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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiff, v. SANDOZ INC., Defendant.	Civil Action No. 2:25-3986 (JKS)(AME) **DEFENDANT SANDOZ INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Sandoz Inc. ("Sandoz"), by and through the undersigned attorneys, submits its answer, affirmative defenses, and counterclaims to the Complaint for patent infringement of Plaintiff Aurinia Pharmaceuticals, Inc. ("Aurinia" or "Plaintiff"). Sandoz denies all allegations in Plaintiff's Complaint except those admitted specifically below. This pleading is based upon Sandoz's 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 patent laws of the United States, Title 35, United States Code, against Sandoz. This action relates to Abbreviated New Drug Application ("ANDA") No. 220223 ("Voclosporin ANDA") filed by Sandoz 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: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that the Complaint purports to bring an action for infringement under the Patent Laws of the United States, Title 35 of the United States Code. Sandoz further admits that Sandoz filed ANDA No. 220223 ("Sandoz's ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to market, use, or sell voclosporin capsules, 7.9 mg ("Sandoz's ANDA Product") prior to the expiration of U.S. Patent Nos. 10,286,036 ("the '036 patent") and 11,622,991 ("the '991 patent") (collectively, the "Patents-in-Suit"). Sandoz also admits that the '036 and '991 patents are listed in the FDA's publication *Approved Drug Products with Therapeutic Evaluations* ("Orange Book") in connection with LUPKYNIS®. Sandoz denies the remaining allegations in this paragraph.

THE 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: Sandoz lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

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: Sandoz lacks knowledge or information sufficient to form a belief as to the truth or falsity of the allegations of this paragraph and, therefore, denies them.

4. On information and belief, Sandoz is a corporation organized under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

ANSWER: Sandoz admits that Sandoz is a corporation organized and existing under the laws of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

5. On information and belief, Sandoz 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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that it seeks regulatory approval of and sells generic products in the United States. Sandoz denies the remaining allegations in this paragraph.

JURISDICTION AND VENUE

6. Each of the preceding paragraphs 1–5 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its responses to paragraphs 1-5 as if fully set forth herein.

7. 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 conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that the Complaint purports to bring an action for infringement under 35 U.S.C. §§ 100 *et seq.* generally and 35 U.S.C. § 271 specifically. Sandoz denies the remaining allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not contest subject matter jurisdiction for purposes of this case only. Sandoz denies the remaining allegations in this paragraph.

9. This Court has personal jurisdiction over Sandoz.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not contest personal jurisdiction for purposes of this case only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Aurinia. Sandoz denies the remaining allegations in this paragraph.

10. On information and belief, Sandoz directly and/or indirectly has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 220223 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, Sandoz directly and/or indirectly 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, Sandoz directly and/or indirectly 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 conclusions of law for which no response is required. To the extent that a response is required, Sandoz does not contest personal jurisdiction for purposes of this case only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Aurinia. Sandoz denies the remaining allegations in this paragraph.

11. On information and belief, Sandoz has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Sandoz maintains a regular and established, physical place of business in the District of New Jersey, at 100 College Road West, Princeton, New Jersey 08540. On information and belief, Sandoz 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 conclusions of law for which no response is required. To the extent a response is required, Sandoz does not contest personal jurisdiction for purposes of this case only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Aurinia. Sandoz denies the remaining allegations in this paragraph.

12. Further, on information and belief, Sandoz directly and/or indirectly 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, Sandoz 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. 0100097265. On information and belief, Sandoz is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003732.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not contest personal jurisdiction for purposes of this case only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Aurinia. Sandoz denies the remaining allegations in this paragraph.

13. On information and belief, Sandoz 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: actions: *Amneal Pharmaceuticals LLC et al v. Sandoz Inc.*, Civil Action No. 25-cv-181; *AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civil Action No. 24-cv-10627; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-cv-9110; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-8855; *Esperion Therapeutics, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-6287; *AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civil Action No. 24-cv-5889; *Axsome Malta Ltd. et al v. Alkem Laboratories, Ltd. et al*, Civil Action No. 24-cv-4608; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-4327; *BeiGene USA, Inc. et al v. Sandoz Inc.*, Civil Action No. 24-cv-1972; *Janssen Pharmaceuticals, Inc. et al v. Sandoz Inc.*, Civil Action No. 23-cv-2943.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not contest personal jurisdiction for purposes of this case only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Aurinia. Sandoz denies the remaining allegations in this paragraph.

14. On information and belief, Sandoz has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See, e.g.*, *Amneal Pharmaceuticals LLC et al v. Sandoz Inc.*, Civil Action No. 25-cv-181; *AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civil Action No. 24-cv-10627; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-cv-9110; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-8855; *Esperion Therapeutics, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-6287; *AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civil Action No. 24-cv-5889; *Axsome Malta Ltd. et al v. Alkem Laboratories, Ltd. et al*, Civil Action No. 24-cv-4608; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-4327; *BeiGene USA, Inc. et al v. Sandoz Inc.*, Civil Action No. 24-cv-1972; *Janssen Pharmaceuticals, Inc. et al v. Sandoz Inc.*, Civil Action No. 23-cv-2943.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz does not contest personal jurisdiction for purposes of this

case only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Aurinia. Sandoz denies the remaining allegations in this paragraph.

15. 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 conclusions of law for which no response is required. To the extent that a response is required, Sandoz does not contest that venue is proper in this judicial district for purposes of this case only. Sandoz denies the remaining allegations in this paragraph.

16. On information and belief, venue is proper against Sandoz 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 conclusions of law for which no response is required. To the extent that a response is required, Sandoz does not contest that venue is proper in this judicial district for purposes of this case only. Sandoz denies the remaining allegations in this paragraph.

17. Sandoz did not contest venue in this judicial district in at least the following actions: *American Regent, Inc. v. Sandoz Pharmaceuticals USA Inc.*, Civil Action No. 24-11118 (D.N.J.); *Amneal Pharmaceuticals LLC et al v. Sandoz Inc.*, Civil Action No. 25-cv-181; *AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civil Action No. 24-cv-10627; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-cv-9110; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv- 8855; *Esperion Therapeutics, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-6287; *AstraZeneca Pharmaceuticals LP et al v. Sandoz Inc.*, Civil Action No. 24-cv-5889; *Axsome Malta Ltd. et al v. Alkem Laboratories, Ltd. et al*, Civil Action No. 24-cv-4608; *Intra-Cellular Therapies, Inc. v. Sandoz Inc.*, Civil Action No. 24-cv-4327; *BeiGene USA, Inc. et al v. Sandoz Inc.*, Civil Action No. 24-cv-1972; *Janssen Pharmaceuticals, Inc. et al v. Sandoz Inc.*, Civil Action No. 23-cv-2943.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Sandoz does not contest that venue is proper in this judicial district for purposes of this case only. Sandoz denies the remaining allegations in this paragraph.

PATENTS-IN-SUIT

18. 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: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Sandoz admits that on its face, the '036 patent was issued on May 14, 2019, and is titled "Protocol for the Treatment of Lupus Nephritis." Sandoz admits that a purported copy of the '036 patent is attached to the Complaint as Exhibit 1. Sandoz specifically denies that the '036 patent was duly and legally issued. Sandoz further admits that, according to the records of the U.S. Patent and Trademark Office ("USPTO"), Aurinia is the assignee of the '036 patent. Sandoz denies the remaining allegations of this paragraph.

19. 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: This paragraph contains legal conclusions to which no answer is required. To the extent that a response is required, Sandoz admits that on its face, the '991 patent was issued on April 11, 2023, and is titled "Protocol for the Treatment of Lupus Nephritis." Sandoz admits that a purported copy of the '991 patent is attached to the Complaint as Exhibit 2. Sandoz specifically denies that the '991 patent was duly and legally issued. Sandoz further admits that, according to the records of the USPTO, Aurinia is the assignee of the '991 patent. Sandoz denies the remaining allegations of this paragraph.

20. 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: Sandoz admits that, according to the records of the FDA, Aurinia is the holder of NDA No. 213716 for LUPKYNIS®, which is the tradename for voclosporin capsules. The prescribing information for LUPKYNIS® states that LUPKYNIS® is indicated in combination with a background immunosuppressive therapy regimen for the treatment of adult patients with active

lupus nephritis. Sandoz further admits that, according to the records of the FDA, the FDA approved NDA No. 213716 on January 22, 2021. Sandoz also admits that the '036 and '991 patents are listed in the FDA's Orange Book in connection with NDA No. 213716. Sandoz lacks knowledge or information sufficient to form a belief as to the truth or falsity of the remaining allegations of this paragraph and, therefore, denies them.

SANDOZ'S INFRINGING ACTIVITIES

21. Each of the preceding paragraphs 1–20 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its responses to paragraphs 1-20 as if fully set forth herein.

22. By letter dated March 24, 2025, addressed to Aurinia ("Notice Letter"), Sandoz notified Aurinia that Sandoz 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: Sandoz admits that it sent Aurinia a letter dated March 24, 2025 ("Sandoz's Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, providing notice that Sandoz submitted ANDA No. 220223 to the FDA. Sandoz denies the remaining allegations in this paragraph.

23. The Notice Letter states that Sandoz 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 Sandoz'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 answer is required. To the extent an answer is required, Sandoz admits that Sandoz's Notice Letter notified Aurinia that Sandoz submitted ANDA No. 220223 seeking approval to manufacture, use, or sell Sandoz's ANDA Product in the United States before the expiration of the '036 and '991 patents. Sandoz denies the remaining allegations in this paragraph.

24. On information and belief, Sandoz, 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 answer is required. To the extent an answer is required, Sandoz admits that Sandoz submitted ANDA No. 220223 seeking approval to manufacture, use, or sell Sandoz's ANDA Product in the United States. Sandoz denies the remaining allegations in this paragraph.

25. On information and belief, if the FDA approves Sandoz's Voclosporin ANDA, Sandoz, 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: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Sandoz submitted ANDA No. 220223 seeking approval to manufacture, use, or sell Sandoz's ANDA Product in the United States. Sandoz denies the remaining allegations in this paragraph.

26. In the Notice Letter, Sandoz 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 Sandoz's generic voclosporin product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Sandoz admits that Sandoz's Notice Letter provided Aurinia notice that Sandoz's ANDA No. 220223 includes a Paragraph IV certification to the '036 and '991 patents. Sandoz denies the remaining allegations in this paragraph.

27. 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 answer is required. To the extent an answer is required, Sandoz admits that the Complaint in this Action was filed on May 8,

2025, which was within forty-five days of receipt of Sandoz's Notice Letter. Sandoz denies the remaining allegations in this paragraph.

COUNT I
INFRINGEMENT OF THE '036 PATENT

28. Each of the preceding paragraphs 1–27 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its responses to paragraphs 1-27 as if fully set forth herein.

29. Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

30. On information and belief, Sandoz 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: Sandoz admits that Sandoz's Notice Letter notified Aurinia that Sandoz's ANDA No. 220223 includes a Paragraph IV Certification that the claims of the '036 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, and/or sale of Sandoz's ANDA Product. Sandoz denies the remaining allegations in this paragraph.

31. On information and belief, Sandoz had actual knowledge of the '036 patent at least since its filing of its Voclosporin ANDA and at least since March 24, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that it was aware of the '036 patent at the time of filing Sandoz's ANDA No. 220223. Sandoz denies the remaining allegations in this paragraph.

32. On information and belief, Sandoz concedes infringement of at least one claim of the '036 patent because Sandoz's Notice Letter did not provide non-infringement allegations addressing indirect infringement for multiple claims.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

34. On information and belief, Sandoz knows, should know, and intends that physicians will prescribe, and patients will take, Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

35. On information and belief, Sandoz has knowledge of the '036 patent and, by its proposed package insert for Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

36. On information and belief, Sandoz 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 Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

38. On information and belief, Sandoz has had and continues to have knowledge that Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

39. On information and belief, upon FDA approval of Sandoz's Voclosporin ANDA, Sandoz 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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

40. If Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

COUNT II
INFRINGEMENT OF THE '991 PATENT

41. Each of the preceding paragraphs 1–40 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: Sandoz incorporates by reference its responses to paragraphs 1-40 as if fully set forth herein.

42. Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

43. On information and belief, Sandoz 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: Sandoz admits that Sandoz's Notice Letter notified Aurinia that Sandoz's ANDA No. 220223 includes a Paragraph IV Certification that the claims of the '991 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, and/or sale of Sandoz's ANDA Product. Sandoz denies the remaining allegations in this paragraph.

44. On information and belief, Sandoz had actual knowledge of the '991 patent at least since its filing of its Voclosporin ANDA and at least since February 24, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz admits that it was aware of the '991 patent at the time of filing Sandoz's ANDA NO. 220223. Sandoz denies the remaining allegations in this paragraph.

45. On information and belief, Sandoz concedes infringement of at least one claim of the '991 patent because Sandoz's Notice Letter did not provide non-infringement allegations addressing indirect infringement for multiple claims.

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

47. On information and belief, Sandoz knows, should know, and intends that physicians will prescribe, and patients will take, Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

48. On information and belief, Sandoz has knowledge of the '991 patent and, by its proposed package insert for Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

49. On information and belief, Sandoz 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 Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

51. On information and belief, Sandoz has had and continues to have knowledge that Sandoz'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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

52. On information and belief, upon FDA approval of Sandoz's Voclosporin ANDA, Sandoz 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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

53. If Sandoz's manufacture, 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 conclusions of law for which no response is required. To the extent a response is required, Sandoz denies the allegations in this paragraph.

PRAYER FOR RELIEF

This section of Plaintiff's Complaint is a prayer for relief and does not require a response. To the extent any response is required, Sandoz denies that Plaintiff is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Sandoz hereby asserts the following defenses without undertaking or otherwise shifting any applicable burdens of proof, without prejudice to the denials in this Answer, and without admitting any allegations of the Complaint not otherwise admitted. Sandoz reserves the right to assert additional defenses and/or otherwise supplement this Answer, as warranted by facts learned through investigation and discovery.

First Affirmative Defense

The manufacture, use, sale, offer for sale, and/or importation of Sandoz's ANDA Product has not infringed, does not infringe, and would not, if marketed, infringe any valid or enforceable claims of the '036 or '991 patents either directly or indirectly, and either literally or under the doctrine of equivalents.

Second Affirmative Defense

The filing of Sandoz's ANDA has not infringed, does not infringe, and will not infringe any valid and enforceable claim of the '036 or '991 patents.

Third Affirmative Defense

Sandoz has not, does not, and will not indirectly infringe any valid and enforceable claim of the ’036 or ’991 patents.

Fourth Affirmative Defense

The claims of the ’036 and ’991 patents 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.

Fifth Affirmative Defense

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

Sixth Affirmative Defense

Sandoz has not willfully infringed any claim of the ’036 or ’991 patents.

Seventh Affirmative Defense

Plaintiff is estopped from asserting infringement by the doctrine of prosecution history estoppel, judicial estoppel, and/or other equitable doctrines.

Eighth Affirmative Defense

Any additional defenses that discovery may reveal.

COUNTERCLAIMS

For its Counterclaims against Plaintiff/Counterclaim-Defendant Aurinia Pharmaceuticals, LLC (“Aurinia”), Defendant/Counterclaim-Plaintiff Sandoz Inc. (“Sandoz”) states as follows:

PARTIES

1. Sandoz is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

2. On information and belief, 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.

NATURE OF ACTION

3. Sandoz seeks declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, that United States Patent Nos. 10,286,036 ("the '036 patent") and 11,622,991 ("the '991 patent") (collectively, the "Patents-in-Suit") are invalid and/or not infringed.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over these Counterclaims pursuant to 28 U.S.C. §§ 1331, 1337, 1338, 1367, 2201, and 2202.

5. This Court has personal jurisdiction over Plaintiff/Counterclaim-Defendant Aurinia because, among other reasons, it subjected itself to the jurisdiction of this Court by filing its Complaint here.

6. Venue is proper in this District pursuant to 28 U.S.C. §§ 1391 and 1400 for purposes of this case, and by Aurinia's choice of forum.

7. There is an actual and justiciable controversy between the parties as to the infringement of the '036 patent and the '991 patent.

FACTUAL BACKGROUND

8. Upon information and belief, Aurinia is the holder of NDA No. 213716, which purportedly covers LUPKYNIS®, voclosporin capsules.

9. An NDA must include, among others, 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).

10. 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).

11. The '036 patent, titled "Protocol for the Treatment of Lupus Nephritis," issued on May 14, 2019.

12. The '991 patent, titled "Protocol for the Treatment of Lupus Nephritis," issued on April 11, 2023.

13. Upon information and belief, Aurinia is the assignee of the '036 and '991 patents.

14. Upon information and belief, Aurinia caused the '036 and '991 patents to be listed in the Orange Book in connection with LUPKYNIS®.

15. By listing the '036 and '991 patents in the Orange Book, Aurinia created a reasonable apprehension that it would file a patent infringement suit against applicants seeking regulatory approval for a generic version of LUPKYNIS®.

16. Sandoz submitted Abbreviated New Drug Application ("ANDA") No. 220223 ("Sandoz's ANDA") to the FDA pursuant to 21 U.S.C. § 355(j)(1) and 2(A) to obtain approval to engage in the commercial manufacture, use, and sale of voclosporin capsules, 7.9 mg ("Sandoz's ANDA Product") in the United States.

17. Sandoz's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 355 5(j)(2)(A)(vii)(IV) that the claims of the '036 and '991 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Sandoz's ANDA Product.

18. By letter dated March 24, 2025, Sandoz sent written notice of Sandoz's Paragraph IV Certifications pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 ("Sandoz's Notice

Letter"). Sandoz's Notice Letter asserted that the claims of the '036 and '991 patents are invalid, unenforceable, and/or will not be infringed by Sandoz's ANDA or the product or activities described therein.

19. Sandoz's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV certifications included in Sandoz's ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6).

20. Aurinia filed its complaint against Sandoz on May 8, 2025, alleging infringement of the '036 and '991.

21. As a consequence of the foregoing, there is an actual and justiciable controversy between Sandoz, 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 Sandoz's ANDA No. 220223 infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the '036 and '991 patents.

COUNT I
(Declaration of Noninfringement of the '036 Patent)

22. Sandoz re-alleges and incorporates the allegations of paragraphs 1-21 as if fully set forth herein.

23. Aurinia alleges ownership, title, and/or interest to the '036 patent and has brought claims against Sandoz alleging infringement of the '036 patent.

24. There is an actual, substantial, continuing, and justiciable controversy exists between Sandoz, on the one hand, and Aurinia, on the other hand, regarding, inter alia, the issue of whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '036 patent.

25. The filing of Sandoz'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.

26. The manufacture, use, or sale of Sandoz's 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.

27. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '036 patent and is not liable for any alleged infringement.

28. Sandoz incorporates by reference Sandoz's Notice Letter, which contains exemplary and nonlimiting explanations for why the '036 patent is not infringed by Sandoz's ANDA, or the Sandoz ANDA Product and/or activities described therein.

29. Sandoz is entitled to a declaration that the manufacture, use, or sale of Sandoz's Product has not, does not, and will not infringe any valid or enforceable claim of the '036 patent.

30. This case is an exceptional one, and Sandoz is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Declaration of Invalidity of the '036 Patent)

31. Sandoz re-alleges and incorporates the allegations of paragraphs 1-30 as if fully set forth herein.

32. Aurinia alleges ownership, title, and/or interest to the '036 patent and has brought claims against Sandoz alleging infringement of the '036 patent.

33. One or more of the 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 and unenforceability.

34. 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.

35. 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.

36. 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.

37. There is an actual, present, genuine, and justiciable controversy between Sandoz and Aurinia regarding, inter alia, the validity of all claims of the ’036 patent.

38. Sandoz incorporates by reference Sandoz’s Notice Letter, which contains exemplary and nonlimiting explanations for why the ’036 patent is not infringed by Sandoz’s ANDA, or the Sandoz ANDA Product and/or activities described therein.

39. Sandoz 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 and unenforceability.

40. This case is an exceptional one, and Sandoz is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
(Declaration of Noninfringement of the '991 Patent)

41. Sandoz re-alleges and incorporates the allegations of paragraphs 1-40 as if fully set forth herein.

42. Aurinia alleges ownership, title, and/or interest to the '991 patent and has brought claims against Sandoz alleging infringement of the '991 patent.

43. There is an actual, substantial, continuing, and justiciable controversy exists between Sandoz, on the one hand, and Aurinia, on the other hand, regarding, inter alia, the issue of whether the filing of Sandoz's ANDA and/or the manufacture, use, or sale in the United States of Sandoz's ANDA Product infringes, has infringed, and/or will infringe any valid or enforceable claim of the '991 patent.

44. The filing of Sandoz's ANDA has not, does not, and will not infringe any valid or enforceable claim of the '991 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

45. The manufacture, use, or sale of Sandoz's Product has not, does not, and will not infringe any valid or enforceable claim of the '991 patent, either directly or indirectly, and either literally or under the doctrine of equivalents.

46. Sandoz has not infringed, contributed to the infringement of, or induced the infringement of any valid and enforceable claim of the '991 patent and is not liable for any alleged infringement.

47. Sandoz incorporates by reference Sandoz's Notice Letter, which contains exemplary and nonlimiting explanations for why the '991 patent is not infringed by Sandoz's

ANDA, or the Sandoz ANDA Product and/or activities described therein.

48. Sandoz is entitled to a declaration that the manufacture, use, or sale of Sandoz's Product has not, does not, and will not infringe any valid or enforceable claim of the '991 patent.

49. This case is an exceptional one, and Sandoz is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT IV
(Declaration of Invalidity of the '991 Patent)

50. Sandoz re-alleges and incorporates the allegations of paragraphs 1-49 as if fully set forth herein.

51. Aurinia alleges ownership, title, and/or interest to the '991 patent and has brought claims against Sandoz alleging infringement of the '991 patent.

52. One or more of the 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 and unenforceability.

53. 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.

54. 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.

55. 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.

56. There is an actual, present, genuine, and justiciable controversy between Sandoz and Aurinia regarding, inter alia, the validity of all claims of the '991 patent.

57. Sandoz incorporates by reference Sandoz's Notice Letter, which contains exemplary and nonlimiting explanations for why the '991 patent is not infringed by Sandoz's ANDA, or the Sandoz ANDA Product and/or activities described therein.

58. Sandoz 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 and unenforceability.

59. This case is an exceptional one, and Sandoz is entitled to an award of its reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff Sandoz Inc. ("Sandoz") respectfully requests that this Court enter a Judgment and Order in its favor and against Counterclaim-Defendant Aurinia as follows:

(a) Declaring that the filing of Sandoz's ANDA has not infringed and does not infringe any valid and enforceable claim of the '036 and '991 patents;

(b) Declaring that the manufacture, use, offer to sell, sale, and/or importation in the United States of Sandoz's ANDA Product does not and will not infringe any valid and enforceable claim of the '036 and '991 patents;

(c) Declaring that all claims of the '036 and '991 patents are invalid and/or unenforceable;

(d) Awarding Sandoz its costs and expenses in this action;

(e) Declaring this an exception case in favor of Sandoz pursuant to 35 U.S.C. § 285 and awarding Sandoz its reasonable attorneys' fees; and

(f) Awarding Sandoz any further and additional relief as the Court deems just and proper.

HILL WALLACK LLP
Attorneys for Defendant,
Sandoz Inc.

By: *s/ Eric I. Abraham*
Eric I. Abraham
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Dated: July 18, 2025

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**Pro Hac Vice forthcoming*

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

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 action currently pending in this District:

- 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. TEVA PHARMACEUTICALS, INC. et al Civil Action No. 2:25-cv-03267-JKS-AME
- AURINIA PHARMACEUTICALS INC. v. DIFGEN PHARMACEUTICALS LLC Civil Action No. 2:25-cv-03533-JKS-AME
- AURINIA PHARMACEUTICALS INC. v. HIKMA PHARMACEUTICALS USA INC., Civil Action No. 2:25-cv-2580-JKS-AME
- AURINIA PHARMACEUTICALS INC. v. DR. REDDY'S LABORATORIES, INC. et al Civil Action No. 2:25-cv-03693-JKS-AME

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

s/ Eric I. Abraham
Eric I. Abraham

Dated: July 18, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Sandoz Inc., by its undersigned counsel, hereby certifies that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

s/ Eric I. Abraham
Eric I. Abraham

Dated: July 18, 2025

CERTIFICATION OF SERVICE

I certify that on July 18, 2025, a true and correct copy of the foregoing Defendant Sandoz Inc.'s Answer, Affirmative Defenses, and Counterclaims to Plaintiff's Complaint for Patent Infringement was served upon all counsel of record by notice of electronic filing and via email.

s/ Eric I. Abraham
Eric I. Abraham

Dated: July 18, 2025