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IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY & COMPANY, and COLUCID PHARMACEUTICALS, INC., Plaintiffs, v. QILU PHARMACEUTICAL CO., LTD., and QILU PHARMA INC., Defendants.	Civil Action No. _____ ***Highly Confidential*** ***Electronically Filed Under Seal***

COMPLAINT

Plaintiffs Eli Lilly & Co. and CoLucid Pharmaceuticals, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Qilu Pharmaceutical Co., Ltd. and Qilu Pharma Inc. (collectively, "Defendants"), hereby allege as follows:

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 Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs'

REYVOW® (lasmiditan) tablets prior to the expiration of United States Patent No. 11,053,214.

THE PARTIES

2. Plaintiff Eli Lilly & Company ("Lilly") is a corporation organized and existing under the laws of the State of Indiana, having a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

3. Plaintiff CoLucid Pharmaceuticals, Inc. ("CoLucid") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. CoLucid is a wholly owned subsidiary of Lilly.

4. Lilly and CoLucid are collectively referred to herein as "Plaintiffs."

5. On information and belief, Defendant Qilu Pharmaceutical Co., Ltd ("Qilu Ltd.") is a corporation organized and existing under the laws of China, having a principal place of business at 8888 Lvyou Road, High-Tech Zone, Jinan, 250104, China.

6. On information and belief, Defendant Qilu Pharma, Inc. ("Qilu Inc.") is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at 101 Lindenwood Drive, Suite 225, Malvern, PA 19355.

7. Qilu Ltd. and Qilu Inc. are collectively referred to herein as "Qilu" or "Defendants."

8. On information and belief, Qilu Ltd. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of New Jersey, through its own actions and through the actions of its partners, agents, and subsidiaries, including U.S. agent Qilu Inc., from which Qilu Ltd. derives a substantial portion of its revenue.

9. On information and belief, Qilu Ltd. is listed as the applicant of ANDA No. 219350 (the "Qilu ANDA") and has sent notice to Lilly stating that Qilu Ltd. included a certification in the

Qilu ANDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(IV).

10. On information and belief, Qilu Inc. is the U.S. agent for Qilu Ltd. in connection with Qilu's ANDA.

11. On information and belief, Qilu Inc. acted in concert with Qilu Ltd. to prepare and submit the Qilu ANDA for Qilu's 50 mg and 100 mg tablets ("Qilu ANDA Products"), which was done at the direction and control of, and for the direct benefit of, Qilu Ltd.

12. On information and belief, following FDA approval of the Qilu ANDA, Qilu, through its own actions and through the actions of its partners, agents and subsidiaries, including Qilu Inc., will manufacture, supply, market, and sell the approved generic products throughout the United States, including New Jersey.

JURISDICTION AND VENUE

13. 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).

14. Venue is proper in this Court as to Qilu Ltd. because, among other things, Qilu Ltd. is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(b), (c); *see also* 28 U.S.C. § 1400(b).

15. Qilu Ltd. has been sued in this district previously in Hatch-Waxman patent infringement disputes and has not contested personal jurisdiction or venue in one or more cases. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.). On information and belief, Qilu Ltd. has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Qilu Ltd. asserted counterclaims in the cases listed above.

16. Venue is proper in this Court as to Qilu Inc. because, among other things, on information and belief, Qilu Inc. has an active business entity ID in the State of New Jersey (0400704255) with a regular and established place of business at 108 Carnegie Ctr., Suite 208, Princeton, NJ 08540. On information and belief, based on Qilu Inc.'s presence in and connections to New Jersey, discoverable information in Qilu Inc.'s possession, custody, or control regarding the Qilu ANDA will likely show that Qilu Inc. engaged in activities in New Jersey relevant to the preparation or submission of the Qilu ANDA.

17. Qilu Inc. has been sued in this district previously in Hatch-Waxman patent infringement disputes and has not contested personal jurisdiction or venue in one or more cases. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.). On information and belief, Qilu Inc. has also affirmatively invoked this Court's jurisdiction by asserting counterclaims in cases that it has litigated in New Jersey. For example, Qilu Inc. asserted counterclaims in the cases listed above.

18. Venue is further proper in this Court as to Qilu because, among other things, Qilu has committed or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of the asserted patent that will lead to foreseeable harm and injury to Plaintiffs by filing the Qilu ANDA with the intention of seeking to market the Qilu ANDA Products nationwide, including within the State of New Jersey. *See* 28 U.S.C. § 1400(b).

PERSONAL JURISDICTION OVER QILU LTD.

19. Plaintiff realleges paragraphs 1–18 as if fully set forth herein.

20. On information and belief, Qilu Ltd. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

21. This Court has personal jurisdiction over Qilu Ltd. because, *inter alia*, Qilu Ltd., on

information and belief, intends to market, sell, and/or distribute the Qilu ANDA Products to residents of this State upon approval of the Qilu ANDA, either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Qilu Inc. Qilu Ltd.'s intent to sell its ANDA Product here is sufficient to support a finding of specific personal jurisdiction. *See Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755, 762–63 (Fed. Cir. 2016). Qilu Ltd. further makes its generic drug products available in this State and enjoys substantial income from sales of its generic pharmaceutical products in this State.

22. Additionally, on information and belief, Qilu Ltd. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.).

23. Alternatively, to the extent the above facts do not establish personal jurisdiction over Qilu Ltd., this Court may exercise jurisdiction over Qilu Ltd. under Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claim arises under federal law; (b) Qilu Ltd. would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Qilu Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, preparing and filing ANDAs with the FDA, marketing its drug product candidates, and manufacturing generic pharmaceutical products that will be distributed throughout the United States, such that this Court's exercise of jurisdiction over Qilu Ltd. satisfies due process, and is consistent with the United States Constitution and Laws.

24. Upon information and belief, if the Qilu ANDA is approved, Qilu's ANDA Products will be marketed and distributed by Qilu Ltd., either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Qilu Inc., in the State of New Jersey, prescribed by

physicians practicing 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.

PERSONAL JURISDICTION OVER QILU INC.

25. Plaintiff realleges paragraphs 1–24 as if fully set forth herein.

26. On information and belief, Qilu Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

27. This Court has personal jurisdiction over Qilu Inc. because, *inter alia*, Qilu Inc., on information and belief: (1) maintains an active business entity ID, as well as a regular and established place of business, in the State of New Jersey; (2) intends to market, sell, or distribute Qilu's ANDA Products to residents of this State; (3) makes its generic drug products available in this State; and (4) enjoys substantial income from its generic pharmaceutical products in this State.

28. Additionally, on information and belief, Qilu Inc. has previously consented to this Court's jurisdiction and has availed itself of the protections afforded by the Court by asserting counterclaims against plaintiffs in this judicial district. *See, e.g.*, *Boehringer Ingelheim Pharms. Inc. v. Qilu Pharm. Co. Ltd., et al.*, No. 3:21-cv-01732 (D.N.J.); *Helsinn Healthcare S.A. et al. v. Qilu Pharm. Co., Ltd. et al.*, No. 3:15-cv-08132 (D.N.J.).

29. Upon information and belief, if the Qilu ANDA is approved, Qilu's ANDA Products will be marketed and distributed by Qilu Ltd., either directly or through at least one of its partners or wholly-owned subsidiaries or agents, including Qilu Inc., in the State of New Jersey, prescribed by physicians practicing 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.

BACKGROUND

U.S. PATENT NO. 11,053,214

30. On July 6, 2021, the United States Patent & Trademark Office ("USPTO") duly and

legally issued United States Patent No. 11,053,214 ("the '214 patent") titled "Compositions and methods related to pyridinoylpiperidine 5-HT_{1F} agonists." The inventors of the patented invention are Brigida Allieri, Paul Fagan, Emma Sharp, and Raymond D. Skwierczynski. A true and correct copy of the '214 patent is attached as Exhibit 1. The '214 patent is assigned to CoLucid Pharmaceuticals, Inc., a wholly owned subsidiary of Lilly.

REYVOW®

31. Lilly is the holder of New Drug Application ("NDA") No. 211280 for lasmiditan, for oral use, in 50 mg and 100 mg dosages, which is sold under the tradename REYVOW®. REYVOW® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Chemical Entity Exclusivity until January 31, 2025.

32. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '214 patent is among the patents listed in the Orange Book with respect to REYVOW®.

33. The '214 patent covers the REYVOW® product.

ACTS GIVING RISE TO THE ACTION

34. Provided here as an exemplary claim, claim 1 of the '214 patent recites:

> 1. A crystalline Form D di-hydrate of the hemisuccinate salt of 2,4,6-trifluoro-N-[6-(1-methyl-piperidine-4-carbonyl)-pyridin-2-yl]-benzamide characterized by an X-ray diffraction pattern when measured using Cu-Kα radiation having at least peaks at about 18.7+/−0.2 degrees 2θ, 26.5+/−0.2 degrees 2θ, 27.0+/−0.2 degrees 2θ, 27.5+/−0.2 degrees 2θ and 27.8+/−0.2 degrees 2θ.

35. On information and belief, when offered for sale, sold, and/or imported, and when used as directed, the Qilu ANDA Products comprise a crystalline Form D di-hydrate of the hemisuccinate salt of 2,4,6-trifluoro-N-[6-(1-methyl-piperidine-4-carbonyl)-pyridin-2-yl]-benzamide characterized by an X-ray diffraction pattern, when measured using Cu-Kα radiation, having at least peaks at about 18.7±0.2 degrees 2θ, 26.5±0.2 degrees 2θ, 27.0±0.2 degrees 2θ,

27.5±0.2 degrees 2θ and 27.8±0.2 degrees 2θ. Therefore, on information and belief, Qilu's ANDA Products will infringe claims of the '214 patent, including claim 1.

36. On information and belief, under the direction and control of Qilu, [redacted]

37. On information and belief, Qilu's ANDA specification [redacted]

38. The information provided in Qilu's ANDA and DMF suggest, on information and belief, [redacted] Despite Plaintiffs' request, Qilu has not provided samples of either its drug substance identified in the DMF or ANDA Products identified in the ANDA.

39. On information and belief, Qilu seeks FDA approval for the Qilu ANDA, [redacted]

COUNT I—INFRINGEMENT OF THE '214 PATENT

40. Plaintiff realleges paragraphs 1–39 as if fully set forth herein.

41. On information and belief, Qilu submitted the Qilu ANDA to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Qilu ANDA Products.

42. Qilu has represented that the Qilu ANDA refers to and relies upon the REYVOW® NDA, and contains data that, according to Qilu, demonstrates the bioavailability or bioequivalence of the Qilu ANDA Products to REYVOW®.

43. On March 22, 2024, Plaintiffs received a letter from Qilu (dated March 21, 2024) stating that Qilu had included a certification in the Qilu ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '214 patent are either invalid or will not be infringed by the commercial manufacture, use, sale, offer to sell or importation into the United States of the Qilu ANDA Products (the "Qilu Paragraph IV Certification"). Qilu intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Qilu ANDA Products prior to the expiration of the '214 patent.

44. Qilu's Paragraph IV letter includes very limited information about the nature and form of the Qilu ANDA Products, including little to no information regarding how the Qilu ANDA Products are manufactured, the ingredients of such Products, and the form of lasmiditan present in the Products. Qilu's Paragraph IV letter offered confidential access to unspecified portions of the Qilu ANDA ("Offer of Confidential Access" or "OCA") on terms and conditions set by Qilu. Qilu requested that Lilly accept the terms of the OCA before receiving access to the unspecified portions of the Qilu ANDA.

45. Under the Hatch-Waxman Act, an owner of a patented drug must file an action in federal court within 45 days of receiving a Paragraph IV letter ("45-day window") to receive certain benefits under the Act, including a stay of approval of the generic drug for 30 months during the pendency of litigation, as appropriate. 21 U.S.C. § 355 (c)(3)(c).

46. On March 27, 2024, Plaintiffs requested access to Qilu's ANDA, DMF, and samples of Qilu's ANDA Products, API, and intermediates. Plaintiffs also requested that Qilu modify its OCA to permit access by certain in-house counsel at Plaintiffs so that they may assess infringement. From

March 29 to April 23, the parties exchanged multiple emails and letters discussing the terms of Qilu's OCA. Qilu produced the Qilu ANDA and DMF on April 25, 2024.

47. [redacted]

To date, Qilu has not provided samples of the drug substance and Qilu's ANDA Products. On information and belief, the samples of the Qilu ANDA Products, if provided to Lilly, would reveal information that is relevant to Qilu's infringement of the '214 patent. *See Hoffman-La Roche, Inc. v. Invamed, Inc.,* 213 F.3d 1359, 1363–64 (Fed. Cir. 2000).

48. On information and belief, Qilu has infringed at least one claim of the '214 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Qilu ANDA—which, on information and belief, [redacted]—by which Qilu seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Qilu ANDA Products prior to the expiration of the '214 patent. *See Sunovion Pharms., Inc. v. Teva Pharms. USA, Inc.*, 731 F.3d 1271, 1278 (Fed. Cir. 2013).

49. Qilu has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Qilu ANDA Products if the FDA approves the Qilu ANDA. Accordingly, an actual and immediate controversy exists regarding Qilu's infringement of the '214 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

50. Qilu's manufacture, use, offer to sell, or sale of the Qilu ANDA Products in the United States or importation of the Qilu ANDA Products into the United States during the term of the '214 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the '214 patent under 35 U.S.C. §§ 271 (a), (b) and/or (c).

51. On information and belief, the Qilu ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '214 patent either literally or under the doctrine of equivalents.

52. On information and belief, the use of the Qilu ANDA Products constitutes a material part of at least one of the claims of the '214 patent; Qilu knows that the Qilu ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '214 patent, either literally or under the doctrine of equivalents; and the Qilu ANDA Products are not a staple article of commerce or commodity of commerce suitable for substantial non-infringing use.

53. Plaintiffs will be substantially and irreparably harmed if Qilu is not enjoined from infringing the '214 patent.

54. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Plaintiffs' reasonable attorney fees.

55. On information and belief, based on the information provided by Qilu to date, the factual contentions in paragraph 34–54 have evidentiary support. On information and belief, the factual contentions in paragraphs 34–54 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that the Court enter judgment against Qilu and for the following relief:

a. A Judgment be entered that Qilu has infringed at least one claim of the '214 patent by submitting the Qilu ANDA;

b. A Judgment be entered that this case is exceptional, and that Plaintiff is entitled to its reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

c. That Qilu, its officers, agents, partners, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '214

patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '214 patents or such other later time as the Court may determine;

d. A Judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Qilu's 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 date of the '214 patent, including any extensions;

e. That Plaintiff be awarded monetary relief if Qilu commercially uses, offers to sell, or sells its respective proposed generic versions of REYVOW® or any other product that infringes or induces or contributes to the infringement of the '214 patent, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Plaintiff with prejudgment interest;

f. Costs and expenses in this action; and

g. Such other and further relief as the Court deems just and appropriate.

Dated: May 3, 2024

Respectfully submitted,

s/ Liza M. Walsh
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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

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

Dated: May 3, 2024

Respectfully submitted,

s/ Liza M. Walsh

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LOCAL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiffs seek, *inter alia*, injunctive relief.

Dated: May 3, 2024

Respectfully submitted,

s/ Liza M. Walsh

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