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Qilu Pharmaceutical (Hainan) Co., Ltd. and Qilu Pharma, Inc.

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

IMPAX LABORATORIES, LLC, *Plaintiff*, *v.* QILU PHARMACEUTICAL (HAINAN) CO., LTD. and QILU PHARMA INC., *Defendants*.	Civil Action No. 2:25-cv-01962-EP-CLW

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

Defendants Qilu Pharmaceutical (Hainan) Co., Ltd. ("Qilu Hainan") 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 Plaintiff Impax Laboratories, LLC ("Impax" or "Plaintiff"), state as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Qilu denies all allegations in Plaintiff's Complaint except those expressly admitted below.

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the food and drug laws and patent laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Impax's RYTARY® (Carbidopa/Levodopa) extended-release capsules prior to the

expiration of United States Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively, the "Patents-in-Suit"), and other patents listed in the Orange Book for RYTARY®.

ANSWER: Paragraph 1 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits Plaintiff purport to bring this civil action for infringement of United States Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively, the "Patents-in-Suit"). Qilu admits that it filed Abbreviated New Drug Application ("ANDA") No. 220177 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, which are generic versions of RYTARY®, prior to expiration of the Patents-in-Suit. Qilu denies any and all remaining allegations contained in this paragraph.

PARTIES

2. Plaintiff Impax Laboratories, LLC is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal Pharmaceuticals LLC. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807. Amneal Pharmaceuticals LLC is a limited liability company organized under the laws of Delaware with a principal place of business at 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

ANSWER: Paragraph 2 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.

3. On information and belief, Defendant Qilu Hainan is a corporation organized and existing under the laws of China, having a principal place of business at Room A, No.273, Nanhai Boulevard, State Hi-and-New Tech Park, Haikou, Hainan, 570314, China.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Hainan is a corporation organized and existing under the laws of China, having a place of business at No. 273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan 570314, China. Qilu denies any and all remaining allegations contained in this paragraph.

4. On information and belief, Defendant Qilu Pharma is a company organized and existing under the laws of the State of Pennsylvania, having principal places of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355 and 104 Carnegie Center, Suite 212, Princeton, NJ 08540.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Pharma is a company organized and existing under the laws of the State of Pennsylvania, having places of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355 and 104 Carnegie Center, Suite 212, Princeton, NJ 08540. Qilu denies any and all remaining allegations contained in this paragraph.

5. On information and belief, Qilu Pharma is the United States agent for Qilu Hainan with respect to ANDA No. 220177.

ANSWER: Paragraph 5 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Hainan with respect to ANDA No. 220177. Qilu denies any and all remaining allegations contained in this paragraph.

6. On information and belief, Defendants are in the business of developing, preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the State of New Jersey.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. Qilu admits that Qilu Hainan manufactures and sells generic pharmaceutical products. Qilu denies any and all remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 et seq., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

ANSWER: Paragraph 7 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Plaintiff's Complaint is for alleged patent infringement and for declaratory judgment of patent infringement, but denies that Plaintiff is entitled to any relief. Qilu denies any and all remaining allegations contained in this paragraph.

8. On information and belief, Defendants purposefully have conducted and continue to conduct business in this Judicial District.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

9. On information and belief, Defendants conduct business in the United States and in the State of New Jersey, including through and using the offices of Qilu Pharma and Qilu Healthcare, Inc.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

10. On information and belief, Defendants are in the business of, among other things, manufacturing, marketing, importing, distributing, offering for sale, and/or selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

11. On information and belief, Defendants directly or indirectly develop, manufacture, import, market, distribute, and/or sell pharmaceutical products that are and/or will be manufactured and sold, pursuant to ANDA filings or other regulatory filings, throughout the United States, including in this Judicial District.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

12. On information and belief, Defendants develop and manufacture generic pharmaceutical products, which they then sell in the United States, the locations or operations of which are in, among other places, the State of New Jersey.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer may be 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. On information and belief, this Judicial District will be a destination for the generic version of Impax's RYTARY® (Carbidopa/Levodopa) extended-release capsules for which Defendants seek FDA approval to manufacture, market, import, offer to sell, and/or sell pursuant to ANDA No. 220177.

ANSWER: Paragraph 13 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. 220177 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, which are generic versions of RYTARY®, prior to expiration of the Patents-in-Suit. Further, 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. On information and belief, if the Qilu ANDA (defined below) is approved, the Qilu ANDA Products (defined below) will be marketed, distributed, and/or sold, directly or indirectly, by Defendants in the State of New Jersey, dispensed by pharmacies located within the State of New Jersey, and used by patients in the State of New Jersey. Specifically, on information and belief, if Defendants succeed in obtaining FDA approval, Defendants will, directly or indirectly, market, distribute, and/or sell the Qilu ANDA Products in the State of New Jersey.

ANSWER: Paragraph 14 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

15. On information and belief, Qilu Pharma has a principal and a regular and established place of business at 104 Carnegie Center, Suite 212, Princeton, NJ 08540.

ANSWER: Paragraph 15 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Pharma is a company organized and existing under the laws of the State of New Jersey, having a place of business at 104 Carnegie Center, Suite 212, Princeton, NJ 08540. Further, 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. Qilu Pharma has a corporate agent for service of process in the State of New Jersey at 108 Carnegie Center, Suite 208, Princeton, New Jersey 08540.

ANSWER: Paragraph 16 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

17. Qilu Pharma is registered with the New Jersey Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Entity ID No. 0400704255.

ANSWER: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Pharma has an active business entity identification number in the State of New Jersey (0400704255), maintains a regular and established place of business at 104 Carnegie Center, 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.

18. Qilu Pharma's affiliate, Qilu Healthcare, Inc., is also registered with the State of New Jersey's Department of Health as a drug wholesaler and manufacturer operating in New Jersey under registration number 5005245. On information and belief, Qilu Hainan operates in the State of New Jersey through and using the offices of Qilu Pharma and/or Qilu Healthcare, Inc.

ANSWER: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu Pharma is the U.S. agent for Qilu Hainan. with respect to ANDA No. 220177, 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, 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.

19. On information and belief, Defendants are in the business of, *inter alia*: (a) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey, and importing generic pharmaceutical products into the United States, including throughout the State of New Jersey; (b) in concert with each other and/or through their various affiliates, including Qilu Healthcare, Inc., the preparation, submission, and filing of Abbreviated New Drug Applications seeking FDA approval to market generic drugs throughout the United States, including throughout the State of New Jersey; and (c) in concert with each other and/or through their various affiliates, including Qilu Healthcare, Inc., the distribution of generic pharmaceutical products for sale throughout the United States, including throughout the State of New Jersey.

ANSWER: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Qilu manufactures and sells generic pharmaceutical products. 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.

20. On information and belief, Defendants intend to benefit directly if the Qilu ANDA is approved by participating in the manufacture, importation, distribution, offer to sell, and/or sale of the generic drug products throughout the United States, including in the State of New Jersey, that are the subject of the Qilu ANDA.

ANSWER: Paragraph 20 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

21. On information and belief, one or both of Defendants, and/or their affiliates, have previously submitted to the jurisdiction of this Court and/or have further previously availed themselves of this Court by

asserting counterclaims in other civil actions initiated in this jurisdiction. *See, e.g.*, *Janssen Pharmaceuticals, Inc. et al v. Qilu Pharmaceutical Co., Ltd. et al*, No. 2:24-cv-7094, Dkt. No. 16 (D.N.J. Aug. 27, 2024); *Astellas Pharma Inc. et al v. Qilu Pharmaceutical Co., Ltd. et al*, No. 3:24-cv-8217, Dkt. No. 17 (D.N.J. Oct. 7, 2024); *AbbVie Inc. et al v. Qilu Pharma Inc. et al*., No. 3:24-cv-6759, Dkt. No. 26 (D.N.J. Sept. 19, 2024); *Eli Lilly & Co., et al v. Qilu Pharmaceutical Co., Ltd., et al*, No. 2:24-cv-05847, Dkt. No. 11 (D.N.J. July 15, 2024); *Boehringer Ingelheim Pharms. Inc., et al v. Qilu Pharm. Co., Ltd., et al*, No. 3:21-cv-01732, Dkt. No. 9 (D.N.J. Apr. 27, 2021); and *Helsinn Healthcare S.A., et al v. Qilu Pharm. Co., Ltd., et al*, No. 2:15-cv-08132, Dkt. No. 14 (D.N.J. Feb. 16, 2016) (collectively, "Prior Actions").

ANSWER: Paragraph 21 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

22. For at least the foregoing reasons set forth above, this Court has personal jurisdiction over Defendants because, on information and belief, Defendants: (a) have substantial, continuous, and systematic contacts with the State of New Jersey; (b) have in the past and intend in the future to manufacture, market, import, offer to sell, sell, and/or distribute Defendants' pharmaceutical products to residents of the State of New Jersey; (c) maintain a distributorship network within the State of New Jersey; (d) enjoy income from sales of their generic pharmaceutical products in the State of New Jersey; (e) are located in and/or have consented to and/or not contested personal jurisdiction in the Prior Actions; and (f) one or both of Defendants, and/or their affiliates, have availed themselves of the jurisdiction of this Court by asserting counterclaims in at least one of the Prior Actions.

ANSWER: Paragraph 22 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

23. For at least the foregoing reasons set forth above, venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and/or 1400(b).

Among other reasons, venue is proper in this Judicial District because: (a) Qilu Pharma has a regular and established place of business in the State of New Jersey and has and will continue to engage in infringement activities in the State of New Jersey; (b) Qilu Hainan is incorporated in China and may be sued in any judicial district in which Qilu Hainan is subject to the court's personal jurisdiction, and further operates in the United States, upon information and belief, through or in concert with at least Qilu Pharma and Qilu Healthcare, Inc., which have principal and regular and established places of business in the State of New Jersey; and (c) one or both of Defendants, and/or their affiliates, have previously consented to and/or not contested venue in this Judicial District in at least one of the Prior Actions.

ANSWER: Paragraph 23 contains legal conclusions to which no answer is required. To the extent an answer may be 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.

BACKGROUND

U.S. Patent No. 8,557,283

24. On October 15, 2013, the United States Patent & Trademark Office ("PTO"), duly and legally issued United States Patent No. 8,557,283 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '283 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '283 patent is attached as Exhibit 1.

ANSWER: Paragraph 24 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 '283 patent was attached to the Complaint as Exhibit 1, that the patent is entitled "Controlled Release Formulations of Levodopa and Uses Thereof," that the patent lists on its face as inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani, and Impax Laboratories, Inc. as assignee, and that it bears an issue date of October 15, 2013. Qilu further admits that the FDA's *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") lists the expiration of the

'283 patent as December 26, 2028. Qilu denies that the '283 patent was duly and legally issued and further denies any suggestion that the '283 patent is valid or enforceable.

U.S. Patent No. 9,089,608

25. On July 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,608 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '608 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '608 patent is attached as Exhibit 2.

ANSWER: Paragraph 25 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 '608 patent is attached to the Complaint as Exhibit 2, that the patent is entitled "Controlled Release Formulations of Levodopa and Uses Thereof," that the patent lists on its face as inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani, and Impax Laboratories, Inc. as assignee, and that it bears an issue date of July 28, 2015. Qilu further admits that the Orange Book lists the expiration of the '608 patent as December 26, 2028. Qilu denies that the '608 patent was duly and legally issued and further denies any suggestion that the '608 patent is valid or enforceable.

U.S. Patent No. 9,463,246

26. On October 11, 2016, the PTO duly and legally issued United States Patent No. 9,463,246 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. The '246 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '246 patent is attached as Exhibit 3.

ANSWER: Paragraph 26 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 '246 patent is attached to the Complaint as Exhibit 3, that the patent is entitled "Controlled Release Formulations of Levodopa and Uses Thereof," that the patent lists on its face as inventors Ann

Hsu, Jim H. Kou and Laman Lynn Alani, and Impax Laboratories, Inc. as assignee, and that it bears an issue date of October 11, 2016. Qilu further admits that the Orange Book lists the expiration of the '246 patent as December 26, 2028.. Qilu denies that the '246 patent was duly and legally issued and further denies any suggestion that the '246 patent is valid or enforceable.

U.S. Patent No. 9,533,046

27. On January 3, 2017, the PTO duly and legally issued United States Patent No. 9,533,046 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim Kou and Laman Alani. The '046 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '046 patent is attached as Exhibit 4.

ANSWER: Paragraph 27 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 '046 patent is attached to the Complaint as Exhibit 4, that the patent is entitled "Controlled Release Formulations of Levodopa and Uses Thereof," that the patent lists on its face as inventors Ann Hsu, Jim Kou and Laman Alani, and Impax Laboratories, Inc. as assignee, and that it bears an issue date of January 3, 2017. Qilu further admits that the Orange Book lists the expiration of the '046 patent as December 26, 2028. Qilu denies that the '046 patent was duly and legally issued and further denies any suggestion that the '046 patent is valid or enforceable.

U.S. Patent No. 9,901,640

28. On February 27, 2018, the PTO duly and legally issued United States Patent No. 9,901,640 entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim Kou and Laman Alani. The '640 patent is owned by assignment by Impax and per the FDA Orange Book patent data will expire on December 26, 2028. A true and correct copy of the '640 patent is attached as Exhibit 5.

ANSWER: Paragraph 28 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 '640 patent

is attached to the Complaint as Exhibit 5, that the patent is entitled "Controlled Release Formulations of Levodopa and Uses Thereof," that the patent lists on its face as inventors Ann Hsu, Jim Kou and Laman Alani, and Impax Laboratories, Inc. as assignee, and that it bears an issue date of February 27, 2018. Qilu further admits that the Orange Book lists the expiration of the '640 patent as December 26, 2028. Qilu denies that the '640 patent was duly and legally issued and further denies any suggestion that the '640 patent is valid or enforceable.

RYTARY®

29. Impax Laboratories, LLC is the holder of New Drug Application ("NDA") No. 203312 ("the NDA") for carbidopa and levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the Proprietary Name RYTARY®.

ANSWER: Paragraph 29 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that, according to the Orange Book, the applicant holder's full name for NDA 203312 for RYTARY® (carbidopa; levodopa) extended-release oral capsules is Impax laboratories, Inc., and the listed dosages are 23.75 mg/95 mg; 36.25 mg/145 mg; 48.75 mg/195 mg, and 61.25 mg/245 mg. Qilu denies any and all remaining allegations contained in this paragraph.

30. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '283,'608, '246, '046, and '640 patents, among others, are listed in the FDA "Orange Book" with respect to RYTARY®.

ANSWER: Paragraph 30 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that the '283,'608, '246, '046, and '640 patents are listed in the Orange Book in connection with NDA 203312 for RYTARY®. Qilu denies any and all remaining allegations contained in this paragraph.

ACTS GIVING RISE TO THIS ACTION

31. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 30 as if fully set forth herein.

32. On information and belief, Defendants submitted ANDA No. 220177 (the "Qilu ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of carbidopa/levodopa extended-release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the "Qilu ANDA Products").

ANSWER: Paragraph 32 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 220177 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 having proposed strengths of 23.75 mg/95mg; 36.25mg/145mg; 48.75mg/195mg; and 61.25mg/245mg. Qilu denies any and all remaining allegations contained in this paragraph.

33. On information and belief, following FDA approval of the Qilu ANDA, Defendants intend to make, use, sell, or offer to sell the Qilu ANDA Products throughout the United States, including in the State of New Jersey, and/or import that generic product into the United States, including into the State of New Jersey.

ANSWER: Paragraph 33 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it filed ANDA No. 220177 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. Qilu denies any and all remaining allegations contained in this paragraph.

34. On information and belief, in connection with the submission of the Qilu ANDA, Defendants provided written certification to the FDA, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or not infringed by the commercial manufacture, use, or sale of the Qilu ANDA Products (the "Qilu Paragraph IV Certifications").

ANSWER: Paragraph 34 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA in connection with patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit. Qilu denies any and all remaining allegations contained in this paragraph.

35. No earlier than March 22, 2025, Impax received written notice of the Qilu ANDA and the Qilu Paragraph IV Certifications from Defendants ("Notice Letter"). The Notice Letter included a Detailed Statement of the Factual and Legal Basis for Paragraph IV Certification(s), alleging that, *inter alia*, certain claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of the Qilu ANDA Products ("Detailed Statement").

ANSWER: Paragraph 35 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated March 21, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

36. By filing the Qilu ANDA, Defendants represented to the FDA that the Qilu ANDA Products have the same active ingredients as RYTARY®, have the same method of administration, dosage forms, and strengths, and are bioequivalent to RYTARY®, and would be sold under a label substantively the same as the label for RYTARY®.

ANSWER: Paragraph 36 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated March 21, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

37. Pursuant to a prior Paragraph IV notice letter dated February 6, 2025, relating to the same Qilu ANDA, Defendants offered confidential access to portions of the Qilu ANDA for the sole purpose of permitting Impax to determine whether to file an infringement action under 35 U.S.C. § 271(e)(2) (the "OCA").

ANSWER: Paragraph 37 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated February 6, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit. An offer of confidential access, as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), was attached to the Notice Letter which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

38. The OCA permitted two outside attorneys engaged or employed by each of Impax Laboratories, LLC and Amneal Pharmaceuticals LLC (collectively, "Recipients") and their in-firm professional staff to access certain information from the produced portions of the Qilu ANDA. The specific information disclosed to Impax was chosen by Defendants.

ANSWER: Paragraph 38 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated February 6, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®,

including the Patents-in-Suit. An offer of confidential access, as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), was attached to the Notice Letter which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

39. Pursuant to the OCA, Recipients' outside attorneys are prohibited from sharing the selected portions of the Qilu ANDA with any other person or entity, including without limitation, any expert or scientific consultant.

ANSWER: Paragraph 39 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated February 6, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit. An offer of confidential access, as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), was attached to the Notice Letter which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

40. The OCA further requires Recipients' outside attorneys to destroy, with notice to Defendants' outside counsel, the provided excerpts from the Qilu ANDA, and any notes, analyses, studies, or other documents containing information from the Qilu ANDA excerpts, within thirty (30) days after the expiration of the forty-five (45) day period following receipt of the Notice Letter and Detailed Statement.

ANSWER: Paragraph 40 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated February 6, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. §

355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit. An offer of confidential access, as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), was attached to the Notice Letter which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

41. The OCA further stated that if Recipients filed suit against Defendants alleging infringement of one or more of the Orange Book patents within the 45-day period, all portions of the ANDA provided, along with any notes, analyses, studies, or other documents containing information from the ANDA, shall be treated with the highest level of confidentiality under any protective order entered in the action brought against Qilu while the litigation is pending. Until such protective order is entered, Recipients' outside attorneys are prohibited from sharing the selected portions of the Qilu ANDA with any other person or entity.

ANSWER: Paragraph 41 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated February 6, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit. An offer of confidential access, as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), was attached to the Notice Letter which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

42. Pursuant to the terms of the OCA, Recipients' outside counsel is also prohibited from publicly disclosing any information in the produced portions of the Qilu ANDA. This prohibition therefore prohibits Impax from including or referencing in this Complaint any information in the limited excerpts from the Qilu ANDA that were provided to Impax's outside counsel under the OCA, beyond general

statements as to whether the Qilu ANDA Products meet patent claim limitations.

ANSWER: Paragraph 42 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated February 6, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) regarding patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit. An offer of confidential access, as provided by 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), was attached to the Notice Letter which satisfied all statutory, legal, and regulatory requirements. Qilu denies any and all remaining allegations contained in this paragraph.

43. Impax's outside counsel executed the OCA on February 28, 2025.

ANSWER: Paragraph 43 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that Impax's counsel executed an amended OCA on February 28, 2025. Qilu denies any and all remaining allegations contained in this paragraph.

44. On March 3, 2025, Defendants provided a limited, 143-page portion of the Qilu ANDA to Recipients' outside counsel under the OCA (the "OCA Production").

ANSWER: Paragraph 44 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that on March 3, 2025, pursuant to 21 U.S.C. § 355(j)(5)(C), as amended by Title XI of the Medicare Prescription Drug, Improvement and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) and restrictions set forth in the agreed-upon OCA. Qilu provided Plaintiff with confidential access to documents for the sole and exclusive purpose of determining whether an infringement action relating to patents listed in the

Orange Book in connection with RYTARY®, including the Patents-in-Suit, could be brought. Qilu denies any and all remaining allegations contained in this paragraph.

45. Defendants' decision to withhold from the OCA Production the vast majority of the Qilu ANDA has severely limited Impax's ability to assess Defendants' non-infringement assertions in the Notice Letter and Detailed Statement. Once Defendants produce the full Qilu ANDA, Impax will be able to assess whether it has a basis to assert additional claims of patent infringement.

ANSWER: Paragraph 45 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

46. This action is being commenced before the expiration of forty-five (45) days from the date Impax received the Notice Letter dated March 21, 2025, under 21 U.S.C. § 355(j)(5)(B)(iii) and thus triggers the thirty (30) month stay under 21 U.S.C. § 355(j)(5)(B)(iii).

ANSWER: Paragraph 46 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it sent a notice letter to Plaintiffs, dated March 21, 2025, which served as written notification to Plaintiffs pursuant to U.S.C. § 355(j)(2)(B) that Qilu submitted ANDA No. 220177 and certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA as to certain patents listed in the Orange Book in connection with RYTARY®, including the Patents-in-Suit, which satisfied all statutory, legal, and regulatory requirements, and that Plaintiffs filed their Complaint on April 25, 2025. Qilu denies the allegations contained in this paragraph.

COUNT I - INFRINGEMENT OF THE '283 PATENT BY QILU

47. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 46 as if fully set forth herein.

48. By submission of the Qilu ANDA with the Qilu Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants

declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '283 patent, in the event that the FDA approves the Qilu ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '283 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

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

49. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '283 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A)..

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

50. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe is a claim construction argument.

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

51. A justiciable controversy exists regarding Defendants' infringement of the '283 patent.

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

52. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '283 patent, including at least claim 1, which can be further assessed upon production by Defendants of the full Qilu ANDA.

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

53. For example, in addition to the act of infringement stemming from the filing of the Qilu ANDA and the Qilu Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Qilu ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 1 of the '283 patent either literally or under the doctrine of equivalents. For example, on information and belief, the Qilu ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '283 patent under 35 U.S.C. § 271(e)(2)(A), Defendants will also indirectly infringe one or more claims of the '283 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

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

54. On information and belief, the Qilu ANDA Products, if approved by FDA, will be prescribed and administered to human patients to reduce motor fluctuations in a patient suffering from Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '283 patent.

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

55. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

ANSWER: Paragraph 55 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

56. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '283 patent and will constitute infringement.

ANSWER: Paragraph 56 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

57. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will induce others to infringe one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Qilu ANDA Products to reduce motor fluctuations in a patient suffering from Parkinson's disease in a manner that meets the limitations of claims in the '283 patent, including at least claim 1.

ANSWER: Paragraph 57 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

58. On information and belief, upon FDA approval of the Qilu ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '283 patent, by at least their promotional activities and package inserts for the Qilu ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER: Paragraph 58 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

59. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will contributorily infringe one or more claims of the '283 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the Qilu ANDA Products constitute a material part of at least one of the claims of the '283 patent; are especially made or adapted for use in infringing the '283 patent; and that the Qilu ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Paragraph 59 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

60. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Qilu ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Qilu ANDA be a date that is not earlier than the expiration date of the '283 patent, or any later expiration of exclusivity for the '283 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER: Paragraph 60 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

61. Defendants have had knowledge of the '283 patent since at least the date Defendants submitted the Qilu ANDA and the Qilu Paragraph IV Certifications and were aware that submission of the Qilu ANDA and the Qilu Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 61 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '283 patent and its listing in the Orange Book as of the date of the submission of Qilu's ANDA with a Paragraph IV certification to the '283 patent. Qilu denies the allegations contained in this paragraph.

62. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Paragraph 62 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT II - INFRINGEMENT OF THE '608 PATENT BY QILU

63. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 62 as if fully set forth herein.

64. By submission of the Qilu ANDA with the Qilu Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '608 patent, in

the event that the FDA approves the Qilu ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '608 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 64 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

65. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '608 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 65 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

66. In the Notice Letter and Detailed Statement, Defendants' basis for asserting that they do not literally infringe claims 1-21 is a claim construction argument.

ANSWER: Paragraph 66 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

67. A justiciable controversy exists regarding Defendants' infringement of the '608 patent.

ANSWER: Paragraph 67 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

68. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will infringe, literally or under the doctrine of equivalents, one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Qilu ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Qilu ANDA and the Qilu Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Qilu ANDA Products practice all the limitations of at least claims 1 and/or 21 of the '608 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, on information and belief, in

addition to literal infringement, the Qilu ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

ANSWER: Paragraph 68 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph..

69. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will also induce others to infringe one or more claims of the '608 patent, including at least claims 1 and/or 21, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '608 patent, by at least their promotional activities and package inserts for the Qilu ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER: Paragraph 69 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

70. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will contributorily infringe one or more claims of the '608 patent, including at least claim 1 and/or 21, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and have had and continue to have knowledge that the Qilu ANDA Products constitute a material part of at least one of the claims of the '608 patent; are especially made or adapted for use in infringing the '608 patent; and that the Qilu ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Paragraph 70 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

71. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Qilu ANDA Products in or into the United States, and are not enjoined

from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Qilu ANDA be a date that is not earlier than the expiration date of the '608 patent, or any later expiration of exclusivity for the '608 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER: Paragraph 71 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

72. Defendants have had knowledge of the '608 patent since at least the date Defendants submitted the Qilu ANDA and the Qilu Paragraph IV Certifications and were aware that submission of the Qilu ANDA and the Qilu Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A), as evidenced by the fact that the Notice Letter and Detailed Statement offer no basis for non-infringement of claim 21 in the '608 patent.

ANSWER: Paragraph 72 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '608 patent and its listing in the Orange Book as of the date of the submission of Qilu's ANDA with a Paragraph IV certification to the '608 patent. Qilu denies the allegations contained in this paragraph.

73. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Paragraph 73 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT III - INFRINGEMENT OF THE '246 PATENT BY QILU

74. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 73 as if fully set forth herein.

75. By submission of the Qilu ANDA with the Qilu Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '246 patent, in the event that the FDA approves the Qilu ANDA. Accordingly, an

actual and immediate controversy exists regarding Defendants' infringement of the '246 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 75 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

76. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '246 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 76 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

77. In the Notice Letter and Detailed Statement, Defendants provide no basis for asserting that they do not infringe claims 1-54 of the '246 patent other than asserted patent invalidity.

ANSWER: Paragraph 77 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

78. A justiciable controversy exists regarding Defendants' infringement of the '246 patent.

ANSWER: Paragraph 78 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

79. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '246 patent, including at least claim 26, which can be further assessed upon production by Defendants of the full Qilu ANDA.

ANSWER: Paragraph 79 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

80. For example, in addition to the act of infringement stemming from the filing of the Qilu ANDA and the Qilu Paragraph IV

Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Qilu ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 26 of the '246 patent either literally or under the doctrine of equivalents. For example, on information and belief, the Qilu ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '246 patent under 35 U.S.C. § 271(e)(2)(A), Defendants will also indirectly infringe one or more claims of the '246 patent, including without limitation claim 26, by inducing at least healthcare professionals and patients to directly infringe that claim.

ANSWER: Paragraph 80 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

81. On information and belief, the Qilu ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '246 patent.

ANSWER: Paragraph 81 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

82. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

ANSWER: Paragraph 82 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

83. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '246 patent and will constitute infringement.

ANSWER: Paragraph 83 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

84. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will induce others to infringe one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Qilu ANDA Products to treat aspects of Parkinson's disease in a manner that meets the limitations of claims in the '246 patent, including at least claim 26.

ANSWER: Paragraph 84 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

85. On information and belief, upon FDA approval of the Qilu ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '246 patent, by at least their promotional activities and package inserts for the Qilu ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER: Paragraph 85 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

86. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will contributorily infringe one or more claims of the '246 patent, including at least claim 26, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the Qilu ANDA Products constitute a material part of at least one of the claims of the '246 patent; are especially made or adapted for use in infringing the '246 patent; and that the Qilu ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Paragraph 86 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

87. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Qilu

ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Qilu ANDA be a date that is not earlier than the expiration date of the '246 patent, or any later expiration of exclusivity for the '246 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER: Paragraph 87 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph

88. Defendants have had knowledge of the '246 patent since at least the date Defendants submitted the Qilu ANDA and the Qilu Paragraph IV Certifications and were aware that submission of the Qilu ANDA and the Qilu Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 88 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '246 patent and its listing in the Orange Book as of the date of the submission of Qilu's ANDA with a Paragraph IV certification to the '246 patent. Qilu denies the allegations contained in this paragraph.

89. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Paragraph 89 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph

COUNT IV - INFRINGEMENT OF THE '046 PATENT BY QILU

90. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 89 as if fully set forth herein.

91. By submission of the Qilu ANDA with the Qilu Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '046 patent, in the event that the FDA approves the Qilu ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants'

infringement of the '046 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 91 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

92. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '046 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 92 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

93. In the Notice Letter and Detailed Statement, Defendants provide no basis for asserting that they do not infringe claims 1-31 of the '046 patent other than asserted patent invalidity.

ANSWER: Paragraph 93 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

94. A justiciable controversy exists regarding Defendants' infringement of the '046 patent.

ANSWER: Paragraph 94 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

95. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will infringe, for example at least under the doctrine of equivalents, one or more claims of the '046 patent, including at least claim 1, which can be further assessed upon production by Defendants of the full Qilu ANDA.

ANSWER: Paragraph 95 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies any and all remaining allegations contained in this paragraph.

96. For example, in addition to the act of infringement stemming from the filing of the Qilu ANDA and the Qilu Paragraph IV Certifications, based on a review of the OCA Production, Impax

believes that it can show after discovery and analysis that the Qilu ANDA Products in combination with at least the label for those products proposed by Defendants in their ANDA submission, practice all the limitations of at least claim 1 of the '046 patent either literally or under the doctrine of equivalents. For example, on information and belief, the Qilu ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial. In addition to direct infringement of the claims of the '046 patent under 35 U.S.C. § 271(e)(2)(A), Defendants will also indirectly infringe one or more claims of the '046 patent, including without limitation claim 1, by inducing at least healthcare professionals and patients to directly infringe that claim.

ANSWER: Paragraph 96 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

97. On information and belief, the Qilu ANDA Products, if approved by FDA, will be prescribed and administered to human patients to treat Parkinson's disease, which uses will constitute direct infringement of one or more claims of the '046 patent.

ANSWER: Paragraph 97 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

98. On information and belief, these directly infringing uses will occur with Defendants' specific intent and encouragement and will be uses that Defendants know or should know will occur.

ANSWER: Paragraph 98 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

99. On information and belief, Defendants will actively induce, encourage, and aid and abet this prescription and administration, with knowledge and specific intent that these uses will be in contravention of Impax's rights under the '046 patent and will constitute infringement.

ANSWER: Paragraph 99 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

100. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will induce others to infringe one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(b), by inducing at least healthcare professionals and patients to use the Qilu ANDA Products to treat aspects of Parkinson's disease in a manner that meets the limitations of claims in the '046 patent, including at least claim 1.

ANSWER: Paragraph 100 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

101. On information and belief, upon FDA approval of the Qilu ANDA, Defendants will intentionally encourage direct infringement, for example *inter alia* under the doctrine of equivalents, with knowledge of the '046 patent, by at least their promotional activities and package inserts for the Qilu ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER: Paragraph 101 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

102. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will contributorily infringe one or more claims of the '046 patent, including at least claim 1, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will contribute to the direct infringement by others, for example *inter alia* under the doctrine of equivalents, and have had and continue to have knowledge that the Qilu ANDA Products constitute a material part of at least one of the claims of the '046 patent; are especially made or adapted for use in infringing the '046 patent; and that the Qilu ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Paragraph 102 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

103. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Qilu ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Qilu ANDA be a date that is not earlier than the expiration date of the '046 patent, or any later

expiration of exclusivity for the '046 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER: Paragraph 103 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

104. Defendants have had knowledge of the '046 patent since at least the date Defendants submitted the Qilu ANDA and the Qilu Paragraph IV Certifications and were aware that submission of the Qilu ANDA and the Qilu Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 104 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '046 patent and its listing in the Orange Book as of the date of the submission of Qilu's ANDA with a Paragraph IV certification to the '046 patent. Qilu denies the allegations contained in this paragraph.

105. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Paragraph 105 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

COUNT V - INFRINGEMENT OF THE '640 PATENT BY QILU

106. Impax realleges all preceding paragraphs as if fully set forth herein.

ANSWER: Qilu incorporates its answers to Paragraphs 1 through 105 as if fully set forth herein.

107. By submission of the Qilu ANDA with the Qilu Paragraph IV Certifications to the FDA and notice to Impax of same, Defendants declared their intent to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '640 patent, in the event that the FDA approves the Qilu ANDA. Accordingly, an actual and immediate controversy exists regarding Defendants' infringement of the '640 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

ANSWER: Paragraph 107 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

108. Defendants' submission of their ANDA to engage in the commercial manufacture, use, sale, offer for sale, or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the '640 patent constitutes infringement of one or more of the claims of that patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 108 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

109. In the Notice Letter and Detailed Statement, Defendants provide no basis for asserting that they do not infringe claims 1-25 of the '640 patent other than asserted patent invalidity.

ANSWER: Paragraph 109 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

110. A justiciable controversy exists regarding Defendants' infringement of the '640 patent.

ANSWER: Paragraph 110 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

111. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will infringe, literally or under the doctrine of equivalents, one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the Qilu ANDA Products. For example, in addition to the act of infringement stemming from the filing of the Qilu ANDA and the Qilu Paragraph IV Certifications, based on a review of the OCA Production, Impax believes that it can show after discovery and analysis that the Qilu ANDA Products practice all the limitations of at least claim 15 of the '640 patent either literally or under the doctrine of equivalents, and thus directly infringe that claim. For example, with regard to the doctrine of equivalents, on information and belief, in addition to literal infringement, the Qilu ANDA Products perform substantially the same function, in substantially the same way, to obtain the same result as the claimed invention, and any alleged differences are insubstantial.

ANSWER: Paragraph 111 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

112. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will also induce others to infringe one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(b). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will intentionally encourage direct infringement, literally or under the doctrine of equivalents, with knowledge of the '640 patent, by at least their promotional activities and package inserts for the Qilu ANDA Products, by at least healthcare professionals and patients, with knowledge that their acts are encouraging infringement.

ANSWER: Paragraph 112 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

113. Unless enjoined by this Court, upon FDA approval of the Qilu ANDA, Defendants will contributorily infringe one or more claims of the '640 patent, including at least claim 15, under 35 U.S.C. § 271(c). On information and belief, upon FDA approval of the Qilu ANDA, Defendants will contribute to the direct infringement by others, literally or under the doctrine of equivalents, and have had and continue to have knowledge that the Qilu ANDA Products constitute a material part of at least one of the claims of the '640 patent; are especially made or adapted for use in infringing the '640 patent; and that the Qilu ANDA Products are not suitable for substantial non-infringing use.

ANSWER: Paragraph 113 contains legal conclusions to which no answer is required.

To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

114. Impax will be substantially and irreparably harmed if Defendants are permitted to make, use, sell, offer to sell, and/or import the Qilu ANDA Products in or into the United States, and are not enjoined from doing so. Impax is entitled to relief including that provided by 35 U.S.C. §§ 271(e)(4) and/or 283, including an order of this Court that the effective date of approval of the Qilu ANDA be a date that is not earlier than the expiration date of the '640 patent, or any later expiration of exclusivity for the '640 patent to which Impax is or becomes entitled, and an injunction against such infringement. Impax does not have an adequate remedy at law.

ANSWER: Paragraph 114 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

115. Defendants have had knowledge of the '640 patent since at least the date Defendants submitted the Qilu ANDA and the Qilu Paragraph IV Certifications and were aware that submission of the Qilu ANDA and the Qilu Paragraph IV Certifications constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 115 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu admits that it was aware of the '640 patent and its listing in the Orange Book as of the date of the submission of Qilu's ANDA with a Paragraph IV certification to the '640 patent. Qilu denies the allegations contained in this paragraph.

116. This is an exceptional case within the meaning of 35 U.S.C. § 285.

ANSWER: Paragraph 116 contains legal conclusions to which no answer is required. To the extent an answer may be required, Qilu denies the allegations contained in this paragraph.

PRAYER FOR RELIEF

WHEREFORE, Impax respectfully requests that the Court enter judgment against Defendants and for the following relief:

(a) A judgment under 35 U.S.C. § 271(e)(2)(A) that Defendants have infringed at least one claim of the Patents-in-Suit through Defendants' submission of the Qilu ANDA and the Qilu Paragraph IV Certifications to the FDA seeking approval to commercially manufacture, use, offer to sell, sell, and/or import in or into the United States the Qilu ANDA Products before the expiration of the Patents-in-Suit;

(b) A judgment under 35 U.S.C. §§ 271(a), (b), and/or (c) that Defendants' commercial manufacture, use, offer to sell, sale, and/or importation in or into the United States of the Qilu ANDA Products prior to the expiration of the Patents-in-Suit will infringe, actively induce

infringement, and/or contribute to the infringement, literally or under the doctrine of equivalents, of at least one claim of the Patents-in-Suit;

(c) An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of the Qilu ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the Patents-in-Suit, including any extensions thereof;

(d) The entry of a preliminary and/or permanent injunction enjoining Defendants, and their affiliates and subsidiaries, and each of their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them, from (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation in or into the United States, of drugs or methods of administering drugs claimed in the Patents-in-Suit, and (ii) seeking, obtaining, or maintaining approval of the Qilu ANDA until the expiration of the Patents-in-Suit or such other later time as the Court may determine;

(e) Damages or other monetary relief to Impax if Defendants commercially manufacture, use, offer to sell, sell, and/or import in or into the United States the Qilu ANDA Products prior to the expiration of the Patents-in-Suit, including any extensions, and that any such monetary relief be awarded to Impax with prejudgment interest;

(f) A finding that this is an exceptional case pursuant to 35 U.S.C. § 285 and awarding Impax its attorney's fees incurred in this action;

(g) A judgment awarding Impax its costs and expenses incurred in this action; and

(h) Such further and other relief as this Court may deem just and proper.

RESPONSE TO PRAYER FOR RELIEF

Qilu denies all allegations not expressly admitted herein. Qilu further denies that Plaintiff is entitled to any of the relief requested in paragraphs (a) through (h), and requests that Plaintiff's 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 Patents-in-Suit)

The claims of the Patents-in-Suit 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 Patents-in-Suit)

Qilu does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the Patents-in-Suit and the Qilu ANDA Products that are the subject of ANDA No. 220177 do not infringe any valid and enforceable claim of the Patents-in-Suit.

THIRD ADDITIONAL DEFENSE
(No Infringement of the Patents-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 Patents-in-Suit, and the marketing, sale, and/or distribution of the Qilu ANDA Products that are the subject of ANDA No. 220177 will not

induce the infringement of, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

FOURTH ADDITIONAL DEFENSE

(Failure to State a Claim)

Plaintiff's 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)

Plaintiff fails 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 (Hainan) Co., Ltd. ("Qilu Hainan") and Qilu Pharma, Inc. ("Qilu Pharma"), (together "Defendants/Counterclaim-Plaintiffs" or "Qilu"), by way of its attorneys, hereby states for its Counterclaims against Impax Laboratories, LLC ("Impax" or "Plaintiff/Counterclaim-Defendant"), the following, without prejudice to the denials in this Answer, without admitting any allegations of the Complaint not otherwise admitted, and without assuming the burden when such burden would otherwise be on Plaintiff/Counterclaim-Defendant:

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 Hainan is a corporation organized and existing under the laws of China, having a place of business at No. 273-A, Nanhai Avenue, National High-Tech Zone, Haikou, Hainan 570314, China.

3. Qilu Pharma 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 Impax is a limited liability company organized and existing under the laws of the State of Delaware and is wholly-owned by Amneal Pharmaceuticals LLC. Impax's registered business address is 400 Crossing Boulevard, 3rd Floor, Bridgewater, New Jersey 08807.

JURISDICTION

5. 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)).

6. 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)).

7. 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 Plaintiff/Counterclaim-Defendant, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

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

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

FACTS COMMON TO ALL COUNTS

10. This is an action for a declaratory judgment of invalidity and noninfringement of one or more claims of United States Patent Nos. 8,557,283 ("the '283 patent"), 9,089,608 ("the '608 patent"), 9,463,246 ("the '246 patent"), 9,533,046 ("the '046 patent"), and 9,901,640 ("the '640 patent") (collectively, the "Patents-in-Suit"). Upon information and belief, true and correct copies of the Patents-in-Suit were attached to the Complaint as Exhibits 1-5.

11. On or about October 15, 2013, the U.S. Patent & Trademark Office ("USPTO") issued the '283 patent.

12. On or about July 28, 2015, the U.S. Patent & Trademark Office ("USPTO") issued the '608 patent.

13. On or about October 11, 2016, the U.S. Patent & Trademark Office ("USPTO") issued the '246 patent.

14. On or about January 3, 2017, the U.S. Patent & Trademark Office ("USPTO") issued the '046 patent.

15. On or about February 27, 2018, the U.S. Patent & Trademark Office ("USPTO") issued the '640 patent.

16. Upon information and belief, Plaintiff/Counterclaim-Defendant Impax is the assignee of each of the Patents-in-Suit.

17. Plaintiff/Counterclaim-Defendant Impax purports to be the holder of New Drug Application ("NDA") No. 203312 for carbidopa and levodopa extended-release capsules for oral use. Impax sells its carbidopa and levodopa extended-release capsules for oral use in the United States under the trademark RYTARY®.

18. Plaintiff/Counterclaim-Defendant purports and claims to have the rights to enforce the Patents-in-Suit, and has listed the Patents-in-Suit in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with RYTARY®.

19. Qilu has filed Abbreviated New Drug Application ("ANDA) No. 220177 ("Qilu's ANDA") with the U.S. Food and Drug Administration (the "FDA") seeking approval for Qilu's

proposed carbidopa and levodopa extended-release capsules for oral use described therein (the "Qilu ANDA Products").

20. Qilu's ANDA seeks FDA approval to market the Qilu ANDA Products described within ANDA No. 220177 before the expiration of the Patents-in-Suit 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 Patents-in-Suit.

21. Plaintiff/Counterclaim-Defendant sued Qilu in this District for alleged infringement of the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Invalidity of the '283 Patent)

22. Qilu realleges and incorporates by reference the allegations of paragraphs 1-21 as though full set forth herein.

23. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '283 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 '283 patent.

24. The claims of the '283 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.

25. The claims of the '283 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 March 21, 2025

Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '283 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '283 patent, including, but not limited to:

i. U.S. Patent Appl. Publication No. 2006/0013875, "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms";

ii. Iida, A., *et al*., "Improvement of Intestinal Absorption of P-glycoprotein Substrate by D-tartaric Acid" Drug Metab. Pharmacokinet. (2006) 21(5): 424-428;

iii. Hayashi, M., *et al.,* "Mechanistic Analysis for Drug Permeation Through Intestinal Membrane" Drug Metab. Pharmacokinet. (2007) 22(2):67–77;

iv. Porter, S. C., *et al*., "Coating of Pharmaceutical Dosage Forms," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 929, 932-933; and

v. Kandukuri, J. M., *et al*., "Pelletization Techniques for Oral Drug Delivery" International Journal of Pharmaceutical Sciences and Drug Research (2009) 1(2):63-70.

26. 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 '283 patent, and would have had a reasonable expectation of success in doing so.

27. There is no objective evidence of non-obviousness of the claims of the '283 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '283 patent.

28. Qilu is entitled to a judicial declaration that the claims of the '283 patent are invalid.

29. Qilu reserves the right to provide additional bases for invalidity of each claim of the '283 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 '283 Patent)

30. Qilu realleges and incorporates by reference the allegations of paragraphs 1-29 as though fully set forth herein.

31. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '283 patent.

32. 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 '283 patent, either literally or under the doctrine of equivalents.

33. 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 '283 patent, either literally or under the doctrine of equivalents.

COUNT III

(Declaratory Judgment of Invalidity of the '608 Patent)

34. Qilu realleges and incorporates by reference the allegations of paragraphs 1-33 as though full set forth herein.

35. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '608 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 '608 patent.

36. The claims of the '608 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.

37. The claims of the '608 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 March 21, 2025 Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '608 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '608 patent, including, but not limited to:

i. U.S. Patent Appl. Publication No. 2006/0013875, "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms";

ii. Iida, A., *et al*., "Improvement of Intestinal Absorption of P-glycoprotein Substrate by D-tartaric Acid" Drug Metab. Pharmacokinet. (2006) 21(5): 424-428;

iii. Hayashi, M., *et al.,* "Mechanistic Analysis for Drug Permeation Through Intestinal Membrane" Drug Metab. Pharmacokinet. (2007) 22(2):67–77;

iv. Porter, S. C., *et al*., "Coating of Pharmaceutical Dosage Forms," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 929, 932-933; and

v. Kandukuri, J. M., *et al*., "Pelletization Techniques for Oral Drug Delivery" International Journal of Pharmaceutical Sciences and Drug Research (2009) 1(2):63-70.

38. 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 '608 patent, and would have had a reasonable expectation of success in doing so.

39. There is no objective evidence of non-obviousness of the claims of the '608 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '608 patent.

40. Qilu is entitled to a judicial declaration that the claims of the '608 patent are invalid.

41. Qilu reserves the right to provide additional bases for invalidity of each claim of the '608 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT IV

(Declaratory Judgment of Noninfringement of the '608 Patent)

42. Qilu realleges and incorporates by reference the allegations of paragraphs 1-41 as though fully set forth herein.

43. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '608 patent.

44. 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 '608 patent, either literally or under the doctrine of equivalents.

45. 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 '608 patent, either literally or under the doctrine of equivalents.

COUNT V

(Declaratory Judgment of Invalidity of the '246 Patent)

46. Qilu realleges and incorporates by reference the allegations of paragraphs 1-45 as though full set forth herein.

47. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '246 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 '246 patent.

48. The claims of the '246 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.

49. The claims of the '246 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 March 21, 2025 Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '246 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '246 patent, including, but not limited to:

i. U.S. Patent Appl. Publication No. 2006/0013875, "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms";

ii. Iida, A., *et al*., "Improvement of Intestinal Absorption of P-glycoprotein Substrate by D-tartaric Acid" Drug Metab. Pharmacokinet. (2006) 21(5): 424-428;

iii. Hayashi, M., *et al*., "Mechanistic Analysis for Drug Permeation Through Intestinal Membrane" Drug Metab. Pharmacokinet. (2007) 22(2):67–77;

iv. Porter, S. C., *et al*., "Coating of Pharmaceutical Dosage Forms," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 929, 932-933; and

v. Kandukuri, J. M., *et al*., "Pelletization Techniques for Oral Drug Delivery" International Journal of Pharmaceutical Sciences and Drug Research (2009) 1(2):63-70.

50. 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 '246 patent, and would have had a reasonable expectation of success in doing so.

51. There is no objective evidence of non-obviousness of the claims of the ’246 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’246 patent.

52. Qilu is entitled to a judicial declaration that the claims of the ’246 patent are invalid.

53. Qilu reserves the right to provide additional bases for invalidity of each claim of the ’246 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT VI

(Declaratory Judgment of Noninfringement of the ’246 Patent)

54. Qilu realleges and incorporates by reference the allegations of paragraphs 1-53 as though fully set forth herein.

55. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the ’246 patent.

56. 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 ’246 patent, either literally or under the doctrine of equivalents.

57. 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 '246 patent, either literally or under the doctrine of equivalents.

COUNT VII

(Declaratory Judgment of Invalidity of the '046 Patent)

58. Qilu realleges and incorporates by reference the allegations of paragraphs 1-57 as though full set forth herein.

59. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '046 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 '046 patent.

60. The claims of the '046 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.

61. The claims of the '046 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 March 21, 2025 Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the '046 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '046 patent, including, but not limited to:

i. U.S. Patent Appl. Publication No. 2006/0013875, "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms";

ii. Iida, A., *et al*., "Improvement of Intestinal Absorption of P-glycoprotein Substrate by D-tartaric Acid" Drug Metab. Pharmacokinet. (2006) 21(5): 424-428;

iii. Hayashi, M., *et al.,* "Mechanistic Analysis for Drug Permeation Through Intestinal Membrane" Drug Metab. Pharmacokinet. (2007) 22(2):67–77;

iv. Porter, S. C., *et al*., "Coating of Pharmaceutical Dosage Forms," in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 929, 932-933; and

v. Kandukuri, J. M., *et al*., "Pelletization Techniques for Oral Drug Delivery" International Journal of Pharmaceutical Sciences and Drug Research (2009) 1(2):63-70.

62. 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 '046 patent, and would have had a reasonable expectation of success in doing so.

63. There is no objective evidence of non-obviousness of the claims of the '046 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '046 patent.

64. Qilu is entitled to a judicial declaration that the claims of the '046 patent are invalid.

65. Qilu reserves the right to provide additional bases for invalidity of each claim of the '046 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT VIII

(Declaratory Judgment of Noninfringement of the '046 Patent)

66. Qilu realleges and incorporates by reference the allegations of paragraphs 1-65 as though fully set forth herein.

67. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '046 patent.

68. 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 '046 patent, either literally or under the doctrine of equivalents.

69. 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 '046 patent, either literally or under the doctrine of equivalents.

COUNT IX

(Declaratory Judgment of Invalidity of the '640 Patent)

70. Qilu realleges and incorporates by reference the allegations of paragraphs 1-69 as though full set forth herein.

71. There is an actual, substantial, and continuing case or controversy between Qilu and the Plaintiff/Counterclaim-Defendant regarding *inter alia*, the invalidity of the '640 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 '640 patent.

72. The claims of the ’640 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.

73. The claims of the ’640 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 March 21, 2025 Notice Letter to Plaintiff/Counterclaim-Defendant, because each and every element of each and every claim of the ’640 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’640 patent, including, but not limited to:

i. U.S. Patent Appl. Publication No. 2006/0013875, “Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms”;

ii. Iida, A., *et al*., “Improvement of Intestinal Absorption of P-glycoprotein Substrate by D-tartaric Acid” Drug Metab. Pharmacokinet. (2006) 21(5): 424-428;

iii. Hayashi, M., *et al.,* “Mechanistic Analysis for Drug Permeation Through Intestinal Membrane” Drug Metab. Pharmacokinet. (2007) 22(2):67–77;

iv. Porter, S. C., *et al*., “Coating of Pharmaceutical Dosage Forms,” in Remington: The Science and Practice of Pharmacy, Gennaro, A. (ed), Lippincot, Wilkins & Williams, (2005), pp. 929, 932-933; and

v. Kandukuri, J. M., *et al*., “Pelletization Techniques for Oral Drug Delivery” International Journal of Pharmaceutical Sciences and Drug Research (2009) 1(2):63-70.

74. 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 ’640 patent, and would have had a reasonable expectation of success in doing so.

75. There is no objective evidence of non-obviousness of the claims of the '640 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '640 patent.

76. Qilu is entitled to a judicial declaration that the claims of the '640 patent are invalid.

77. Qilu reserves the right to provide additional bases for invalidity of each claim of the '640 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT X

(Declaratory Judgment of Noninfringement of the '640 Patent)

78. Qilu realleges and incorporates by reference the allegations of paragraphs 1-77 as though fully set forth herein.

79. There is an actual, substantial, and continuing case or controversy between Qilu and Plaintiff/Counterclaim-Defendant regarding, *inter alia*, non-infringement of the claims of the '640 patent.

80. 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 '640 patent, either literally or under the doctrine of equivalents.

81. 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 '640 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 Plaintiff/Counterclaim Defendant Impax Laboratories, LLC as follows:

A. Dismissing Plaintiff's 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 claims of the Patents-in-Suit, and that the claims of the Patents-in-Suit 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. 220177 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 Patents-in-Suit, 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 Plaintiff/Counterclaim-Defendant 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 Patents-in-Suit 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: June 17, 2025

By: */s/ Ian Scott l*

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Attorneys for Defendants
Qilu Pharmaceutical (Hainan) 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 not related to any pending actions 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: June 17, 2025

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: June 17, 2025

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

CERTIFICATE OF SERVICE

The undersigned certifies that, on June 17, 2025, a true and accurate copy of DEFENDANTS QILU PHARMACEUTICAL (HAINAN) 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.

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Attorneys for Plaintiff Impax Laboratories, LLC

Dated: June 17, 2025

TAFT, STETTINIUS & HOLLISTER, LLC

By: */s/ Ian Scott*
IAN SCOTT