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Eli Lilly & Co.

IN THE UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

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

COMPLAINT

Plaintiff Eli Lilly & Co. ("Plaintiff" or "Lilly"), by its undersigned attorneys, for its 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 Plaintiff's REYVOW® (lasmiditan) tablets prior to the expiration of United States Patent No. 12,071,423.

THE PARTIES

2. Plaintiff Eli Lilly & Company 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. 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.

4. 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.

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

6. 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.

7. 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. filed a certification in support of the Qilu ANDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(IV).

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

9. 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.

10. 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

11. 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).

12. 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).

13. 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.

14. Qilu Ltd. likewise did not contest personal jurisdiction or venue in a case brought against Qilu Ltd. which was also based on Qilu's filing of ANDA No. 219350. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-05847 (D.N.J.).

15. 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.

16. 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.

17. Qilu Inc. likewise did not contest personal jurisdiction or venue in a case brought against Qilu Inc. which was also based on Qilu's filing of ANDA No. 219350. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-05847 (D.N.J.).

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 Plaintiff 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.). Moreover, Qilu Ltd. also consented to personal jurisdiction and venue in a case naming Qilu Ltd. as defendant which was also based on Qilu's filing of ANDA No. 219350. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-05847 (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) Plaintiff's 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.). Moreover, Qilu Inc. also consented to personal jurisdiction and venue in a case naming Qilu Inc. as defendant which was also based on Qilu's filing of ANDA No. 219350. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-05847 (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. 12,071,423

30. On August 27, 2024, the United States Patent & Trademark Office ("USPTO") duly and legally issued United States Patent No. 12,071,423 ("the '423 patent") titled "Processes and intermediate for the large-scale preparation of 2,4,6-trifluoro-N-[6-(1-methyl-piperidine-4-carbonyl)-pyridin-2-yl]-benzamide hemisuccinate, and preparation of 2,4,6-trifluoro-N-[6-(1-methyl-piperidine-4-carbonyl)-pyridin-2-yl]-benzamide acetate." The inventors of the patented invention are Aktham Aburub, David Andrew Coates, Scott Alan Frank, Mark Steven Kerr, Roger Ryan Rothhaar, Radhe Krishan Vaid. A true and correct copy of the '423 patent is attached as Exhibit 1. The '423 patent is assigned to Eli Lilly and Company.

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 '423 patent is among the patents listed in the Orange Book with respect to REYVOW®.

33. The '423 patent covers the REYVOW® product.

Prior Action Related to ANDA No. 219350

34. On March 21, 2024, Qilu sent to Plaintiff a Paragraph IV letter in support of ANDA No. 219350 pertaining to U.S. Patent No. 11,053,214 ("the '214 patent"). The '214 patent also covers the Reyvow® product and is assigned to CoLucid Pharmaceuticals, Inc. ("CoLucid"), a wholly owned subsidiary of Plaintiff. Plaintiff and CoLucid filed a complaint for patent infringement with respect to Qilu's conduct on May 3, 2024. *See Eli Lilly & Co., et al., v. Qilu Pharma. Co., Ltd., et al.*, No. 2:24-cv-05847 (D.N.J.).

35. Because the '423 patent did not issue until August 27, 2024, it was not included in that action. Upon issuance of the '423 patent, the parties jointly sought the Court's permission to adjourn the initial schedule conference in that matter to provide time for Plaintiff to list the '423 patent in the Orange Book, for Qilu to serve a Paragraph IV notice regarding the '423 patent, and for Plaintiff to file the present complaint.

ACTS GIVING RISE TO THE ACTION

36. Provided here as an exemplary claim, claim 1 of the '423 patent recites:

> 1. An immediate-release tablet, wherein the tablet comprises:
> (a) from 50 mg to 100 mg free base equivalent of 2,4,6-trifluoro-N-[6-(1-methyl-piperidine-4-carbonyl)-pyridin-2-yl]-benzamide hemisuccinate;
> (b) from 30.86 mg to 61.71 mg of microcrystalline cellulose;
> (c) from 7.5 mg to 15.00 mg of pregelatinized starch;
> (d) from 0.56 mg to 1.12 mg of sodium lauryl sulfate;
> (e) from 5.63 mg to 40.53 mg of croscarmellose sodium;
> (f) from 2.25 mg to 4.50 mg of magnesium stearate; and
> (g) from 3.519 mg to 7.035 mg of the film coating.

37. On information and belief, when offered for sale, sold, and/or imported, and when used as directed, the Qilu ANDA Products comprise [redacted]

[redacted] Therefore, on information and belief, Qilu's ANDA Products [redacted]

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

39. Qilu's ANDA permits, on information and belief, [redacted] Despite Plaintiff's request, Qilu has not yet provided samples of its ANDA Products identified in the ANDA.

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

COUNT I—INFRINGEMENT OF THE '423 PATENT

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

42. 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.

43. 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®.

44. On November 11, 2024, Plaintiff received a letter from Qilu (dated November 8, 2024) stating that Qilu had submitted a certification in support the Qilu ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, the '423 patent is either invalid, unenforceable, and/or would 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 '423 patent.

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, Plaintiff requested access to Qilu's ANDA, DMF, and samples of Qilu's ANDA Products, API, and intermediates. Qilu produced the Qilu ANDA and DMF on April 25, 2024.

47. [redacted]

To date, Qilu has not provided samples of the drug substance or 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 '423 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 '423 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, permits [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 '423 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 '423 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 '423 patent would further infringe, literally or under the doctrine of equivalents, at least one claim of the '423 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 '423 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 '423 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 '423 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. Plaintiff will be substantially and irreparably harmed if Qilu is not enjoined from infringing the '423 patent.

54. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants

reimbursement of Plaintiff's reasonable attorney fees.

55. On information and belief, based on the information provided by Qilu to date, the factual contentions in paragraph 36–54 have evidentiary support. On information and belief, the factual contentions in paragraphs 36–54 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 '423 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 formulations claimed in the '423 patent, and (ii) seeking, obtaining or maintaining approval of ANDAs until the expiration of the '423 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 '423 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 ’423 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: November 27, 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 related to the following action: *Eli Lilly & Company, et al. v. Qilu Pharmaceutical Co., Ltd., et al*., Civil Action No. 2:24-cv-05847 (EP-JSA), pending before the United States District Court for the District of New Jersey, in which Plaintiff asserted claims of patent infringement against Defendants in connection with Defendants' submission of ANDA No. 219350.

Dated: November 27, 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 Plaintiff seek, *inter alia*, injunctive relief.

Dated: November 27, 2024

Respectfully submitted,

s/ Liza M. Walsh

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