IN THE UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MISSOURI
EASTERN DIVISION

ELI LILLY & COMPANY, and COLUCID PHARMACEUTICALS, INC., Plaintiffs, v. HUMANWELL PHARMACEUTICAL US, INC., and EPIC PHARMA, LLC, 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 Humanwell Pharmaceutical US, Inc. and Epic Pharma, LLC (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 Humanwell Pharmaceutical US, Inc. ("Humanwell US") is a corporation organized and existing under the laws of the State of Missouri, having a principal place of business at 421 Sovereign Court, Ballwin, Missouri 63011.

6. On information and belief, Defendant Epic Pharma, LLC ("Epic Pharma") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 227-15 N. Conduit Avenue, Laurelton, New York 11413.

7. On information and belief, Humanwell US 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 Missouri, through its own actions and through the actions of its partners, agents, and subsidiaries, including Epic Pharma, from which Humanwell US derives a substantial portion of its revenue.

8. On information and belief, Epic Pharma 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 Missouri, through its own actions and through the actions of its partners, agents, and subsidiaries, including Humanwell US, from which Epic Pharma derives a substantial portion of its revenue.

9. On information and belief, Humanwell US and Epic Pharma are both indirect subsidiaries of the same parent company, Humanwell Healthcare (Group) Co., Ltd., a corporation

organized and existing under the laws of China, having a principal place of business at No. 666 Gaoxin Avenue, Donghu High-Tech District, Wuhan, Hubei, 430075, China.

10. On information and belief, Humanwell US is listed as the applicant of ANDA No. 219669 (the "Humanwell ANDA") and has sent notice to Lilly stating that Humanwell US included a certification in the Humanwell ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

11. On information and belief, Epic Pharma is the United States agent for Humanwell US in connection with the Humanwell ANDA.

12. On information and belief, Humanwell US and Epic Pharma are agents of each other with respect to the development, regulatory approval, marketing, sale, and/or distribution of the 50 mg and 100 mg lasmiditan hemisuccinate tablets that are the subject of the Humanwell ANDA ("Humanwell ANDA Products").

13. On information and belief, Defendants acted in concert to prepare and submit the Humanwell ANDA for the Humanwell ANDA Products through their own actions and through the actions of their partners, agents, and subsidiaries, and at least in part for the benefit of each other.

14. On information and belief, following FDA approval of the Humanwell ANDA, Defendants, through their own actions and through the actions of their partners, agents, and subsidiaries, will manufacture, supply, market, and sell the approved generic products throughout the United States, including Missouri.

JURISDICTION AND VENUE

15. 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).

16. Venue is proper in this Court because, among other things, on information and belief, Humanwell US is incorporated in the State of Missouri, and Defendants have a regular and

established place of business at 421 Sovereign Court, Ballwin, MO 63011. On information and belief, Defendants engaged in activities in Missouri relevant to the preparation or submission of the Humanwell ANDA.

17. Venue is further proper in this Court as to Defendants because, among other things, Defendants have 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 Humanwell ANDA with the intention of seeking to market the Humanwell ANDA Products nationwide, including within the State of Missouri. *See* 28 U.S.C. § 1400(b).

PERSONAL JURISDICTION OVER HUMANWELL US

18. Plaintiffs reallege paragraphs 1–17 as if fully set forth herein.

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

20. This Court has personal jurisdiction over Humanwell US because, *inter alia*, Humanwell US, on information and belief: (1) is incorporated and maintains its principal place of business in the State of Missouri; (2) intends to market, sell, or distribute Humanwell US'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.

21. Upon information and belief, if the Humanwell ANDA is approved, Humanwell US's ANDA Products will be marketed and distributed by Humanwell US, either directly or through at least one of its partners, subsidiaries or agents in the State of Missouri, prescribed by physicians practicing in the State of Missouri, dispensed by pharmacies located within the State of Missouri, and used by patients in the State of Missouri.

PERSONAL JURISDICTION OVER EPIC PHARMA

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

23. This Court has personal jurisdiction over Epic Pharma because, *inter alia*, Epic Pharma, on information and belief, intends to market, sell, and/or distribute the Humanwell ANDA Products to residents of this State upon approval of the Humanwell ANDA, either directly or through at least one of its partners, subsidiaries, or agents, including Humanwell US. Epic Pharma'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). On information and belief, Epic Pharma further makes its generic drug products available in this State and enjoys substantial income from sales of its generic pharmaceutical products in this State.

24. Upon information and belief, if the Humanwell ANDA is approved, the Humanwell ANDA Products will be marketed and distributed by Epic Pharma, either directly or through at least one of its partners, subsidiaries or agents in the State of Missouri, prescribed by physicians practicing in the State of Missouri, dispensed by pharmacies located within the State of Missouri, and used by patients in the State of Missouri.

BACKGROUND

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

25. 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®

26. 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.

27. 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®.

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

ACTS GIVING RISE TO THE ACTION

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

30. Defendants have represented that the Humanwell ANDA refers to and relies upon the REYVOW® NDA, and contains data that, according to Defendants, demonstrates the bioavailability or bioequivalence of the Humanwell ANDA Products to REYVOW®.

31. On February 10, 2025, Plaintiffs received a letter from Humanwell US (dated February 5, 2025) stating that Humanwell US had included a certification in the Humanwell 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 Humanwell ANDA Products (the "Humanwell Paragraph IV Certification"). Defendants intend to engage in the commercial manufacture, use, offer for sale, and/or sale of the Humanwell ANDA Products prior to the expiration of the '214 patent.

32. Humanwell US's Paragraph IV letter includes very limited information about the nature and form of the Humanwell ANDA Products, including little to no information regarding how the Humanwell ANDA Products are manufactured, the ingredients of such Products, and the form of

lasmiditan present in the Products. Humanwell US's Paragraph IV letter offered confidential access to unspecified portions of the Humanwell ANDA ("Offer of Confidential Access" or "OCA") on terms and conditions set by Humanwell US. Humanwell US requested that Lilly accept the terms of the OCA before receiving access to the unspecified portions of the Humanwell ANDA.

33. 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).

34. On February 14, 2025, Plaintiffs requested access to the Humanwell ANDA, drug master file ("DMF"), and samples of the Humanwell ANDA Products, active pharmaceutical ingredient ("API"), and intermediates. From February 19 to February 28, the parties exchanged multiple emails and letters discussing the terms of Humanwell US's OCA. Humanwell US produced the Humanwell ANDA and portions of the DMF on March 3, 2025.

35. On February 28, 2025, Humanwell US indicated that it intended to send samples of the active pharmaceutical ingredient, final product blend, and finished product tablets of its ANDA Products. Samples were not delivered to Plaintiffs until March 17, 2025, and the package containing API was damaged in shipment. Samples of the excipients used in the Humanwell ANDA Products have also been requested, but not yet received. On information and belief, the samples of the Humanwell ANDA Products, would reveal information that is relevant to Defendants' infringement of the '214 patent. *See Hoffman-La Roche, Inc. v. Invamed, Inc.,* 213 F.3d 1359, 1363–64 (Fed. Cir. 2000).

COUNT I—INFRINGEMENT OF THE '214 PATENT

36. Plaintiffs reallege paragraphs 1–35 as if fully set forth herein.

37. 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.

38. On information and belief, when offered for sale, sold, and/or imported, and when used as directed, the Humanwell 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, the Humanwell ANDA Products will infringe claims of the ’214 patent, including claim 1.

39. On information and belief, under the direction and control of Defendants, [redacted]

40. On information and belief, the Humanwell ANDA specification for lasmiditan hemisuccinate content permits both the drug substance and Humanwell ANDA Products to contain crystalline lasmiditan hemisuccinate Form D.

41. The information provided in the Humanwell ANDA and DMF suggest, on information and belief, that the drug substance may convert to crystalline lasmiditan hemisuccinate Form D, as claimed in the ’214 patent, given the manufacturing process and specifications for the Humanwell ANDA Products. Additionally, the analytical methods Humanwell US uses in its DMF and ANDA do not establish that crystalline lasmiditan hemisuccinate Form D is not present in the drug substance or ANDA Products. Crystalline material is often too small to be detected by the

naked eye or the methods used by Defendants, which, on information and belief, are not sufficiently robust or sensitive to detect lasmiditan hemisuccinate Form D.

42. On information and belief, Defendants seek FDA approval for the Humanwell ANDA, which permits inclusion of crystalline Form D of exemplary claim 1 of the '214 patent.

43. On information and belief, Defendants have 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 Humanwell ANDA—which, on information and belief, permits Humanwell ANDA Products to contain crystalline lasmiditan hemisuccinate Form D—by which Defendants seek approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Humanwell 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).

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

45. Defendants' manufacture, use, offer to sell, or sale of the Humanwell ANDA Products in the United States or importation of the Humanwell 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).

46. On information and belief, the Humanwell 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.

47. On information and belief, the use of the Humanwell ANDA Products constitutes a material part of at least one of the claims of the '214 patent; Defendants know that the Humanwell 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 Humanwell ANDA Products are not a staple article of commerce or commodity of commerce suitable for substantial non-infringing use.

48. Plaintiffs will be substantially and irreparably harmed if Defendants are not enjoined from infringing the '214 patent.

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

50. On information and belief, based on the information provided by Defendants to date, the factual contentions in paragraphs 29–49 have evidentiary support. On information and belief, the factual contentions in paragraphs 29–49 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Defendants and for the following relief:

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

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

c. That Defendants, their 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 patent 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 Defendants' ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the expiration date of the '214 patent, including any extensions;

e. That Plaintiffs be awarded monetary relief if Defendants commercially use, offer to sell, or sell their 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 patent, including any extensions, and that any such monetary relief be awarded to Plaintiffs with prejudgment interest;

f. Costs and expenses in this action; and

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

Respectfully submitted,

BERKOWITZ OLIVER LLP

Dated: March 21, 2025

By: s/ Stacey R. Gilman

Stacey R. Gilman, Bar No. 55690 (MO)
2600 Grand Blvd. Suite 1200,
Kansas City, Mo 64108
Phone: 816.627.0216
sgilman@berkowitzoliver.com

and

Bryan S. Hales (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
333 W Wolf Point Plaza
Chicago, IL 60654
(312) 862-2000

Jeanna M. Wacker (*pro hac vice* forthcoming)
Sam Kwon (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4679

Ashley Cade (*pro hac vice* forthcoming)
KIRKLAND & ELLIS LLP
1301 Pennsylvania Ave. NW
Washington, DC 20004
(202) 879-5000

Attorneys for Plaintiffs Eli Lilly & Co. and CoLucid Pharmaceuticals, Inc.