UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiff, v. TEVA PHARMACEUTICALS, INC, Defendant.	Civil Action No. 2:25-cv-03267 (JKS-AME) *Document Electronically Filed* **DEFENDANT TEVA PHARMACEUTICALS, INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS**

Defendant Teva Pharmaceuticals, Inc. ("Teva"), by and through its undersigned counsel, provides the following answers, affirmative defenses and counterclaims to the Complaint for Patent Infringement ("Complaint") (Civ. No. 25-cv-3267, D.I. 1) filed by Plaintiff Aurinia Pharmaceuticals Inc., ("Aurinia"). This pleading is based upon Defendant's knowledge as to its own activities, and upon information and belief as to other matters. Pursuant to Fed. R. Civ. P. 8(b)(3), Defendant denies all allegations in the Complaint except those admitted specifically below.

NATURE OF THIS ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Teva. This action relates to Abbreviated New Drug Application ("ANDA") No. 220211 ("Voclosporin ANDA") filed by Teva with the U.S. Food and Drug Administration ("FDA") for approval to market, manufacture, use, import, offer to sell, and/or sell generic versions of Aurinia's LUPKYNIS® (voclosporin) drug product ("generic voclosporin products") prior to expiration of Aurinia's U.S. Patent No. 10,286,036 ("the '036 patent") and U.S. Patent No. 11,622,991 ("the '991 patent"), that are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for LUPKYNIS®.

ANSWER: Defendant admits that the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") lists the '036 and the '991 patents (together, "the

patents-in-suit") for LUPKYNIS®. Defendant further admits that it submitted ANDA No. 220211 ("Teva's ANDA" or the "Teva ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, sale, and/or importation of a generic version of LUPKYNIS® (voclosporin, 7.9 mg/capsules) ("the ANDA Product" or "Teva's ANDA Product") prior to the expiration dates of the patents-in-suit that are listed in the Orange Book. Defendant further admits that the Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100 *et. seq.*, but denies that Plaintiff is entitled to relief. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations set forth in this paragraph and therefore denies the same.

PARTIES

2. Aurinia is a corporation organized and existing under the laws of Canada, having a principal place of business at #140, 14315 – 118 Avenue Edmonton, AB T5L 4S6 Canada.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph and therefore denies the same.

3. Aurinia is a research-driven pharmaceutical company that discovers, develops, manufactures, and markets innovative products to improve health in patients with autoimmune diseases, including lupus nephritis.

ANSWER: Defendant lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations set forth in this paragraph and therefore denies the same.

4. On information and belief, Teva Pharmaceuticals, Inc. ("Teva Inc.") is a corporation organized under the laws of Delaware, having a principal place of business at 400 Interpace Parkway #3 Parsippany, New Jersey 07054.

ANSWER: Admitted.

5. On information and belief, Teva Pharmaceutical Industries Ltd. ("Teva Ltd.") is a corporation organized and existing under the laws of Israel, having a principal place of business

at 124 Dvora HaNevi'a St., Tel Aviv, Israel, 6944020. On information and belief, Teva Inc. is a wholly owned subsidiary of Teva Ltd. On information and belief, Teva Ltd. collaborated with Teva Inc, in development of ANDA No. 220211.

ANSWER: This paragraph contains legal conclusions and is directed to an entity who was, at the time of filing, a separate Defendant to this action. The parties stipulated to a dismissal of Teva Pharmaceutical Industries Ltd. from this litigation that was entered on June 6. 2025. *See* Civ. No. 25-cv-3267, D.I. 9. Therefore, no response is required from Defendant. To the extent a response is required, denied.

6. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, and selling generic copies of branded pharmaceutical products throughout the United States, including in the State of New Jersey.

ANSWER: Teva admits that it sells products that are the subjects of Abbreviated New Drug Applications, providing high-quality pharmaceuticals which deliver value to patients, customers and the healthcare system throughout the United States, including in the State of New Jersey. Defendant denies any remaining allegations set forth in this paragraph.

JURISDICTION AND VENUE

7. Each of the preceding paragraphs 1–6 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: To the extent an answer to this paragraph is required, Defendant incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., including 35 U.S.C. § 271.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits that the Complaint purports to bring an action for patent infringement under the patent laws of the United States, 35 U.S.C. § 100, *et seq*.

Defendant denies any remaining allegations set forth in this paragraph.

9. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits that the Complaint cites the patent laws of the United States generally. Teva does not contest subject matter jurisdiction for purposes of this action only. Defendant denies any remaining allegations set forth in this paragraph.

10. On information and belief, Teva Ltd. and its subsidiary Teva Inc. hold themselves out as a unitary entity where Teva Ltd. directs and controls its subsidiary in the manufacture, importation, offer for sale, sale, and distribution of generic products in the United States, including New Jersey. For example, Teva Inc.'s website explains: "Teva Pharmaceuticals, Inc. and its US affiliates are subsidiaries of Teva Pharmaceutical Industries Ltd., headquartered in Israel." Teva Generics: Who We Are, Teva USA, https://www.tevausa.com/our-products/tevagenerics/who-we are/ (last visited Apr. 22, 2025).

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

11. This Court has personal jurisdiction over Teva Inc.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest personal jurisdiction in this Court for the purposes of this action only. Defendant denies any remaining allegations set forth in this paragraph.

12. On information and belief, Teva Inc. directly and/or indirectly through, and/or in concert with Teva Ltd., has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 220211 with the intent to make, use, sell, offer for sale, and/or import the generic voclosporin products in or into this judicial district, prior to the expiration of the '036 and '991 patents. On information and belief, Teva Inc. directly and/or indirectly through, and/or in concert with Teva Ltd., will engage in marketing, sale, and

distribution of the generic voclosporin products in New Jersey upon approval of its Voclosporin ANDA. On information and belief, such generic voclosporin products will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Additionally, on information and belief, Teva Inc. directly and/or indirectly through, and/or in concert with Teva Ltd., will offer its generic voclosporin products for sale and place them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in New Jersey and/or purchased by consumers in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Defendant admits that it has submitted Teva's ANDA No. 220211 to the FDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the ANDA Product prior to expiration of the patents-in-suit. Defendant denies any remaining allegations of this paragraph.

13. On information and belief, Teva Inc. has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Teva Inc. maintains a regular and established, physical place of business in the District of New Jersey, at 400 Interpace Parkway #3 Parsippany, New Jersey 07054. On information and belief, Teva Inc. operates in New Jersey to develop, manufacture, import, market, distribute, offer for sale, and/or sell generic drugs throughout the United States, including New Jersey.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest personal jurisdiction in this Court for the purposes of this action only. Additionally, Defendant admits that it is organized under the State of Delaware and has a principal place of business in Parsippany, NJ. Defendant denies any remaining allegations set forth in this paragraph.

14. Further, on information and belief, Teva Inc. directly and/or indirectly through, and/or in concert with Teva Ltd., has established distribution channels for its generic drug products in New Jersey and derives substantial revenue from the sale of drug products in New Jersey. For instance, on information and belief, Teva Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action . To the extent a response is required, Defendant does not contest personal jurisdiction in this Court for the purposes of this action only. Defendant admits that it is registered to do business in New Jersey under Business ID No. 0450614134. Defendant denies any remaining allegations set forth in this paragraph.

15. On information and belief, Teva Inc. has availed itself of the rights, benefits, and privileges of this Court by asserting counterclaims in at least the following District of New Jersey actions: *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-cv 9535; *Jazz Pharmaceuticals Ireland Limited v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24 cv-8785; *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.,* Civil Action No. 24-cv 6489; *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-cv 23142; *Theravance Biopharma R&D IP, LLP et al v. Eugia Pharma Specialties Limited et al*, Civil Action No. 23-6667; *Catalyst Pharmaceuticals, Inc et al v. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 23-1190; *GW Research Limited v. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 23-18; *Takeda Pharmaceuticals America, Inc. et al v. Teva Pharmaceuticals, Inc. et al*, Civil Action 22-7454; *Evoke Pharma, Inc. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 22-2019; *Horizon Therapeutics U.S. Holding LLC et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 22 1382.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest jurisdiction in this Court for the purposes of this action only and states that pleadings in previous actions speak for themselves. Defendant denies any remaining allegations set forth in this paragraph.

16. On information and belief, Teva Inc. has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See, e.g.*, *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-cv-9535; *Jazz Pharmaceuticals Ireland Limited v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-cv-8785; *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-cv-6489; *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-cv-23142; *Theravance Biopharma R&D IP, LLP et al v. Eugia Pharma Specialties Limited et al*, Civil Action No. 23-6667; *Catalyst Pharmaceuticals, Inc et al v. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 23-1190; *GW Research Limited v. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 23-18; *Takeda Pharmaceuticals America, Inc. et al v. Teva Pharmaceuticals, Inc. et al*, Civil Action 22-7454; *Evoke Pharma, Inc. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 22-2019; *Horizon Therapeutics U.S. Holding LLC et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 22-1382.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest jurisdiction in this Court for the purposes of this action only and states that pleadings in previous actions speak for themselves. Defendant denies any remaining allegations set forth in this paragraph.

17. This Court has personal jurisdiction over Teva Ltd.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

18. On information and belief, Teva Ltd. directly and/or indirectly through, and/or in concert with Teva Inc., has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 220211 with the intent to make, use, sell, offer for sale, and/or import the generic voclosporin products in or into this judicial district, prior to the expiration of the '036 and '991 patents. On information and belief, Teva Ltd. directly and/or indirectly through, and/or in concert with Teva Inc., will engage in marketing, sale, and distribution of the generic voclosporin products in New Jersey upon approval of its Voclosporin ANDA. On information and belief, such generic voclosporin products will be prescribed by physicians practicing in New Jersey, dispensed by pharmacies located within New Jersey, and used by patients in New Jersey. Additionally, on information and belief, Teva Ltd. directly and/or indirectly through, and/or in concert with Teva Inc., will offer its generic voclosporin products for sale and place them into the stream of commerce with the awareness, knowledge, and intent that they would be used, offered for sale, and/or sold by others in New Jersey and/or purchased by consumers in New Jersey.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

19. On information and belief, Teva Ltd. has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Teva Ltd. directly and/or indirectly through, and/or in concert with Teva Inc., operates a facility in the District of New Jersey, at 400 Interpace Parkway #3 Parsippany, New Jersey 07054. On information and belief, Teva Ltd. actively contracts with, inter alia, Teva Inc., to operate in New Jersey to develop, manufacture, import, market, distribute, offer for sale, and/or sell generic drugs throughout the United States, including New Jersey.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

20. Further, on information and belief, Teva Ltd. directly and/or indirectly through, and/or in concert with Teva Inc., has established distribution channels for its generic drug products in New Jersey and derives substantial revenue from the sale of drug products in New Jersey. For instance, on information and belief, Teva Inc. is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0450614134.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

21. In the alternative, this Court has jurisdiction over Teva Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because, inter alia, (a) Aurinia's claims arise under federal law; (b) Teva Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Ltd. has substantial contacts with the United States as a whole, including, but not limited to participating in the preparation and submission of the Voclosporin ANDA and/or manufacturing, importing, offering for sale, and selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Ltd. satisfies due process.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

22. On information and belief, Teva Ltd. has availed itself of the rights, benefits, and privileges of this Court by asserting claims and counterclaims in at least the following District of New Jersey action: *Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al,* Civil Action No. 17-cv-11510; *Teva Pharmaceuticals USA, Inc. et al v. Dr. Reddy's Laboratories, Ltd.*, Civil Action No. 17-cv-517; *Teva Pharmaceuticals USA, Inc. et al v. Sandoz Inc. et al*, Civil Action No. 17-cv-275; *Teva Pharmaceuticals USA, Inc. et al v. Dr. Reddy's Laboratories, Ltd. et al*, Civil Action No. 15-cv-471.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is

required from the Defendant. To the extent a response is required, Defendant states that pleadings in previous actions speak for themselves and denies any remaining allegations set forth in this paragraph.

23. On information and belief, Teva Ltd. has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See e.g.*, *Adapt Pharma Operations Limited et al v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 18-cv-9880; *Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 18-cv-734; *Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 17-cv-11510.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, Defendant states that pleadings in previous actions speak for themselves and denies any remaining allegations set forth in this paragraph.

24. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391(c) and (d), and 1400(b).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest venue in this Court for the purposes of this action only. Defendant denies any remaining allegations set forth in this paragraph.

25. On information and belief, venue is proper against Teva Inc. in this judicial district because, inter alia, it maintains a regular and established place of business in this judicial district and has committed an act of infringement in this judicial district.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest venue in this Court for the purposes of this action only. Defendant denies any remaining allegations set forth in this

paragraph.

26. Venue is proper in the District of New Jersey for Teva Ltd. because it is an Israeli corporation not resident in the United States, and thus venue is proper in any judicial district that has personal jurisdiction, including the District of New Jersey.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, denied.

27. Teva Inc. did not contest venue in this judicial district in at least the following actions: *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-cv 9535; *Jazz Pharmaceuticals Ireland Limited v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24 cv-8785; *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 24-cv 6489; *Axsome Therapeutics, Inc. et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 23-cv 23142; *Theravance Biopharma R&D IP, LLP et al v. Eugia Pharma Specialties Limited et al*, Civil Action No. 23-6667; *Catalyst Pharmaceuticals, Inc et al v. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 23-1190; *Takeda Pharmaceuticals America, Inc. et al v. Teva Pharmaceuticals, Inc. et al*, Civil Action 22-7454; *Evoke Pharma, Inc. Teva Pharmaceuticals, Inc. et al*, Civil Action No. 22-2019; *Horizon Therapeutics U.S. Holding LLC et al v. Teva Pharmaceuticals, Inc.*, Civil Action No. 22-1382.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant does not contest venue in this Court for the purposes of this action only and states that pleadings in previous actions speak for themselves. Defendant denies any remaining allegations set forth in this paragraph.

28. Teva Ltd. did not contest venue in this judicial district in at least the following actions: *Adapt Pharma Operations Limited et al v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 18-cv-9880; *Janssen Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 18-cv-734; *Boehringer Ingelheim Pharmaceuticals, Inc. et al v. Teva Pharmaceuticals USA, Inc. et al*, Civil Action No. 17-cv-11510.

ANSWER: This paragraph contains legal conclusions to which no response is required and is directed to an entity that has been dismissed from this action. Therefore, no response is required from Defendant. To the extent a response is required, Defendant states that pleadings in

previous actions speak for themselves and denies any remaining allegations set forth in this paragraph.

THE PATENTS-IN-SUIT

29. On May 14, 2019, the U.S. Patent and Trademark Office duly and legally issued the '036 patent, titled "Protocol for the Treatment of Lupus Nephritis." A true and correct copy of the '036 patent is attached hereto as Exhibit 1. The claims of the '036 patent are valid and enforceable. Aurinia is the owner of the '036 patent by assignment and has the right to enforce it.

ANSWER: Defendant admits that a purported copy of the '036 patent is attached to the Complaint as Exhibit 1. Defendant admits that on its face, the '036 patent is entitled "Protocol for Treatment of Lupus Nephritis." Defendant denies any remaining allegations set forth in this paragraph.

30. On April 11, 2023, the U.S. Patent and Trademark Office duly and legally issued the '991 patent, titled "Protocol for the Treatment of Lupus Nephritis." A true and correct copy of the '991 patent is attached hereto as Exhibit 2. The claims of the '991 patent are valid and enforceable. Aurinia is the owner of the '991 patent by assignment and has the right to enforce it.

ANSWER: Defendant admits that a purported copy of the '991 patent is attached to the Complaint as Exhibit 2. Defendant admits that on its face, the '991 patent is entitled "Protocol for the Treatment of Lupus Nephritis." Defendant denies any remaining allegations set forth in this paragraph.

31. Aurinia is the holder of NDA No. 213716 for LUPKYNIS®, voclosporin capsules for the treatment of lupus nephritis. The FDA approved NDA No. 213716 on January 22, 2021. The FDA's official publication of approved drugs, the Orange Book, lists, inter alia, the '036 and '991 patents for NDA. No. 213716. Aurinia markets voclosporin tablets in the United States under the trade name "LUPKYNIS®" through its subsidiary Aurinia Pharma U.S., Inc.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits that FDA's website indicates Aurinia is the holder of NDA No. 213716 for LUPKYNIS® (voclosporin, 7.9 mg/capsules) with an approval

date of Jan 22, 2021, and that the FDA's Orange Book lists the '036 and '991 patents in connection with NDA No. 213716. Defendant denies any remaining allegations set forth in this paragraph.

TEVA'S INFRINGING ACTIVITIES

32. Each of the preceding paragraphs 1–31 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: To the extent an answer to this paragraph is required, Defendant incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

33. By letter dated March 11, 2025, addressed to Aurinia ("Notice Letter"), Teva notified Aurinia that Teva had submitted its Voclosporin ANDA to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)).

ANSWER: Admitted that Defendant mailed Aurinia a Notice Letter referencing LUPKYNIS® and the patents-in-suit dated March 11, 2025 (the "Teva Notice Letter").

34. The Notice Letter states that Teva is seeking approval from the FDA to engage in the commercial manufacture, use, and sale of generic voclosporin products before the expiration of the '036 and '991 patents. On information and belief, the Voclosporin ANDA seeks approval of Teva's generic voclosporin products that are the same, or substantially the same, as Aurinia's LUPKYNIS®.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits it mailed Aurinia the Teva Notice Letter, which speaks for itself. Defendant denies any remaining allegations set forth in this paragraph.

35. On information and belief, Teva, through its own actions and/or the actions of its agents, affiliates, and subsidiaries, intends to engage in the importation, commercial manufacture, offer for sale, and sale of generic voclosporin products after receiving FDA approval to do so.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits the Teva Notice Letter notified Plaintiff

of the submission of the Teva ANDA to FDA. Defendant denies any remaining allegations set forth in this paragraph.

36. On information and belief, if the FDA approves Teva's Voclosporin ANDA, Teva, through its own actions and through the actions of its agents, affiliates, and subsidiaries, will actively induce or contribute to the manufacture, use, offer for sale, sale, or importation of generic voclosporin products in or into the United States.

ANSWER: Defendant denies the allegations of this paragraph.

37. In the Notice Letter, Teva notified Aurinia that its Voclosporin ANDA contained a "Paragraph IV certification" asserting that the '036 and '991 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Teva's generic voclosporin product.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits it mailed Aurinia the Teva Notice Letter, which speaks for itself. Defendant denies any remaining allegations set forth in this paragraph.

38. This Complaint is being filed before the expiration of the forty-five days from the date Aurinia received the Notice Letter.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, the Defendant does not dispute this Complaint was brought within forty-five (45) days of receipt of the Teva Notice Letter. Defendant denies any remaining allegations set forth in this paragraph.

COUNT I - INFRINGEMENT OF THE '036 PATENT

39. Each of the preceding paragraphs 1–38 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: To the extent an answer to this paragraph is required, Defendant incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

40. Teva's submission of its Voclosporin ANDA with a Paragraph IV certification against the '036 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, or sale of generic voclosporin products prior to the expiration of the '036 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits it mailed Aurinia the Teva Notice Letter, which speaks for itself. Defendant denies any remaining allegations set forth in this paragraph.

41. On information and belief, Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '036 patent are purportedly invalid, unenforceable, and/or will not be infringed.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits it mailed Aurinia the Teva Notice Letter, which speaks for itself. Defendant denies any remaining allegations set forth in this paragraph.

42. On information and belief, Teva had actual knowledge of the '036 patent at least since its filing of its Voclosporin ANDA and at least since March 11, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits that it was aware of the '036 patent at the time of filing Teva's ANDA No. 220211. Defendant denies any remaining allegations set forth in this paragraph.

43. On information and belief, Teva concedes infringement of at least one claim of the '036 patent because Teva's Notice Letter did not provide any specific non-infringement allegations.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

44. On information and belief, Teva's generic voclosporin products will, if approved and marketed, infringe at least one claim of the '036 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

45. On information and belief, Teva knows, should know, and intends that physicians will prescribe, and patients will take, Teva's generic voclosporin products for which approval is sought in its Voclosporin ANDA and therefore, will infringe at least one claim in the '036 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, the Defendant denies the allegations of this paragraph.

46. On information and belief, Teva has knowledge of the '036 patent and, by its proposed package insert for Teva's generic voclosporin products, knows or should know that it will induce direct infringement of at least one claim of the '036 patent, either literally or under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

47. On information and belief, Teva has knowledge that its proposed package insert will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic voclosporin products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '036 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

48. On information and belief, Teva has had and continues to have knowledge that its generic voclosporin products constitute a material part of the invention and are especially adapted for a use that infringes at least one claim of the '036 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

49. On information and belief, Teva has had and continues to have knowledge that Teva's generic voclosporin products are not a staple article or commodity of commerce suitable for substantial non-infringing use for at least one claim of the '036 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

50. On information and belief, upon FDA approval of Teva's Voclosporin ANDA, Teva will further infringe, literally or under the doctrine of equivalents, at least one claim of the '036 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), contributorily under 35 U.S.C. § 271(c), and/or under 35 U.S.C. § 271(g) by making, using, offering to sell, marketing, and selling its generic voclosporin products in the United States and/or importing such products into the United States, unless enjoined by this Court.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

51. If Teva's manufacture, marketing, and sale of generic voclosporin products prior to expiration of the '036 patent and all other relevant exclusivities is not enjoined, Aurinia will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

COUNT II – INFRINGEMENT OF THE '991 PATENT

52. Each of the preceding paragraphs 1–51 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: To the extent an answer to this paragraph is required, Defendant incorporates by reference its answers to the foregoing paragraphs as if fully set forth herein.

53. Teva's submission of its Voclosporin ANDA with a Paragraph IV certification against the '991 patent to obtain approval to engage in the commercial manufacture, use, offer for sale, or sale of generic voclosporin products prior to the expiration of the '991 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits it mailed Aurinia the Teva Notice Letter, which speaks for itself. Defendant denies any remaining allegations set forth in this paragraph.

54. On information and belief, Teva filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and 21 C.F.R. § 314.94(a)(12)(i)(A)(4), a certification alleging that the claims of the '991 patent are purportedly invalid, unenforceable, and/or will not be infringed.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits it mailed Aurinia the Teva Notice Letter, which speaks for itself. Defendant denies any remaining allegations set forth in this paragraph.

55. On information and belief, Teva had actual knowledge of the '991 patent at least since its filing of its Voclosporin ANDA and at least since March 11, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant admits that it was aware of the '036 patent at the time of filing Teva's ANDA No. 220211. Defendant denies any remaining allegations set forth in this paragraph.

56. On information and belief, Teva concedes infringement of at least one claim of the '991 patent because Teva's Notice Letter did not provide any specific non-infringement allegations.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

57. Upon information and belief, Teva's generic voclosporin products will, if approved and marketed, infringe at least one claim of the '991 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

58. On information and belief, Teva knows, should know, and intends that physicians will prescribe, and patients will take, Teva's generic voclosporin products for which approval is sought in its Voclosporin ANDA and therefore, will infringe at least one claim in the '991 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

59. On information and belief, Teva has knowledge of the '991 patent and, by its proposed package insert for Teva's generic voclosporin products, knows or should know that it will induce direct infringement of at least one claim of the '991 patent, either literally or under the doctrine of equivalents.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

60. On information and belief, Teva has knowledge that its proposed package insert will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because healthcare professionals and/or patients will use Teva's generic voclosporin products according to the instructions in the proposed package insert in a way that directly infringes at least one claim of the '991 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

61. On information and belief, Teva has had and continues to have knowledge that its generic voclosporin products constitute a material part of the invention and are especially adapted for a use that infringes at least one claim of the '991 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

62. On information and belief, Teva has had and continues to have knowledge that Teva's generic voclosporin products are not a staple article or commodity of commerce suitable for substantial non-infringing use for at least one claim of the '991 patent.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

63. On information and belief, upon FDA approval of Teva's Voclosporin ANDA, Teva will further infringe, literally or under the doctrine of equivalents, at least one claim of the '991 patent directly under 35 U.S.C. § 271(a), by inducement under 35 U.S.C. § 271(b), contributorily under 35 U.S.C. § 271(c), and/or under 35 U.S.C. § 271(g) by making, using, offering to sell, marketing, and selling its generic voclosporin products in the United States and/or importing such products into the United States, unless enjoined by this Court.

ANSWER: This paragraph contains legal conclusions to which no response is required.

To the extent a response is required, Defendant denies the allegations of this paragraph.

64. If Teva's marketing and sale of generic voclosporin products prior to expiration of the '991 patent and all other relevant exclusivities is not enjoined, Aurinia will suffer substantial and irreparable harm for which there is no remedy at law.

ANSWER: This paragraph contains legal conclusions to which no response is required. To the extent a response is required, Defendant denies the allegations of this paragraph.

RESPONSE TO PRAYER FOR RELIEF

The remainder of the Complaint recites a prayer for relief for which no response is required. To the extent a response is required, Defendant denies that Plaintiff is entitled to any relief.

AFFIRMATIVE DEFENSES

Defendant asserts the following defenses without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Defendant requests that judgment be entered in its favor, dismissing the Complaint with prejudice, awarding Defendant attorneys' fees and costs incurred in this litigation under 35 U.S.C. § 285, and granting further relief as the Court may deem just and proper. Defendant does not assume the burden of proof on any such defenses, except as required by applicable law with respect to the particular defense asserted. Defendant reserves the right to assert other defenses and/or to otherwise supplement or amend this Answer upon discovery of facts or evidence rendering such action appropriate in accordance with the Federal Rules of Civil Procedure and Local Civil Rules of the U.S. District Court for the District of New Jersey.

FIRST AFFIRMATIVE DEFENSE

Each purported claim in the Complaint, in whole or in part, is barred for failure to state a

claim upon which relief can be granted.

SECOND AFFIRMATIVE DEFENSE

The claims of the '036 patent are invalid for failure to comply with the statutory provisions of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

THIRD AFFIRMATIVE DEFENSE

Defendant does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '036 patent. If the products that are the subject of ANDA No. 220211 were marketed, Defendant would not infringe any valid and enforceable claim of the '036 patent.

FOURTH AFFIRMATIVE DEFENSE

Defendant has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '036 patent. If the products that are the subject of ANDA No. 220211 were marketed, Defendant would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '036 patent.

FIFTH AFFIRMATIVE DEFENSE

Plaintiff is barred from asserting the claims of the '036 patent in whole or in part, either literally or by application of the doctrine of equivalents, by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

SIXTH AFFIRMATIVE DEFENSE

The claims of the '991 patent are invalid for failure to comply with the statutory provisions

of Title 35 of the United States Code, including without limitation sections 101, 102, 103, and/or 112, or other judicially created bases for invalidity.

SEVENTH AFFIRMATIVE DEFENSE

Defendant does not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '991 patent. If the products that are the subject of ANDA No. 220211 were marketed, Defendant would not infringe any valid and enforceable claim of the '991 patent.

EIGHTH AFFIRMATIVE DEFENSE

Defendant has not, does not, and will not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '991 patent. If the products that are the subject of ANDA No. 220211 were marketed, Defendant would not induce the infringement of, or contribute to the infringement of, any valid and enforceable claim of the '991 patent.

NINTH AFFIRMATIVE DEFENSE

Plaintiff is barred from asserting the claims of the '991 patent in whole or in part, either literally or by application of the doctrine of equivalents, by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

TENTH AFFIRMATIVE DEFENSE

Defendant's actions in defending this case do not give rise to an exceptional case under 35 U.S.C. § 285.

ELEVENTH AFFIRMATIVE DEFENSE

Certain of Defendant's activities are reasonably related to Defendant's development and submission of information to the FDA and are protected by the safe harbor of 35 U.S.C.

§ 271(e)(1).

TWEFLTH AFFIRMATIVE DEFENSE

Any additional defenses or counterclaims that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Aurinia Pharmaceuticals Inc. ("Aurinia") ("Counterclaim Defendant/Plaintiff"), Teva Pharmaceuticals, Inc. ("Counterclaim Plaintiff/Defendant"), states as follows:

THE PARTIES

1. On information and belief and as it pled in its Complaint, Aurinia is a corporation organized and existing under the laws of Canada, having a principal place of business at #140, 14315 – 118 Avenue Edmonton, AB T5L 4S6 Canada.

2. Teva Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 400 Interpace Parkway #3 Parsippany, New Jersey 07054.

JURISDICTION AND VENUE

3. These counterclaims arise under the patent laws of the United States and the Declaratory Judgment Act. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

4. This Court has personal jurisdiction over Counterclaim Defendant/Plaintiff on the basis of, *inter alia*, its contacts with New Jersey relating to the subject matter of this action, including having filed the Complaint in the underlying suit.

5. Venue is proper under 28 U.S.C. §§ 1391 and 1400 and as a result of Plaintiff's

filing of the Complaint in the underlying suit.

BACKGROUND

6. Upon information and belief, Aurinia holds approved New Drug Application ("NDA") No. 213716 for LUPKYNIS® (voclosporin, 7.9 mg/capsules).

7. An NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an authorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

8. Upon approval of the NDA, the U.S. Food and Drug Administration ("FDA") publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

9. On information and belief, U.S. Patent No. 10,286,036 ("the '036 patent"), entitled "Protocol for Treatment of Lupis Nephritis," issued on May 14, 2019.

10. On information and belief, based upon the United States Patent Office's assignment database, Aurinia is the assignee of the '036 patent.

11. On information and belief, U.S. Patent No. 11,622,991 ("the '991 patent"), entitled "Protocol for Treatment of Lupis Nephritis," issued on April 11, 2023.

12. On information and belief, based upon the United States Patent Office's assignment database, Aurinia is the assignee of the '991 patent.

13. On information and belief, after the issuance of the '036 and the '991 patents ("the patents-in-suit"), Counterclaim Defendant/Plaintiff caused the patents-in-suit to be listed in the Orange Book for NDA No. 213716.

14. Counterclaim Plaintiff/Defendant submitted Abbreviated New Drug Application ("ANDA") No. 220211 ("Teva's ANDA" or the "Teva ANDA") to obtain FDA approval to market generic versions of LUPKYNIS® (voclosporin, 7.9 mg/capsules) ("Teva's ANDA Product") prior to the expiration of the patents-in-suit.

15. Pursuant to 21 U.S.C. § 355(j)(2)(B), Teva notified Counterclaim Defendant/Plaintiff by letter dated March 11, 2025 (the "Teva Notice Letter") that Counterclaim Plaintiff/Defendant had submitted Paragraph IV Certifications with its ANDA for the '036 and the '991 patents. The Teva Notice Letter, which is incorporated herein by reference, contained a detailed statement of the factual and legal bases for Teva's Paragraph IV Certifications that the claims of the patents-in-suit are invalid, not infringed, and/or unenforceable.

16. Pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III) and 21 C.F.R. § 314.95(c)(8), Teva offered Counterclaim Defendant/Plaintiff confidential access to information from Teva's ANDA No. 220211 for the purpose of determining whether an infringement action under 21 U.S.C. § 355(j)(5)(B)(iii) can be brought against Teva relating to Teva's ANDA Product.

17. On April 25, 2025, Counterclaim Defendant/Plaintiff filed the instant lawsuit alleging infringement of the patents-in-suit.

18. As a consequence of the foregoing, there is an actual and justiciable controversy between Defendant, on the one hand, and Aurinia, on the other hand, as to whether the claims of the '036 and '991 patents are invalid and/or unenforceable, and whether the products and/or activities described in Defendant's ANDA No. 220211 infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the '036 and '991 patents.

COUNT I

(Declaratory Judgment of Invalidity or Unenforceability of the '036 Patent)

19. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 18 of its Counterclaims as though fully set forth herein.

20. Aurinia alleges ownership of the '036 patent and has brought claims against Defendant, alleging infringement of the '036 patent.

21. One or more claims of the '036 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

22. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Teva's ANDA and/or the commercial marketing of Teva's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '036 patent.

23. The '036 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

24. The alleged invention of the '036 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '036 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '036 patent and would have had a reasonable expectation of success in doing so.

25. The subject matter claimed in the '036 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such

that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

26. Counterclaim Plaintiff/Defendant incorporates by reference the Teva Notice Letter, which contains exemplary and nonlimiting explanations for why the '036 patent is invalid and/or not infringed by the Teva ANDA, or Teva's ANDA Product, and/or activities described therein.

27. Counterclaim Plaintiff/Defendant is entitled to a declaration that all claims of the '036 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

28. This case is an exceptional one, and Counterclaim Plaintiff/Defendant is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II

(Declaratory Judgment of Non-Infringement of the '036 Patent)

29. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 28 of its Counterclaims as though fully set forth herein.

30. Aurinia alleges ownership of the '036 patent and has brought claims against Defendant, alleging infringement of the '036 patent.

31. Counterclaim Plaintiff/Defendant has not and will not infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '036 patent and is not liable for such infringement.

32. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Teva's ANDA and/or the commercial marketing of Teva's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the

'036 patent.

33. The filing of Teva's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '036 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

34. The manufacture, use, or sale of Teva's ANDA Product has not, does not, and will not infringe any valid or enforceable claim of the '036 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

35. Counterclaim Plaintiff/Defendant incorporates by reference the Teva Notice Letter, which contains exemplary and nonlimiting explanations for why the '036 patent is invalid and/or not infringed by the Teva ANDA, or Teva's ANDA Product, and/or activities described therein. Counterclaim Plaintiff/Defendant is entitled to a declaration that the manufacture, use, or sale of Teva's ANDA Product would not infringe any valid or enforceable claim of the '036 patent.

36. This case is an exceptional one, and Counterclaim Plaintiff/Defendant is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III

(Declaratory Judgment of Invalidity or Unenforceability of the '991 Patent)

37. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 36 of its Counterclaims as though fully set forth herein.

38. Aurinia alleges ownership of the '991 patent and has brought claims against Defendant, alleging infringement of the '991 patent.

39. One or more claims of the '991 patent are invalid under one or more provisions of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

40. There is an actual, substantial, continuing, and justiciable controversy between the

parties regarding whether the filing of Teva's ANDA and/or the commercial marketing of Teva's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '991 patent.

41. The '991 patent describes and claims an alleged invention, the making of which did not involve the inventive faculty but only the obvious judgment, knowledge, and mechanical skill possessed by persons having ordinary skill in the art to which the alleged invention pertains.

42. The alleged invention of the '991 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '991 patent is not more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '991 patent and would have had a reasonable expectation of success in doing so.

43. The subject matter claimed in the '991 patent fails to comply with 35 U.S.C. § 103 in that the differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

44. Counterclaim Plaintiff/Defendant incorporates by reference the Teva Notice Letter, which contains exemplary and nonlimiting explanations for why the '991 patent is invalid and/or not infringed by the Teva ANDA, or Teva's ANDA Product, and/or activities described therein.

45. Counterclaim Plaintiff/Defendant is entitled to a declaration that all claims of the '991 patent are invalid under 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or other judicially created bases for invalidity.

46. This case is an exceptional one, and Counterclaim Plaintiff/Defendant is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV

(Declaratory Judgment of Non-Infringement of the '991 Patent)

47. Counterclaim Plaintiff/Defendant re-alleges and incorporates by reference the allegations in Paragraphs 1 through 46 of its Counterclaims as though fully set forth herein.

48. Aurinia alleges ownership of the '991 patent and has brought claims against Defendant, alleging infringement of the '991 patent.

49. Counterclaim Plaintiff/Defendant has not and will not infringe, contribute to the infringement of, or induce the infringement of any valid and enforceable claim of the '991 patent and is not liable for such infringement.

50. There is an actual, substantial, continuing, and justiciable controversy between the parties regarding whether the filing of Teva's ANDA and/or the commercial marketing of Teva's ANDA Product infringes, has infringed, and/or will infringe a valid and enforceable claim of the '991 patent.

51. The filing of Teva's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '036 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

52. The manufacture, use, or sale of Teva's ANDA Product has not, does not, and will not infringe any valid or enforceable claim of the '036 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

53. Counterclaim Plaintiff/Defendant incorporates by reference the Teva Notice Letter, which contains exemplary and nonlimiting explanations for why the '991 patent is invalid and/or

not infringed by the Teva ANDA, or Teva's ANDA Product, and/or activities described therein.

54. Counterclaim Plaintiff/Defendant is entitled to a declaration that the manufacture, use, or sale of Teva's ANDA Product would not infringe any valid or enforceable claim of the '991 patent.

55. This case is an exceptional one, and Counterclaim Plaintiff/Defendant is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim Plaintiff/Defendant respectfully requests judgment in its favor and against Counterclaim Defendant/Plaintiff as follows:

a. Declaring that the filing of Teva's ANDA No. 220211 ("Teva's ANDA" or the "Teva ANDA") has not infringed and does not infringe any valid and enforceable claim of the patents-in-suit;

b. Declaring that the manufacture, use, offer to sell, sale, and/or importation into the United States of Teva's ANDA Product does not, and would not, if marketed, infringe any valid and enforceable claim of the patents-in-suit;

c. Declaring that each claim of the patents-in-suit is invalid and/or unenforceable;

d. Declaring this an exceptional case in favor of Defendant and awarding its attorneys' fees pursuant to 35 U.S.C. § 285 and/or under all applicable statutes and rules in common law that would be appropriate;

e. Awarding costs and expenses under all applicable statutes and rules in common law that would be appropriate; and

f. Awarding any and all such other relief as the Court determines to be just and proper.

DATED: July 14, 2025

By: *s/ Liza M. Walsh*

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following actions currently pending in this District:

• AURINIA PHARMACEUTICALS INC. v. DIFGEN PHARMACEUTICALS LLC Civil Action No. 2:25-cv-02580-JKS-AME

• AURINIA PHARMACEUTICALS INC. v. LOTUS PHARMACEUTICAL CO., LTD. Civil Action No. 2:25-cv-02613-JKS-AME

• AURINIA PHARMACEUTICALS INC. v. GALENICUM HEALTH S.L.U. Civil Action No. 2:25-cv-02807-JKS-AME

• AURINIA PHARMACEUTICA LS INC. v. ZYDUS PHARMACEUTICALS (USA) INC. al Civil Action No. 2:25-cv-02893-JKS-AME

• AURINIA PHARMACEUTICALS INC. v. HIKMA PHARMACEUTICALS USA INC., Civil Action No. 2:25-cv-03267-JKS-AME

• AURINIA PHARMACEUTICALS INC. v. DR. REDDY'S LABORATORIES, INC. et al Civil Action No. 2:25-cv-03693-JKS-AME

• AURINIA PHARMACEUTICALS INC. v. SANDOZ INC. Civil Action No. 2:25-cv-03986-JKS-AME

Defendant is not aware of any other action in any court or any pending arbitration or administrative proceeding related to this matter.

Dated: July 14, 2025

s/ Liza M. Walsh
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Christine P. Clark
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Attorneys for Defendant
Teva Pharmaceuticals, Inc.

LOCAL RULE 201.1 CERTIFICATION

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

Dated: July 14, 2025

s/ Liza M. Walsh

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Attorneys for Defendant
Teva Pharmaceuticals, Inc.

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Defendant Teva Pharmaceuticals, Inc.'s foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on July 14, 2025.

s/ Liza M. Walsh
Liza M. Walsh

DATED: July 14, 2025