, and therefore denies the same.

5. On information and belief, Qilu Ltd. is a corporation organized and existing under the laws of China, having places of business at 8888, Lvyou Road, High-Tech Zone, Jinan, 250104, China; No. 849, Dongjia Town, Licheng District, Jinan, 250105, China; and No. 23999 Gong Ye Bei Road, Jinan, 250100, China.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Ltd. is a corporation organized and existing under the laws of China, having places of business at 8888, Lvyou Road, High-Tech Zone, Jinan, 250104, China; No. 849, Dongjia Town, Licheng District, Jinan, 250105, China; and No. 23999 Gong Ye Bei Road, Jinan, 250100, China; Qilu denies any and all remaining allegations contained in this paragraph.

6. On information and belief, Qilu Pharma is a corporation organized and existing under the laws of Pennsylvania, having places of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355 and 104 Carnegie Center, Suite 212, Princeton, NJ 08540. Upon information and belief, Qilu Pharma is an agent and/or affiliate of Qilu Ltd.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is a company organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355, and that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

7. On information and belief, Qilu Ltd. and Qilu Pharma 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: Paragraph 7 contains legal conclusions and allegations to which no answer is required. Qilu admits that Qilu Ltd. manufactures and sells generic pharmaceutical products. Qilu denies any and all remaining allegations contained in this paragraph.

8. On information and belief, Qilu Ltd. is acting on behalf of itself and on behalf of Qilu Pharma with respect to Qilu's ANDA No. 217889.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 217889 with the FDA for approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

9. 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: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of patent

infringement, but denies that Plaintiffs are entitled to any relief. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiffs are entitled to any relief. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

Qilu Ltd.

12. This Court has personal jurisdiction over Qilu Ltd. because, *inter alia*, Qilu Ltd. 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. 217889, Qilu Ltd. will, directly or through its affiliate Qilu Pharma, make, use, import, sell, and/or offer for sale Qilu's Proposed Generic Products in the United States, including in New Jersey, prior to the expiration of the 906 Patent.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

13. Exercising personal jurisdiction over Qilu Ltd. in this district would not be unreasonable given Qilu Ltd.'s contacts in this district and this district's interest in resolving disputes related to products to be sold herein.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

14. This Court also has personal jurisdiction over Qilu Ltd. because Qilu Ltd. 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, Qilu Ltd. regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Qilu Pharma—including by selling pharmaceutical products in New Jersey. On information and belief, Qilu Ltd. 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: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

15. On information and belief, Qilu Ltd., either directly or indirectly through Qilu Pharma, 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: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

16. This Court also has personal jurisdiction over Qilu Ltd. because, *inter alia*, this action arises from the actions of Qilu Ltd. directed toward New Jersey. For example, Qilu Ltd.'s counsel sent a letter dated May 8, 2024 to JPI, a corporation with its principal place of business in this Judicial District, stating that Qilu Ltd. had

> submitted ANDA No. 217889 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import Qilu's Proposed Generic Products prior to the expiration of the 906 Patent. If Qilu Ltd. succeeds in obtaining FDA approval, it would sell Qilu's Proposed Generic Products in New Jersey and other states, either directly or through its affiliate Qilu Pharma, causing injury to Plaintiffs in New Jersey.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

> 17. Qilu Ltd. has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Janssen Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial

District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

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

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

19. Qilu Ltd. has consented to or did not contest venue in patent cases in this Judicial District in at least the following District of New Jersey actions: *Janssen Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

20. Venue is proper in this Judicial District for Qilu Ltd. pursuant to 28 U.S.C. § 1400(b), including, for example, because Qilu Ltd.

is a company organized and existing under the laws of China and may be sued in any judicial district.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

Qilu Pharma

21. On information and belief, Qilu Pharma, either directly or indirectly through Qilu Ltd., 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: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

22. On information and belief, Qilu Pharma has substantial, continuous, and systematic contacts with New Jersey, including, but not limited to, maintaining a place of business in New Jersey, designating an agent for service of process in New Jersey, and being registered to conduct business in New Jersey. On information and belief, Qilu Pharma has an active business entity

ID in the State of New Jersey (0400704255) with a place of business at 104 Carnegie Ctr., Suite 212, Princeton, NJ 08540.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889, and that Qilu Pharma has an active business entity ID in the State of New Jersey (0400704255) with a place of business at 104 Carnegie Ctr., Suite 212, Princeton, NJ 08540. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

23. This Court has personal jurisdiction over Qilu Pharma because, *inter alia*, Qilu Pharma 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. 217889, Qilu Pharma will, directly or through its affiliate Qilu Ltd., make, use, import, sell, and/or offer for sale Qilu's Proposed Generic Products in the United States, including in New Jersey, prior to the expiration of the 906 Patent.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

24. Exercising personal jurisdiction over Qilu Pharma in this district would not be unreasonable given Qilu Pharma's contacts in this district and this district's interest in resolving disputes related to products to be sold herein.

ANSWER: Paragraph 24 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

25. This Court also has personal jurisdiction over Qilu Pharma because Qilu Pharma 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, Qilu Pharma regularly and continuously transacts business within New Jersey, either directly or through its affiliates—including Qilu Healthcare, Inc., a company registered with the State of New Jersey's Department of Health (reg. no. 5005245) as a drug manufacturer and wholesaler with a principal place of business in 104 Carnegie Center Suite 212, Princeton, New Jersey 08540—including by selling pharmaceutical products in New Jersey. On information and belief, Qilu Pharma 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: Paragraph 25 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889, and that Qilu Healthcare, Inc. is a company registered with the State of New Jersey's Department of Health (Reg. no. 5005245) as a drug manufacturer and wholesaler with a principal

place of business in 104 Carnegie Center Suite 212, Princeton, New Jersey 08540. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

26. This Court also has personal jurisdiction over Qilu Pharma because, *inter alia*, this action arises from the actions of Qilu Pharma directed toward New Jersey, either directly or through Qilu Ltd. For example, Qilu Pharma's counsel sent a letter dated May 8, 2024 to JPI, a corporation with its principal place of business in this Judicial District, stating that Qilu Pharma had submitted ANDA No. 217889 seeking approval to commercially manufacture, use, sell, offer for sale, and/or import Qilu's Proposed Generic Products prior to the expiration of the 906 Patent. If Qilu Pharma succeeds in obtaining FDA approval, Qilu Pharma would sell Qilu's Proposed Generic Products in New Jersey and other states, either directly or through its affiliate Qilu Ltd., causing injury to Plaintiffs in New Jersey. Furthermore, upon information and belief, Qilu Pharma is Qilu Ltd.'s authorized agent with respect to ANDA No. 217889.

ANSWER: Paragraph 26 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No.

217889. Solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph.

27. Qilu Pharma has consented to or did not contest the jurisdiction of this Court in at least the following District of New Jersey actions: *Janssen Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 27 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest personal jurisdiction in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph

28. Venue is proper in this district pursuant to 28 U.S.C. § 1400(b) because, on information and belief, Qilu Pharma has a regular and established place of business in this district and has committed acts of infringement—e.g., preparing and/or submitting ANDA No. 217889—in this district.

ANSWER: Paragraph 28 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph

29. Qilu Pharma has consented to or did not contest venue in patent cases in this Judicial District in at least the following District of New Jersey actions: *Janssen Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.).

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer is required, solely to conserve the resources of the parties and the Court, Qilu does not contest venue in this Judicial District solely for the limited purposes of this action only. Qilu denies any and all remaining allegations contained in this paragraph

Qilu Ltd. and Qilu Pharma

30. On information and belief, Qilu Ltd. and Qilu Pharma, along with other subsidiaries of Qilu Ltd., 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: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

31. On information and belief, Qilu Ltd. and Qilu Pharma employ people and maintain a regular and established office in New Jersey, including at least at 104 Carnegie Center, Suite 212, Princeton, New Jersey 08540.

ANSWER: Paragraph 31 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that Qilu Pharma is a

company organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355, and that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

32. On information and belief, Qilu Ltd. and Qilu Pharma 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. 217889.

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it filed ANDA No. 217889 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the '906 Patent. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

33. On information and belief, Qilu Ltd. and Qilu Pharma 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. 217889.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it filed ANDA No. 217889 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the '906 Patent. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

34. On information and belief, Qilu Ltd. and Qilu Pharma filed the Qilu ANDA with the FDA that is at issue in this patent infringement suit.

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it filed ANDA No. 217889 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the '906 Patent. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

35. On information and belief, Qilu Ltd. and Qilu Pharma, 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)—including preparing and/or submitting ANDA No. 217889—that has led and/or will lead to

foreseeable harm and injury to Plaintiffs, including JPI, which has a place of business in New Jersey.

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it filed ANDA No. 217889 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the '906 Patent. Qilu further admits that Qilu Pharma is the U.S. agent for Qilu Ltd. with respect to ANDA No. 217889. Qilu denies any and all remaining allegations contained in this paragraph.

THE PATENT-IN-SUIT

36. On September 13, 2016, the 906 Patent, titled "Dosing Regimen With Long Acting Injectable Paliperidone Esters" was duly and legally issued by the United States Patent & Trademark Office to JPN as assignee. A copy of the 906 Patent is attached as Exhibit A.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent Qilu is required to answer, Qilu admits that what purports to be a copy of the '906 Patent is attached to the Complaint as Exhibit A, that the patent is entitled "Dosing Regimen With Long Acting Injectable Paliperidone Esters," and that it bears an issue date of September 13, 2016. Qilu denies that the '906 Patent was duly and legally issued and further denies any suggestion that the '906 Patent is valid or enforceable.

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

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. Qilu admits that, according to FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* (the "Orange Book"), the applicant holder's full name for NDA 022264 for INVEGA SUSTENNA® (paliperidone palmitate) suspension, extended release, intramuscular is JPI. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

38. 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 injectable suspension products.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that the '906 Patent is listed in the Orange Book in connection with NDA 022264 for Invega Sustenna®. Qilu is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

COUNT I

INFRINGEMENT OF THE '906 PATENT BY QILU'S ANDA FOR INVEGA SUSTENNA®

39. Plaintiffs incorporate by reference paragraphs 1–38 as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 38 as if fully set forth herein.

40. An actual controversy exists between the parties as to whether Qilu's proposed sale of Qilu's Proposed Generic Products infringe claims 1-21 of the 906 Patent.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

41. By letter dated May 8, 2024 ("Qilu Notice Letter"), Qilu notified Plaintiffs that it had submitted ANDA No. 217889 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. 217889 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 Qilu's Proposed Generic Products prior to the expiration of certain Orange Book listed patents. ANDA No. 217889 specifically seeks FDA approval to market generic versions of JPI's Invega Sustenna® brand paliperidone palmitate extended-release injectable suspension products in 117 mg, 156 mg, and 234 mg doses prior to the expiration of the 906 Patent.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter

to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements, and that the May 8, 2014 notice letter states that the proposed strengths of the Qilu ANDA Products are 117 mg/0.75 mL, 156 mg/mL, and 234 mg/1.5mL. Qilu further admits that it filed ANDA No. 217889 with the FDA with a paragraph IV certification to obtain approval to engage in the commercial manufacture, use or sale of the Qilu ANDA Products prior to expiration of the '906 Patent. Qilu denies any and all remaining allegations contained in this paragraph.

42. ANDA No. 217889 includes a Paragraph IV Certification that the claims of the 906 Patent are invalid, unenforceable, and/or not infringed.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

43. Upon information and belief, the Qilu Notice Letter was sent to Plaintiffs via overnight mail no earlier than May 8, 2024.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

44. The Qilu Notice Letter was subsequently received by Plaintiffs, and Plaintiffs commenced this action within 45 days of the date of receipt of Qilu's Notice Letter.

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements, and that Plaintiffs filed their Complaint on June 18, 2024. Qilu denies any and all remaining allegations contained in this paragraph.

45. The Qilu Notice Letter purports to include a Notice of Certification for ANDA No. 217889 under 37 C.F.R. §

314.95(c)(6) as to the 906 Patent. The Qilu Notice Letter did not include a detailed statement of allegations of non-infringement as to any claims of the 906 Patent.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

46. Qilu has actual knowledge of the 906 Patent, as shown by the Qilu Notice Letter.

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu admits that it sent a notice letter to Plaintiffs, dated May 8, 2024, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 217889 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to the '906 Patent, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

47. On information and belief, Qilu's Proposed Generic Products, if approved and marketed, will infringe, either literally or under the doctrine of equivalents, claims 1-21 of the 906 Patent, under at least one of 35 U.S.C. § 271(a), (b), and/or (c).

ANSWER: Paragraph 47 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

48. On information and belief, under 35 U.S.C. § 271(e)(2)(A), Qilu has infringed claims 1-21 of the 906 Patent by submitting, or causing to be submitted, to the FDA ANDA No. 217889 seeking approval to manufacture, use, import, offer to sell or sell Qilu's Proposed Generic Products before the expiration date of the 906 Patent. Upon information and belief, the products described in ANDA No. 217889 would infringe, either literally or under the doctrine of equivalents, claims 1-21 of the 906 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 48 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

49. On information and belief, upon approval of ANDA No. 217889, physicians and/or patients will directly infringe claims 1-21 of the 906 Patent by use of Qilu's Proposed Generic Products.

ANSWER: Paragraph 49 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

50. On information and belief, upon approval of ANDA No. 217889, Qilu will take active steps to encourage the use of Qilu's Proposed Generic Products by physicians and/or patients with the knowledge and intent that Qilu's Proposed Generic Products will be used by physicians and/or patients in a manner that infringes claims 1-21 of the 906 Patent for the pecuniary benefit

of Qilu. Pursuant to 21 C.F.R. § 314.94, Qilu is required to copy the FDA-approved Invega Sustenna® labeling. Qilu specifically intends Qilu's Proposed Generic Products to be used according to its proposed labeling in a manner that infringes claims 1-21 of the 906 Patent. Upon information and belief, Qilu will thus induce the infringement of claims 121 of the 906 Patent.

ANSWER: Paragraph 50 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

51. On information and belief, upon approval of ANDA No. 217889, Qilu will sell or offer to sell Qilu's Proposed Generic Products specifically labeled for use in practicing claims 1-21 of the 906 Patent, wherein Qilu's Proposed Generic Products are a material part of the claimed invention, wherein Qilu knows that physicians will prescribe and patients will use Qilu's Proposed Generic Products in accordance with the instructions and/or label provided by Qilu in practicing claims 1-21 of the 906 Patent, and wherein Qilu's Proposed Generic Products are not staple articles or commodities of commerce suitable for substantial non-infringing use. Qilu's Proposed Generic Products are specifically designed for use in a manner that infringes claims 1-21 of the 906 Patent. On information and belief, Qilu will thus contribute to the infringement of claims 1-21 of the 906 Patent.

ANSWER: Paragraph 51 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

52. On information and belief, the actions described in this Complaint relating to Qilu's ANDA No. 217889 were done by and for the benefit of Qilu.

ANSWER: Paragraph 52 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 53 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

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

ANSWER: Paragraph 54 contains legal conclusions to which no answer is required. To the extent an answer is required, Qilu denies the allegations contained in this paragraph.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully pray for the following relief:

A. Enter judgment under 35 U.S.C. § 271(e)(2)(A) that Qilu has infringed claims 1-21 of the 906 Patent through Qilu's submission of ANDA No. 217889 to the FDA to obtain approval to manufacture, use, import, offer to sell, and sell Qilu's Proposed Generic Products 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 Qilu's commercial manufacture use, offer for sale, or sale within the United States, or importation into the United States of Qilu's Proposed Generic 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. 217889 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 Qilu, its affiliates, officers, agents, servants, and employees, and those persons in active concert or participation with Qilu, are preliminarily and permanently enjoined from commercially manufacturing, using, importing, offering for sale, and selling Qilu's Proposed Generic 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 Qilu engages in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Qilu's Proposed Generic 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.

RESPONSE TO PRAYER FOR RELIEF

Qilu denies all allegations not expressly admitted herein. Qilu further denies that Plaintiffs are entitled to any of the relief requested in paragraphs (A) through (G), and requests that Plaintiffs' Complaint be dismissed with prejudice and that Qilu be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

QILU'S ADDITIONAL DEFENSES

Qilu asserts the following additional defenses without prejudice to the denials in this Answer and without admitting any allegations of the Complaint not otherwise admitted. Qilu asserts these additional defenses without conceding that it bears a burden of proof on them, and reserves the right to assert additional defenses as warranted.

FIRST ADDITIONAL DEFENSE

(Invalidity of the '906 Patent)

The claims of the '906 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq*. or under other judicially-created bases for invalidation.

SECOND ADDITIONAL DEFENSE

(No Direct Infringement of the Patent-in-Suit)

Qilu does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patent-in-Suit and Qilu's products that are the subject of ANDA No. 217889 do not infringe any valid and enforceable claim of the Patent-in-Suit.

THIRD ADDITIONAL DEFENSE

(No Infringement of the Patent-in-Suit)

Qilu has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the Patent-in-Suit, and the marketing, sale, and/or distribution of Qilu's products that are the subject of ANDA No. 217889 does not induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the Patent-in-Suit.

FOURTH ADDITIONAL DEFENSE

(Failure to State a Claim)

Plaintiffs' complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

FIFTH ADDITIONAL DEFENSE

(Failure to State a Claim for Exceptional or Willful Infringement)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL DEFENSES

Qilu reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Qilu Pharmaceutical Co., Ltd. ("Qilu Ltd.") and Qilu Pharma, Inc. ("Qilu Pharma"), (together "Defendants/Counterclaim-Plaintiffs" or "Qilu"), by way of its attorneys, hereby states for its Counterclaims against Janssen Pharmaceuticals, Inc. ("JPI") and Janssen Pharmaceutica NV, LLC ("JPN") (collectively, "Janssen" or "Plaintiffs/Counterclaim-Defendants"), the following, without prejudice to the denials in this Answer, without admitting any allegations of the Amended Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiffs/Counterclaim-Defendants:

THE PARTIES

1. Qilu repeats and incorporates by reference each of the foregoing paragraphs of Qilu's Answer and Separate Defenses to the Complaint.

2. Qilu Ltd. is a corporation organized and existing under the laws of China, having places of business at 8888, Lvyou Road, High-Tech Zone, Jinan, 250104, China.

3. Qilu Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355

4. Upon information and belief, Plaintiff/Counterclaim-Defendant JPI is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey 08560.

5. Upon information and belief, Plaintiff/Counterclaim-Defendant JPN is a corporation organized and existing under the laws of Belgium, and having a place of business at Turnhoutseweg, 30, B-2340, Beerse, Belgium.

JURISDICTION

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Qilu, and Plaintiffs/Counterclaim-Defendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

9. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants based, *inter alia*, on the filing of this lawsuit in this jurisdiction and because Plaintiffs/Counterclaim-Defendants are doing business in this jurisdiction.

10. Venue is proper in this judicial district under 28 U.S. C. §§ 1391(b) and (c), and 1400(b).

FACTS COMMON TO ALL COUNTS

11. This is an action for a declaratory judgment of invalidity and noninfringement of one or more claims of United States Patent No. 9,439,906 ("the '906 Patent" or "the Patent-in-Suit"). Upon information and belief, a true and correct copy of the Patent-in-Suit was attached to the Complaint as Exhibit A.

12. On or about September 13, 2016, the U.S. Patent & Trademark Office ("USPTO") issued the '906 Patent.

13. Upon information and belief, Plaintiff/Counterclaim-Defendant JPN is the assignee of the '906 Patent.

14. Plaintiff/Counterclaim-Defendant JPI purports to be the holder of New Drug Application ("NDA") No. 022264 for paliperidone palmitate extended-release injectable suspension. Janssen sells its paliperidone palmitate extended-release injectable suspension in the United States under the trademark INVEGA SUSTENNA®.

15. Plaintiffs/Counterclaim-Defendants purport and claim to have the rights to enforce the Patent-in-Suit, and have listed the Patent-in-Suit in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with INVEGA SUSTENNA®.

16. Qilu has filed the Abbreviated New Drug Application ("ANDA) No. 217889 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Qilu's proposed paliperidone palmitate extended-release injectable suspensions described therein (the "Qilu ANDA Products").

17. Qilu's ANDA seeks FDA approval to market the Qilu ANDA Products described within ANDA No. 217889 before the expiration of the '906 Patent listed in the Orange Book, and Qilu's ANDA includes a certification under 21 U.S.C. §

355(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the '906 Patent.

18. Plaintiffs/Counterclaim-Defendants sued Qilu in this District for alleged infringement of the '906 Patent.

COUNT I

(Declaratory Judgment of Invalidity of the '906 Patent)

19. Qilu realleges and incorporates by reference the allegations of paragraphs 1-18 as though full set forth herein.

20. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiffs/Counterclaim-Defendants regarding *inter alia*, the invalidity of the '906 Patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '906 Patent.

21. The claims of the '906 Patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

22. The claims of the '906 Patent are invalid under 35 U.S.C. § 103 because they would have been obvious to a person of ordinary skill in the art, as set forth in Qilu's Notice Letter to Plaintiffs/Counterclaim-Defendants, because each and every

element of each and every claim of the ’906 Patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’906 Patent, including, but not limited to:

1. U.S. Patent No. 6,555,544, “Aqueous Suspensions of Submicron 9-Hydroxyrisperidone Fatty Acid Esters;”
2. Cleton, A. *et al.*, Abstracts of the Annual Meeting of the American Society for Clinical Pharmacology and Therapeutics, 83 Supp. 1, *Clin. Pharmacol. & Therapeutics* S31, PI-74 and PI-75 (Mar. 2008);
3. Citrome, L., “Paliperidone: Quo Vadis?” *Int. J. Clin. Pract.*, 61(1):653-662 (Apr. 2007);
4. Cada, D. J., *et al.*, “Paliperidone” *Hospital Pharmacy*, 42(7):637-647, (2007);
5. U.S. Patent No. 6,495,534, “Stabilized Aqueous Suspensions For Parenteral Use;”
6. Kane, J. M., *et al.*, “Guidelines for Depot Antipsychotic Treatment in Schizophrenia.” *Eur. Neuropharmacol*, 8(1):55-65 (1998);
7. Aulton, M.E., Pharmaceutics: The Science of Dosage Form Design (2002), Chapter 19; and
8. Goodman & Gilman’s, The Pharmacological Basis of Therapeutics (2001), Chapter 1.

Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the ’906 Patent, and would have had a reasonable expectation of success in doing so.

23. There is no objective evidence of non-obviousness of the claims of the ’906 Patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’906 Patent.

24. Qilu is entitled to a judicial declaration that the claims of the ’906 Patent are invalid.

25. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’906 Patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT II

(Declaratory Judgment of Noninfringement of the ’906 Patent)

26. Qilu realleges and incorporates by reference the allegations of paragraphs 1-25 as though fully set forth herein.

27. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, non-infringement of the claims of the ’906 Patent.

28. The manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Products described in Qilu’s ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or

marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '906 Patent, either literally or under the doctrine of equivalents.

29. Qilu is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of the Qilu ANDA Products described in Qilu's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '906 Patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Qilu respectfully requests that the Court enter judgment in its favor and against Plaintiffs/Counterclaim Defendants Janssen Pharmaceuticals, Inc. and Janssen Pharmaceutica NV, LLC as follows:

A. Dismissing Plaintiff's Amended Complaint, and each and every claim by Plaintiff against Qilu for relief contained therein, with prejudice;

B. Declaring that Qilu does not infringe any valid claim of the '906 Patent, and that the claims of the '906 Patent are invalid for failure to comply with one or more provisions of 35 U.S.C. § 101, *et seq.*;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Qilu ANDA Products in Qilu's ANDA No. 217889 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claims of the '906 Patent, either literally or under the doctrine of equivalents;

D. Declaring this case exceptional and awarding Qilu reasonable attorneys' fees and costs under 35 U.S.C. § 285;

E. Awarding Qilu its costs and expenses

F. Ordering that Plaintiffs/Counterclaim-Defendants and its officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using the '906 Patent to block, hamper, hinder or obstruct FDA approval of the products described in Qilu's ANDA; and

G. Awarding Qilu such other and further relief as the Court may deem just and proper.

Dated: August 27, 2024

By: */s/ Ian Scott l*

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Qilu Pharmaceutical Co., Ltd. and
Qilu Pharma Inc.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that the matter in controversy is related to Civil Actions Nos. 2:18-cv-00734 and 2:19-cv-16484 which are currently pending in this Judicial District.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court, or of any pending arbitration or administrative proceeding.

Dated: August 27, 2024

TAFT, STETTINIUS & HOLLISTER, LLC

By: */s / Ian Scott*
IAN SCOTT

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, I hereby certify that the causes of action asserted herein as counterclaims seek primarily declaratory judgment relief and as such, this is not appropriate for compulsory arbitration.

Dated: August 27, 2024

TAFT, STETTINIUS & HOLLISTER, LLC
By: */s/ Ian Scott*
IAN SCOTT

CERTIFICATE OF SERVICE

The undersigned certifies that, on August 27, 2024, a true and accurate copy of DEFENDANTS QILU PHARMACEUTICAL CO., LTD and QILU PHARMA, INC.'S ANSWER AND COUNTERCLAIMS was filed with the Court and served on all counsel of record for Plaintiff via the Court's electronic filing system.

Dated: August 27, 2024

TAFT, STETTINIUS & HOLLISTER, LLC

By: */s/ Ian Scott*
IAN SCOTT