UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ELI LILLY & COMPANY and COLUCID PHARMACEUTICALS, INC., Plaintiffs, v. HUMANWELL PHARMACEUTICAL US, INC. and EPIC PHARMA, LLC, Defendants.	Redacted Civil Action No. 2:25-cv-02020-EP-JSA

ANSWER AND AFFIRMATIVE DEFENSES

Defendants, Humanwell Pharmaceutical US, Inc. and Epic Pharma, LLC (collectively, "Defendants"), submits this Answer and Defenses in response to the Complaint of Plaintiffs Eli Lilly & Co. and CoLucid Pharmaceuticals, Inc. (collectively, "Plaintiffs"). Defendants deny all allegations in Plaintiffs' Complaint except those specifically admitted below. This pleading is based on Defendants' present knowledge of its own activities, and upon information and belief as to the activities of others.

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.

ANSWER: Defendants admit that the Complaint purports to state an action for alleged infringement of U.S. Patent No. 11,053,214 under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code. Defendants admit that Humanwell Pharmaceutical US, Inc. ("Humanwell US") filed 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 expiration of the '214 patent. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore deny the same.

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.

ANSWER: Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore deny the same.

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

ANSWER: Defendants admit the Complaints refers to Lilly and CoLucid collective 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.

ANSWER: Defendants admit Humanwell US is a corporation organized and existing under the laws of the State of Missouri, having a place of business at 421 Sovereign Court, Ballwin, Missouri 63011. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: Defendants admit Epic Pharma, LLC ("Epic Pharma") is organized and existing under the laws of the State of Delaware, having a place of business at 227-15 N. Conduit Avenue, Laurelton, New York 11413. Defendants deny any remaining allegations of this paragraph.

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 New Jersey, 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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 New Jersey, 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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).

ANSWER: Admitted.

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

ANSWER: Admitted.

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").

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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 New Jersey.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that this Court has subject-matter jurisdiction only over claims asserted against Humanwell US under 35 U.S.C. § 271(e)(2)(A). Defendants deny that this Court has subject-matter jurisdiction over any other asserted claims. Defendants deny any remaining allegations of this paragraph.

16. Venue is proper in this Court because, among other things, on information and belief, Epic Pharma has an active business registration (Entity No. 0451053165) in Bridgewater, New Jersey, and Defendants have a regular and established place of business in New Jersey. On information and belief, Defendants engaged in activities in New Jersey relevant to the preparation or submission of the Humanwell ANDA.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest venue for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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 New Jersey. *See* 28 U.S.C. § 1400(b).

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest venue for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

PERSONAL JURISDICTION OVER HUMANWELL US

18. Plaintiffs reallege paragraphs 1–0 as if fully set forth herein.

ANSWER: Defendants incorporate by reference their answers to the foregoing paragraphs 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction

over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

20. This Court has personal jurisdiction over Humanwell US because, inter alia, Humanwell US, 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 Epic Pharma. Humanwell US'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, Humanwell US further makes its generic drug products available in this State and enjoys substantial income from sales of its generic pharmaceutical products in this State..

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

21. Upon information and belief, if the Humanwell ANDA is approved, the Humanwell 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 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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 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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants do not contest this Court exercising personal jurisdiction over them for purposes of this action only. Defendants otherwise deny the allegations of this paragraph as specifically stated.

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.

ANSWER: This paragraph states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that a copy of what purports to be the '214 patent is attached to the Complaint as Exhibit 1. Defendants state that the '214 patent speaks for

itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the patent. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations concerning ownership of New Drug Application ("NDA") No. 211280, and therefore denies the same. Defendants admit that the FDA's website indicates that Lilly is the holder of NDA No. 211280 for lasmiditan, for oral use, in 50 mg and 100 mg dosages, which is sold under the tradename REYVOW®. Defendants admit that according to the FDA's Orange Book, NDA No. 211280 had New Chemical Entity Exclusivity until January 31, 2025. Defendants deny any remaining allegations of this paragraph.

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®.

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the FDA's Orange Book includes the '214 patent is among the patents listed in the Orange Book with respect to REYVOW®.

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

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations in this paragraph, and therefore deny the same

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.

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Humanwell US submitted the Humanwell ANDA to the FDA seeking approval to market the Humanwell ANDA Products. Defendants deny any remaining allegations of this paragraph.

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®.

ANSWER: Defendants state that the Humanwell ANDA speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Humanwell ANDA. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: Defendants admit that 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 deny any remaining allegations of this paragraph.

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.

ANSWER: Defendants state that Humanwell US's Paragraph IV letter speaks for itself and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe Humanwell US's Paragraph IV letter. Defendants admit Humanwell US's Paragraph IV letter offered confidential access to portions of the Humanwell ANDA ("Offer of Confidential Access" or "OCA") on terms and conditions set by Humanwell US. Defendants admit that Humanwell US requested that Lilly accept the terms of the OCA before receiving access to the unspecified portions of the Humanwell ANDA. Defendants deny any remaining allegations of this paragraph.

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).

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants deny Plaintiffs are entitled to any relief under the Hatch-Waxman Act. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: Admitted.

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).

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that 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. Defendants admit that the active pharmaceutical ingredient, final product blend, and finished product tablets samples were delivered to Plaintiff on March 17, 2025. Defendants admit that the outside package was damaged in shipment, and Defendants further state that after subsequent correspondence Plaintiffs confirmed on March 20, 2025, that the vials of API samples were intact and not damaged. Defendants admit that samples of excipients were requested by Plaintiffs for the first time on March 18, 2025, and Defendants further state that Humanwell US immediately mailed out the excipients upon request, and confirmed receipt of the same on April 2, 2025. Defendants deny any remaining allegations of this paragraph.

COUNT I—INFRINGEMENT OF THE '214 PATENT

36. Plaintiffs reallege paragraphs 1–0 as if fully set forth herein.

ANSWER: Defendants incorporate by reference their answers to the foregoing paragraphs 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.

ANSWER: Defendants admit this paragraph recites claim 1 of the '214 patent. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: Denied.

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

ANSWER: Defendants admit that Redacted [redacted] Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants state that the Humanwell ANDA speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Humanwell ANDA. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants state that the Humanwell ANDA speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Humanwell ANDA. Defendants deny any remaining allegations of this paragraph.

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.

ANSWER: This paragraph of the Complaint states legal conclusions to which no response is required. To the extent a response is required, Defendants state that the Humanwell ANDA speaks for itself, and Defendants deny the allegations of this paragraph to the extent they deviate from or otherwise do not accurately reflect or describe the Humanwell ANDA. Defendants deny any remaining allegations of this paragraph.

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).

ANSWER: Denied.

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).

ANSWER: Denied.

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).

ANSWER: Denied.

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.

ANSWER: Denied.

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.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

50. On information and belief, based on the information provided by Defendants to date, the factual contentions in paragraphs 29–0 have evidentiary support. On information and belief, the factual contentions in paragraphs 29–0 will have further evidentiary support following a reasonable opportunity for further investigation or discovery.

ANSWER: Denied.

RESPONSE TO PRAYER FOR RELIEF

Defendants deny that Plaintiffs are entitled to any of the relief set forth in their “Prayer for Relief” in the Complaint, or to any other relief for any remaining allegations set forth in the Complaint.

AFFIRMATIVE DEFENSES

Without any admission as to burden of proof and expressly reserving its right to assert any additional defenses or counterclaims that discovery may reveal, Defendants state the following defenses:

FIRST AFFIRMATIVE DEFENSE

Defendants do not, have not, and will not infringe, literally or under the doctrine of equivalents, willfully or otherwise, any valid, properly construed claim of U.S. Patent No. 11,053,214, either directly, indirectly, contributorily, by inducement, or in any other manner.

SECOND AFFIRMATIVE DEFENSE

The claims of the '214 patent are invalid for failure to comply with and/or satisfy one or more of the conditions and requirements of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, 116, and/or 120 thereof.

THIRD AFFIRMATIVE DEFENSE

On information and belief, by virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the issuance of the '214 patent, Plaintiffs are estopped from maintaining that Defendants infringe any valid claim of the '214 patent.

FOURTH AFFIRMATIVE DEFENSE

The Complaint fails to state a claim upon which relief can be granted.

FIFTH AFFIRMATIVE DEFENSE

This Court lacks subject matter jurisdiction over portions of the claims asserted against Defendants, in particular, any infringement claims Plaintiffs assert under 35 U.S.C. § 271(a), (b), and/or (c) and any infringement claims Plaintiffs asserted against Epic Pharma.

* * *

Defendants expressly reserve the right to supplement and/or amend their Answer to Plaintiffs' Complaint, including but not limited to supplementation and/or amendment of their defenses and amplifications of denials, as additional facts and information become known through the course of this case and discovery.

Dated: June 24, 2025

Respectfully submitted,

POLSINELLI PC

s/ *Hyun (Eric) Yoon*
Hyun (Eric) Yoon

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CERTIFICATE OF SERVICE

I hereby certify that on June 24, 2025, a copy of the foregoing document was filed with the Court by ECF and is hereby served by ECF on all counsel of record. Parties may accordingly access this filing through the Court's CM/ECF System.

By: *Hyun (Eric) Yoon*
Hyun (Eric) Yoon