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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiff, v. ZYDUS PHARMACEUTICALS (USA) INC.; ZYDUS LIFESCIENCES LTD., Defendants.	Civil Action No. 2:25-02893 (JKS)(AME) *Document Electronically Filed*

ZYDUS PHARMACEUTICALS (USA) INC. AND ZYDUS LIFESCIENCES LIMITED'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT

Defendants Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Defendants") for their Answer, Affirmative Defenses, and Counterclaims to the Complaint of Plaintiff Aurinia Pharmaceuticals Inc. ("Aurinia" or "Plaintiff"), state as follows:

All averments not expressly admitted are denied.

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 Zydus. This action relates to Abbreviated New Drug

Application ("ANDA") No. 220141 ("Voclosporin ANDA") filed by Zydus 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: The allegations in paragraph 1 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to be a civil action alleging infringement of U.S. Patent Nos. 10,286,036 ("the '036 patent") and 11,622,991 ("the '991 patent") under Title 35 of the United States Code. Defendants admit that Zydus USA submitted Abbreviated New Drug Application ("ANDA") No. 220141 to U.S. Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of voclosporin capsules, 7.9 mg described in ANDA No. 220141 ("Zydus USA's Proposed ANDA Product") in or into the United States and that ANDA No. 220141 identifies LUPKYNIS® (voclosporin) capsules, 7.9 mg (NDA No. 213716) as the Reference Listed Drug. Defendants further admit that ANDA No. 220141 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '036 and '991 patents. Defendants further admit that the '036 and '991 patents are listed in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") in connection with New Drug Application ("NDA") No. 213716 and that the Orange Book lists "LUPKYNIS" as Proprietary Name in connection with NDA No. 213716. Defendants deny all other allegations in paragraph 1.

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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore deny 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: Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 3 and therefore deny them.

4. On information and belief, Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") is a corporation organized under the laws of New Jersey, having a principal place of business at 73 Route 31 N. Pennington, New Jersey 08534.

ANSWER: Admitted.

5. On information and belief, Zydus Lifesciences Limited ("Zydus Lifesciences") is a corporation organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, Gujarat, India. On information and belief, Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. On information and belief, Zydus Lifesciences in concert with its subsidiary Zydus USA developed ANDA No. 220141.

ANSWER: Defendants admit that Zydus Lifesciences is an entity organized and existing under the laws of India, and that Zydus Lifesciences has a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382481, India. Zydus admits the allegations in the second sentence of paragraph 5. The allegations in the third sentence of paragraph 5 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 5.

6. On information and belief, Zydus 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: Defendants admit that Zydus USA sells generic pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 6.

JURISDICTION & VENUE

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

ANSWER: Defendants incorporate their answers to paragraphs 1-6, 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: The allegations in paragraph 8 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to be a civil action alleging infringement of the '036 and '991 patents under Title 35 of the United States Code. Defendants deny all other allegations in paragraph 8.

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

ANSWER: The allegations in paragraph 9 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest subject matter jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 9.

10. On information and belief, Zydus Lifesciences and its subsidiary Zydus USA hold themselves out as a unitary entity where Zydus Lifesciences 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. According to Zydus Lifesciences' 2023-2024 Annual Report, it "predominantly operates in the generics and specialty segments of the marker through its wholly-owned subsidiary Zydus Pharmaceuticals USA Inc." *Leap for Life Annual Report 2023-2024*, Zydus Lifesciences Limited, 71, https://www.zyduslife.com/investor/admin/uploads/14/2/2023-2024_1.pdf (last visited Apr. 17, 2025).

ANSWER: The allegations in paragraph 10 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences and that Zydus USA sells generic pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants further admit that page 71 of the PDF document at https://www.zyduslife.com/investor/admin/uploads/14/2/2023-2024_1.pdf (last accessed July 8, 2025) states, *inter alia*, "[t]he Company pre-dominantly operates in the generics and specialty segments of the market through its wholly-owned subsidiary Zydus Pharmaceuticals USA Inc." Defendants deny all other allegations in paragraph 10.

11. On information and belief, Zydus USA is an agent of Zydus Lifesciences and acts at the direction, and for the benefit, of Zydus Lifesciences, and is controlled and/or dominated by Zydus Lifesciences. For instance, on information and belief, Zydus USA is the U.S. Regulatory Agent for Zydus Lifesciences. Zydus USA's website explains: "Zydus Pharmaceuticals (USA) Inc. is the US generic drug division of a much larger company known as Zydus Lifesciences." *Your Life, Our Core*, Zydus Pharmaceuticals USA, https://zydususa.com/#:~:text=Zydus%20Pharmaceuticals%20(USA)%20Inc.,and%20in%20the%20United%20States (last visited Apr. 17, 2025).

ANSWER: The allegations in paragraph 11 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences and that Zydus USA sells generic pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants further admit that Zydus USA's website states, *inter alia*, that Zydus USA "is the US generic drug division of a much larger company known as Zydus Lifesciences." *See* https://zydususa.com (last accessed July 8, 2025). Defendants deny all other allegations in paragraph 11.

12. This Court has personal jurisdiction over Zydus USA.

ANSWER: The allegations in paragraph 12 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 12.

13. On information and belief, Zydus USA directly and/or indirectly through, and/or in concert with Zydus Lifesciences, has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 220141 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, Zydus USA directly and/or indirectly through, and/or in concert with Zydus Lifesciences, 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, Zydus USA directly and/or indirectly through, and/or in concert with Zydus Lifesciences, 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: The allegations in paragraph 13 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first sentence of paragraph 13. Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in the third sentence of paragraph 13 and therefore deny them. Defendants deny all other allegations in paragraph 13.

14. On information and belief, Zydus USA has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Zydus USA maintains a regular and established, physical place of business in the District of New Jersey, at 73 Route 31 N. Pennington, New Jersey 08534. On information and belief, Zydus USA actively contracts with, *inter alia*, Zydus Lifesciences, 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: The allegations in paragraph 14 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants further admit that Zydus USA sells generic pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 14.

15. Further, on information and belief, Zydus USA directly and/or indirectly through, and/or in concert with Zydus Lifesciences, 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, Zydus USA 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. 0100915422. On information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003171.

ANSWER: The allegations in paragraph 15 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA sells generic pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants further admit that the State of New Jersey Division of Revenue and Enterprise Services Business Name Search lists "ZYDUS PHARMACEUTICALS (USA) INC." in connection with Entity ID No. 0100915422. Defendants further admit that the State of New Jersey's Department of Health lists "ZYDUS PHARMACEUTICALS USA INC" in connection with Registration No. 5003171 as "Wholesale." Defendants deny all other allegations in paragraph 15.

16. On information and belief, Zydus USA 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: *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10629; *Genentech, Inc. et al v. Natco Pharma Limited et al*, Civil Action No. 24-10567; *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10458; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10240; *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9748; *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9512; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-9110; *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 24-7812; *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-4603; *Fresenius Kabi USA, LLC v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 22-1702; *Almirall, LLC v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 20-343.

ANSWER: The allegations in paragraph 16 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA admits that it asserted counterclaims in this Court in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al,* C.A. No. 3:24-cv-10629-RK-TJB (D.N.J.); *Genentech, Inc. et al v. Natco Pharma Limited et al*, C.A. No. 2:24-cv-10567-BRM-JSA (D.N.J.); *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-10458-RK-TJB (D.N.J.); *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, C.A. No. 3:24-cv-04264-MAS-JBD (consolidated); *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-09748-MAS-RLS (D.N.J.); *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:24-cv-09512-ESK-AMD (D.N.J.); *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, C.A. No. 3:24-cv-09110-RK-RLS (D.N.J.); *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 2:24-cv-07812-BRM-CLW (D.N.J.); *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-04603-ZNQ-JBD (D.N.J.); *Fresenius Kabi USA, LLC v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 3:22-cv-01702-GC-RLS (D.N.J.); *Almirall, LLC v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:20-cv-00343-FLW-DEA (D.N.J.). Defendants deny all other allegations in paragraph 16.

17. On information and belief, Zydus USA has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See e.g., AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10629; *Genentech, Inc. et al v. Natco Pharma Limited et al*, Civil Action No. 24-10567; *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10458; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10240; *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9748; *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9512; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-9110; *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 24-7812; *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-4603; *Fresenius Kabi USA, LLC v. Zydus Pharmaceuticals (USA) Inc.*, Civil Action No. 22-1702; *Almirall, LLC v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 20-343.

ANSWER: The allegations in paragraph 17 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that: in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al,* C.A. No. 3:24-cv-10629-RK-TJB (D.N.J.), D.I. 11 at ¶¶ 17-20, 22, Defendants stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Genentech, Inc. et al v. Natco Pharma Limited et al*, C.A. No. 2:24-cv-10567-BRM-JSA (D.N.J.), D.I. 30 at ¶ 29, Defendants stated that "Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product"; in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-10458-RK-TJB (D.N.J.), D.I. 12 at ¶¶ 17-20, 22, Defendants stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, C.A. No. 3:24-cv-04264-MAS-JBD (D.N.J.) (consolidated), D.I. 89 at ¶ 19, Defendants stated that "Zydus USA does

not contest personal jurisdiction in this Court for the sole and limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-09748-MAS-RLS (D.N.J.), D.I. 22 at ¶ 17, Defendants stated that "Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217322"; in *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:24-cv-09512-ESK-AMD (D.N.J.), D.I. 33 at ¶ 14, Defendants stated that "Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, C.A. No. 3:24-cv-09110-RK-RLS (D.N.J.), D.I. 52 at ¶¶ 75-76, Defendants stated that "Zydus USA does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *American Regent, Inc. v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No. 2:24-cv-07812-BRM-CLW (D.N.J.), D.I. 9 at ¶¶ 5-7, 12-13, Zydus USA stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's alleged claims against Zydus in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product described in ANDA No. 219322"; in *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-04603-ZNQ-JBD (D.N.J.), D.I. 24 at ¶ 16, Defendants stated that "Zydus USA do not content personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product"; in *Fresenius Kabi USA, LLC v. Zydus Pharmaceuticals (USA) Inc.*, C.A. No.

3:22-cv-01702-GC-RLS (D.N.J.), D.I. 14 at ¶¶ 6-7, Zydus USA stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Products described in ANDA No. 217066"; and in *Almirall, LLC v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:20-cv-00343-FLW-DEA (D.N.J.), D.I. 28 at ¶ 161, Zydus USA stated that "Zydus USA does not contest personal jurisdiction in this Court solely for purposes of Plaintiff's claims against Zydus USA in this case and solely as 4 they apply to the dapsone gel, 7.5% that is the subject of ANDA No. 214019." Defendants deny all other allegations in paragraph 17.

18. This Court has personal jurisdiction over Zydus Lifesciences.

ANSWER: The allegations in paragraph 18 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 18.

19. On information and belief, Zydus Lifesciences directly and/or indirectly through, and/or in concert with Zydus USA, has committed an act of infringement in this judicial district by preparing, aiding in the preparation, and/or filing ANDA No. 220141 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, Zydus Lifesciences directly and/or indirectly through, and/or in concert with Zydus USA, 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, Zydus Lifesciences directly and/or indirectly through, and/or in concert with Zydus USA, 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: The allegations in paragraph 19 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants deny the allegations in the first

sentence of paragraph 19. Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants lack knowledge or information sufficient to form a belief about the truth of the allegations in the third sentence of paragraph 19 and therefore deny them. Defendants deny all other allegations in paragraph 19.

20. On information and belief, Zydus Lifesciences has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Zydus Lifesciences directly and/or indirectly through, and/or in concert with Zydus USA, operates a facility in the District of New Jersey, at 73 Route 31 N. Pennington, New Jersey 08534. On information and belief, Zydus Lifesciences actively contracts with, *inter alia*, Zydus USA, 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: The allegations in paragraph 20 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences and is a corporation organized and existing under the laws of the State of New Jersey, having its principal place of business at 73 Route 31 North, Pennington, New Jersey 08534. Defendants further admit that Zydus USA sells generic pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants deny all other allegations in paragraph 20.

21. Further, on information and belief, Zydus Lifesciences directly and/or indirectly through, and/or in concert with Zydus USA, 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, Zydus USA 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. 0100915422. On information and belief, Zydus USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5003171.

ANSWER: The allegations in paragraph 21 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA sells generic

pharmaceutical products, including generic pharmaceutical products manufactured by Zydus Lifesciences, in the United States. Defendants further admit that the State of New Jersey Division of Revenue and Enterprise Services Business Name Search lists "ZYDUS PHARMACEUTICALS (USA) INC." in connection with Entity ID No. 0100915422. Defendants further admit that the State of New Jersey's Department of Health lists "ZYDUS PHARMACEUTICALS USA INC" in connection with Registration No. 5003171 as "Wholesale." Defendants deny all other allegations in paragraph 21.

22. In the alternative, this Court has jurisdiction over Zydus Lifesciences pursuant to Fed. R. Civ. P. 4(k)(2) because, *inter alia*, (a) Aurinia's claims arise under federal law; (b) Zydus Lifesciences is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Zydus Lifesciences 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 Zydus Lifesciences satisfies due process.

ANSWER: The allegations in paragraph 22 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that the Complaint purports to be a civil action alleging infringement of the '036 and '991 patents under Title 35 of the United States Code. Defendants further admit that Zydus Lifesciences is an entity organized and existing under the laws of India. Defendants further admit that Zydus Lifesciences manufactures pharmaceutical products, including generic pharmaceutical products sold in the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 22.

23. On information and belief, Zydus Lifesciences 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: *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10629; *Genentech, Inc. et al v. Natco Pharma Limited et al*, Civil Action No. 24-10567; *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10458; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals*

(USA) Inc. et al, Civil Action No. 24-10240; *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9748; *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9512; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-9110; *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-4603.

ANSWER: The allegations in paragraph 23 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences admits that it asserted counterclaims in this Court in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al,* C.A. No. 3:24-cv-10629-RK-TJB (D.N.J.); *Genentech, Inc. et al v. Natco Pharma Limited et al*, C.A. No. 2:24-cv-10567-BRM-JSA (D. N.J.); *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-10458-RK-TJB (D.N.J.); *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, C.A. No. 3:24-cv-04264-MAS-JBD (consolidated); *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-09748-MAS-RLS (D.N.J.); *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:24-cv-09512-ESK-AMD (D.N.J.); *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, C.A. No. 3:24-cv-09110-RK-RLS (D.N.J.); *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-04603-ZNQ-JBD (D.N.J.). Defendants deny all other allegations in paragraph 23.

24. On information and belief, Zydus Lifesciences has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See e.g.*, *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10629; *Genentech, Inc. et al v. Natco Pharma Limited et al*, Civil Action No. 24-10567; *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10458; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10240; *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9748; *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9512; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-9110; *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-4603.

ANSWER: The allegations in paragraph 24 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest personal

jurisdiction in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that: in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-10629-RK-TJB (D.N.J.), D.I. 11 at ¶¶ 17-20, 22, Defendants stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Genentech, Inc. et al v. Natco Pharma Limited et al*, C.A. No. 2:24-cv-10567-BRM-JSA (D.N.J.), D.I. 30 at ¶ 23, Defendants stated that "Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences and solely as they apply to the Proposed ANDA Product"; in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-10458-RK-TJB (D.N.J.), D.I. 12 at ¶¶ 17-20, 22, Defendants stated that "Zydus does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, C.A. No. 3:24-cv-04264-MAS-JBD (D.N.J.) (consolidated), D.I. 89 at ¶ 18, Defendants stated that "Zydus Lifesciences does not contest personal jurisdiction in this Court for the sole and limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-09748-MAS-RLS (D.N.J.), D.I. 22 at ¶ 19, Defendants stated that "Zydus Lifesciences does not contest personal jurisdiction in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217322"; in *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:24-cv-

09512-ESK-AMD (D.N.J.), D.I. 33 at ¶ 15, Defendants stated that "Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, C.A. No. 3:24-cv-09110-RK-RLS (D.N.J.), D.I. 52 at ¶ 79, Defendants stated "Zydus Lifesciences does not contest personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product"; and in *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-04603-ZNQ-JBD (D.N.J.), D.I. 24 at ¶ 17, Defendants stated that "Defendants do not content personal jurisdiction in this Court solely for the limited purpose of Plaintiffs' claims against Defendants in this case and solely as those alleged claims apply to Zydus's Proposed ANDA Product." Defendants deny all other allegations in paragraph 24.

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

ANSWER: The allegations in paragraph 25 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 25.

26. On information and belief, venue is proper against Zydus USA 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: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus USA does not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Zydus USA in this case and solely as

they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus USA maintains its principal place of business in the State of New Jersey. Defendants deny all other allegations in paragraph 26.

27. Venue is proper in the District of New Jersey for Zydus Lifesciences because it is an Indian 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: The allegations in paragraph 27 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus Lifesciences does not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that Zydus Lifesciences is an entity organized and existing under the laws of India. Defendants deny all other allegations in paragraph 27.

28. Zydus did not contest venue in this judicial district in at least the following actions: *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10629; *Genentech, Inc. et al v. Natco Pharma Limited et al*, Civil Action No. 24-10567; *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10458; *Intra-Cellular Therapies, Inc. v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-10240; *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9748; *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-9512; *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, Civil Action No. 24-9110; *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, Civil Action No. 24-4603;.

ANSWER: The allegations in paragraph 28 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants do not contest venue in this Court solely for the limited purpose of Plaintiff's claims against Defendants in this case and solely as they apply to Zydus USA's Proposed ANDA Product. Defendants admit that: in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al,* C.A. No. 3:24-cv-10629-RK-TJB (D.N.J.), D.I. 11 at ¶ 26, Defendants stated that "Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as

they apply to Zydus's Proposed ANDA Product"; in *Genentech, Inc. et al v. Natco Pharma Limited et al*, C.A. No. 2:24-cv-10567-BRM-JSA (D.N.J.), D.I. 30 at ¶¶ 36-37, Defendants stated that "[Zydus Lifesciences does] not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against [Zydus Lifesciences] and solely as they apply to the Proposed ANDA Product" and "Zydus USA does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA and solely as they apply to the Proposed ANDA Product"; in *AstraZeneca Pharmaceuticals LP et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-10458-RK-TJB (D.N.J.), D.I. 24 at ¶ 26, Defendants stated that "Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Intra-Cellular Therapies, Inc. v. Aurobindo Pharma Ltd. et al*, C.A. No. 3:24-cv-04264-MAS-JBD (D.N.J) (consolidated), D.I. 89 at ¶¶ 22-23, Defendants stated that "Defendants do not contest venue in this Court for the sole and limited purpose of Plaintiff's claims against Zydus USA in this case and solely as they apply to Zydus's Proposed ANDA Product" and "Defendants do not contest venue in this Court for the sole and limited purpose of Plaintiff's claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Astellas Pharma Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-09748-MAS-RLS (D.N.J.), D.I. 22 at ¶ 20, Defendants stated that "Zydus does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to Zydus's Proposed ANDA Product described in ANDA No. 217322"; in *Salix Pharmaceuticals, Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 1:24-cv-09512-ESK-AMD (D.N.J.) D.I. 33 at ¶¶ 18-19, Defendants stated that "Zydus USA does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus USA in this case and solely as they apply to Zydus's Proposed

ANDA Product" and "Zydus Lifesciences does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus Lifesciences in this case and solely as they apply to Zydus's Proposed ANDA Product"; in *Jazz Pharmaceuticals Ireland Limited et al v. Sandoz Inc. et al*, C.A. No. 3:24-cv-09110-RK-RLS (D.N.J.), D.I. 52 at ¶ 80, Defendants stated that "Zydus does not contest venue in this Court solely for the limited purpose of Plaintiffs' claims against Zydus and solely as they apply to Zydus's Proposed ANDA Product"; and in *AbbVie Inc. et al v. Zydus Pharmaceuticals (USA) Inc. et al*, C.A. No. 3:24-cv-04603-ZNQ-JBD (D.N.J.), D.I. 24 at ¶¶ 33-34, Defendants stated that "Zydus USA does not contest venue in this judicial district solely for the limited purpose of Plaintiffs' alleged claims arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus USA and solely as those alleged claims apply to Zydus's Proposed ANDA Product" and "Zydus Lifesciences does not contest venue in this Court solely for purposes of Plaintiffs' claims against Zydus Lifesciences in this case arising under 28 U.S.C. §§ 1391 and 1400(b) against Zydus Lifesciences and solely as they apply to Zydus's Proposed ANDA Products." Defendants deny all other allegations in paragraph 28.

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: The allegations in paragraph 29 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of the '036 patent is attached to the Plaintiff's Complaint as Exhibit 1. Defendants further admit that Exhibit 1 is titled "Protocol for the Treatment of Lupus Nephritis" and lists May 14, 2019, as Date of Patent. Defendants further admit that according to the United States Patent and Trademark Office's Patent Assignment Search database, "Aurinia

Pharmaceuticals Inc." is listed as the current assignee of the '036 patent under Reel No. 045117, Frame No. 0172. Defendants deny the allegations in the third sentence of paragraph 29. Defendants deny all other allegations in paragraph 29.

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: The allegations in paragraph 30 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit on information and belief that what purports to be a copy of the '991 patent is attached to the Plaintiff's Complaint as Exhibit 2. Defendants further admit that Exhibit 2 is titled "Protocol for the Treatment of Lupus Nephritis" and lists April 11, 2023, as Date of Patent. Defendants further admit that according to the United States Patent and Trademark Office's Patent Assignment Search database, "Aurinia Pharmaceuticals Inc." is listed as the current assignee of the '991 patent under Reel No. 060742, Frame No. 0521. Defendants deny the allegations in the third sentence of paragraph 30. Defendants deny all other allegations in paragraph 30.

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.

ANSWER: Defendants admit that FDA's Orange Book lists "LUPKYNIS" as Proprietary Name, "AURINIA PHARMACEUTICALS INC" as Applicant Holder, "CAPSULE; ORAL" as Dosage Form and Route of Administration, and "Jan 22, 2021" as Approval Date in connection with NDA No. 213716. Defendants deny all other allegations in paragraph 31.

ZYDUS' INFRINGING ACTIVITIES

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

ANSWER: Defendants incorporate their answers to paragraphs 1-31, as if fully set forth herein.

33. By letter dated March 7, 2025, addressed to Aurinia ("Notice Letter"), Zydus notified Aurinia that Zydus 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: Defendants admit that Zydus USA transmitted a letter dated March 7, 2025 ("Zydus USA's Notice Letter") to Aurinia notifying Aurinia that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants deny all other allegations in paragraph 33.

34. The Notice Letter states that Zydus 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 Zydus' generic voclosporin products that are the same, or substantially the same, as Aurinia's LUPKYNIS®.

ANSWER: The allegations in paragraph 34 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA transmitted Zydus USA's Notice Letter dated March 7, 2025 to Aurinia notifying Aurinia that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States and that ANDA No. 220141 includes a Paragraph IV Certification with respect to the '036 and '991 patents. Defendants further admit that ANDA No. 220141 identifies LUPKYNIS® (voclosporin) capsules, 7.9 mg (NDA No. 213716) as the Reference Listed Drug. Defendants deny all other allegations in paragraph 34.

35. On information and belief, Zydus, 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: The allegations in paragraph 35 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 35.

36. On information and belief, if the FDA approves Zydus' Voclosporin ANDA, Zydus, 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: The allegations in paragraph 36 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 36.

37. In the Notice Letter, Zydus 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 Zydus' generic voclosporin product.

ANSWER: Defendants admit that Zydus USA transmitted Zydus USA's Notice Letter dated March 7, 2025 to Aurinia notifying Aurinia that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States and that ANDA No. 220141 includes a Paragraph IV Certification with respect to

the ’036 and ’991 patents. Defendants further admit that Zydus USA’s Notice Letter states in part that “Zydus has certified that, in the opinion of Zydus and to the best of its knowledge, the importation, manufacture, use, sale of, or offer to sell within the United States of [Zydus’s Proposed ANDA Product] will not infringe any valid and enforceable claim of the ’036 and ’991 patents.” Defendants deny all other allegations in paragraph 37.

38. Upon information and belief, Zydus’ actions related to the Voclosporin ANDA complained of herein were done at the direction of, with the authorization of, or with the cooperation, the participation, the assistance of, or at least in part for the benefit of Zydus USA, and Zydus Lifesciences.

ANSWER: The allegations in paragraph 38 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA’s Proposed ANDA Product in or into the United States. Defendants further admit that ANDA No. 220141 identifies Zydus Lifesciences as the manufacturer of Zydus USA’s Proposed ANDA Product. Defendants further admit that Zydus USA is a wholly owned subsidiary of Zydus Lifesciences. Defendants deny all other allegations in paragraph 38.

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

ANSWER: Defendants admit, on information and belief, that Aurinia received Zydus USA’s Notice Letter on March 10, 2025. Defendants further admit that Plaintiff’s Complaint was filed on April 21, 2025. Defendants deny all other allegations in paragraph 39.

COUNT I
INFRINGEMENT OF THE ’036 PATENT

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

ANSWER: Defendants incorporate their answers to paragraphs 1-39, as if fully set forth herein.

41. Zydus' 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: Denied.

42. On information and belief, Zydus 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: Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States and that ANDA No. 220141 includes a Paragraph IV Certification with respect to the '036 and '991 patents, which states that pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4), Zydus USA certifies that the '036 and '991 patents are invalid, unenforceable, or will not be infringed by the manufacture, use or sale of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 42.

43. On information and belief, Zydus had actual knowledge of the '036 patent at least since its filing of its Voclosporin ANDA and at least since March 7, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: The allegations in paragraph 43 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA transmitted Zydus USA's Notice Letter dated March 7, 2025 to Aurinia notifying Aurinia that Zydus USA submitted ANDA No. 220141 to FDA to obtain approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the

United States and that ANDA No. 220141 includes a Paragraph IV Certification with respect to the ’036 and ’991 patents. Defendants deny all other allegations in paragraph 43.

44. On information and belief, Zydus concedes infringement of at least one claim of the ’036 patent because Zydus’ Notice Letter did not provide any specific non-infringement allegations.

ANSWER: Denied.

45. On information and belief, Zydus’ generic voclosporin products will, if approved and marketed, infringe at least one claim of the ’036 patent.

ANSWER: Denied.

46. On information and belief, Zydus knows, should know, and intends that physicians will prescribe, and patients will take, Zydus’ 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: Denied.

47. On information and belief, Zydus has knowledge of the ’036 patent and, by its proposed package insert for Zydus’ 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: Denied.

48. On information and belief, Zydus 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 Zydus’ 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: Denied.

49. On information and belief, Zydus 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: Denied.

50. On information and belief, Zydus has had and continues to have knowledge that Zydus’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: Denied.

51. On information and belief, upon FDA approval of Zydus' Voclosporin ANDA, Zydus 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: Denied.

52. If Zydus' 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: Denied.

COUNT II
INFRINGEMENT OF THE '991 PATENT

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

ANSWER: Defendants incorporate their answers to paragraphs 1-52, as if fully set forth herein.

54. Zydus' 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: Denied.

55. On information and belief, Zydus 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: Defendants admit that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States and that ANDA No. 220141 includes a Paragraph IV Certification with respect to the '036 and '991 patents, which states that pursuant to 21 C.F.R. § 314.94(a)(12)(i)(A)(4), Zydus USA certifies that the '036 and '991 patents are invalid, unenforceable, or will not be infringed by

the manufacture, use or sale of Zydus USA's Proposed ANDA Product. Defendants deny all other allegations in paragraph 55.

56. On information and belief, Zydus had actual knowledge of the '991 patent at least since its filing of its Voclosporin ANDA and at least since March 7, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: The allegations in paragraph 56 state legal conclusions to which no answer is required. To the extent an answer is required, Defendants admit that Zydus USA transmitted Zydus USA's Notice Letter dated March 7, 2025 to Aurinia notifying Aurinia that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States and that ANDA No. 220141 includes a Paragraph IV Certification with respect to the '036 and '991 patents. Defendants deny all other allegations in paragraph 56.

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

ANSWER: Denied.

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

ANSWER: Denied.

59. On information and belief, Zydus knows, should know, and intends that physicians will prescribe, and patients will take, Zydus' 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: Denied.

60. On information and belief, Zydus has knowledge of the '991 patent and, by its proposed package insert for Zydus' 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: Denied.

61. On information and belief, Zydus 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 Zydus' 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: Denied.

62. On information and belief, Zydus 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: Denied.

63. On information and belief, Zydus has had and continues to have knowledge that Zydus'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: Denied.

64. On information and belief, upon FDA approval of Zydus' Voclosporin ANDA, Zydus 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: Denied.

65. If Zydus' 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: Denied.

PRAYER FOR RELIEF

Defendants specifically deny that Plaintiff is entitled to the general or specific relief requested against Defendants, or to any relief whatsoever, and pray for judgment in favor of Defendants dismissing this action with prejudice, and awarding Defendants their reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in their Answer and without admitting any allegations of the Complaint not otherwise admitted, Defendants aver and assert the following Affirmative Defenses to Plaintiff's Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,286,036)

Plaintiff will not and cannot meet the burden of proof required to show that the submission of Zydus USA's ANDA No. 220141 and/or the commercial importation, manufacture, use, offer to sell, and/or sale of Zydus USA's Proposed ANDA Product in or into the United States will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '036 patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,286,036)

Upon information and belief, the claims of the '036 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 11,622,991)

Plaintiff will not and cannot meet the burden of proof required to show that the submission of Zydus USA's ANDA No. 220141 and/or the commercial importation, manufacture, use, offer to sell, and/or sale of Zydus USA's Proposed ANDA Product in or into the United States will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '991 patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 11,622,991)

Upon information and belief, the claims of the '991 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or obviousness-type double patenting.

RESERVATION OF DEFENSES

Defendants hereby reserve any and all defenses that are available under the Federal Rules of Civil Procedure and the U.S. Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this litigation.

COUNTERCLAIMS

Zydus Pharmaceuticals (USA) Inc. ("Zydus USA"), and Zydus Lifesciences Limited ("Zydus Lifesciences") (collectively, "Counterclaim Plaintiffs"), by their attorneys, allege the following counterclaims against Plaintiff/Counterclaim Defendant Aurinia Pharmaceuticals, Inc. ("Aurinia" or "Counterclaim Defendant").

PARTIES

1. Zydus USA is a corporation organized and existing under the laws of the State of New Jersey with its primary place of business at 73 Route 31 North, Pennington, New Jersey 08534.

2. Zydus Lifesciences is an entity organized and existing under the laws of India, having a principal place of business at Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Nr. Vaishnodevi Circle, S.G. Highway, Ahmedabad 382 481, India.

3. Upon 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.

JURISDICTION AND VENUE

4. This Court has jurisdiction over the subject matter of these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202, 35 U.S.C. § 1 *et seq.*, 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5).

5. This Court has personal jurisdiction over Counterclaim Defendant because Counterclaim Defendant commenced and continues to maintain this action against Counterclaim Plaintiffs in this judicial district.

6. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), 21 U.S.C. § 355(j)(5)(C)(i)(II), and because Counterclaim Defendant commenced and continues to maintain this action against Counterclaim Plaintiffs in this judicial district.

REGULATORY FRAMEWORK

7. Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271) (the "Hatch-Waxman Act"), and the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. No. 108-173, 117 Stat. 2066 (2003) (codified as amended at 21 U.S.C. § 355 and 35 U.S.C. § 271), a pharmaceutical company seeking approval from the U.S. Food and Drug Administration ("FDA") to sell a new drug must file a New Drug Application ("NDA"), which includes specific data concerning the safety and effectiveness of the drug referenced in the NDA, i.e., the reference-listed drug or RLD.

8. The Hatch-Waxman Act provides that NDA holders shall submit to FDA the patent number and expiration date of any patent that the NDA holder believes "claims the drug for which the applicant submitted the [NDA] . . . and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the [NDA] owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. § 355(b)(1). FDA lists the patent number(s) and expiration date(s) in its publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book").

ORANGE-BOOK-LISTED PATENTS FOR LUPKYNIS®

9. Upon information and belief, Aurinia is the holder of NDA No. 213716 on LUPKYNIS® (voclosporin) capsules, 7.9 mg.

10. United States Patent No. 10,286,036 ("the '036 patent"), titled "Protocol for Treatment of Lupus Nephritis"—a copy of which Counterclaim Defendant purported to attach to the Complaint as Exhibit 1—was issued on May 14, 2019. According to the United States Patent and Trademark Office's Patent Assignment Search database, under Reel No. 045117, Frame No. 0172, the '036 patent is assigned to "Aurinia Pharmaceuticals Inc." FDA's Orange Book lists the expiration date of the '036 patent as December 7, 2037.

11. Upon information and belief, Aurinia submitted on February 11, 2021, the '036 patent to FDA for listing in the Orange Book with respect to NDA No. 213716 on LUPKYNIS® (voclosporin) capsules, 7.9 mg. Accordingly, Aurinia maintains and has affirmatively represented that the '036 patent claims the approved drug LUPKYNIS® (voclosporin) or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell voclosporin capsules before the expiration of the '036 patent has a reasonable apprehension of suit with respect to the '036 patent.

12. United States Patent No. 11,622,991 ("the '991 patent"), titled "Protocol for Treatment of Lupus Nephritis"—a copy of which Counterclaim Defendant purported to attach to the Complaint as Exhibit 2—was issued on April 11, 2023. According to the United States Patent and Trademark Office's Patent Assignment Search database, under Reel No. 060742, Frame No. 0521, the '991 patent is assigned to "Aurinia Pharmaceuticals Inc." FDA's Orange Book lists the expiration date of the '991 patent as December 7, 2037.

13. Upon information and belief, Aurinia submitted on May 5, 2023, the '991 patent to FDA for listing in the Orange Book with respect to NDA No. 213716 on LUPKYNIS® (voclosporin) capsules, 7.9 mg. Accordingly, Aurinia maintains and has affirmatively represented that the '991 patent claims the approved drug LUPKYNIS® (voclosporin) or a method of using that drug. Therefore, any ANDA applicant, including Zydus USA, attempting to sell voclosporin capsules before the expiration of the '991 patent has a reasonable apprehension of suit with respect to the '991 patent.

ZYDUS USA'S ANDA

14. On January 22, 2025, Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of voclosporin capsules, 7.9 mg ("Zydus USA's Proposed ANDA Product").

15. Because Zydus USA seeks FDA approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product described in ANDA No. 220141 in or into the United States before the expiration of the '036 and '991 patents, ANDA No. 220141 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '036 and '991 patents.

16. Zydus USA sent a letter dated March 7, 2025, notifying Aurinia that Zydus USA submitted ANDA No. 220141 to FDA under 21 U.S.C. § 355(j), seeking approval to engage in the commercial importation, manufacture, use, offer to sell, or sale of Zydus USA's Proposed ANDA Product in or into the United States, and that ANDA No. 220141 includes a Paragraph IV Certification with respect to the '036 and '991 patents ("Zydus USA's Notice Letter").

17. Zydus USA's Notice Letter includes a detailed statement of the factual and legal bases in support of Zydus USA's Paragraph IV Certification for the '036 and '991 patents.

COUNT I
(Declaratory Judgment of Noninfringement of U.S. Patent No. 10,286,036)

18. Counterclaim Plaintiffs repeat and reallege the allegations in paragraphs 1-17 above as though fully set forth herein.

19. By asserting its claim against Counterclaim Plaintiffs for infringement of the '036 patent, Counterclaim Defendant has created a case or controversy regarding the noninfringement of the '036 patent.

20. The commercial importation, manufacture, use, offer to sell, or sale in the United States of Zydus USA's Proposed ANDA Product that is the subject of ANDA No. 220141 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '036 patent.

COUNT II
(Declaratory Judgment of Invalidity of U.S. Patent No. 10,286,036)

21. Counterclaim Plaintiffs repeat and reallege the allegations in paragraphs 1-20 above as though fully set forth herein.

22. By asserting its claim against Counterclaim Plaintiffs for infringement of the '036 patent, Counterclaim Defendant has created a case or controversy regarding the validity of the '036 patent for failure to comply with one or more of the provisions of Title 35 of the United States

Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

23. The claims of the '036 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

COUNT III
(Declaratory Judgment of Noninfringement of U.S. Patent No. 11,622,991)

24. Counterclaim Plaintiffs repeat and reallege the allegations in paragraphs 1-23 above as though fully set forth herein.

25. By asserting its claim against Counterclaim Plaintiffs for infringement of the '991 patent, Counterclaim Defendant has created a case or controversy regarding the noninfringement of the '991 patent.

26. The commercial importation, manufacture, use, offer to sell, or sale in the United States of Zydus USA's Proposed ANDA Product that is the subject of ANDA No. 220141 would not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '991 patent.

COUNT IV
(Declaratory Judgment of Invalidity of U.S. Patent No. 11,622,991)

27. Counterclaim Plaintiffs repeat and reallege the allegations in paragraphs 1-26 above as though fully set forth herein.

28. By asserting its claim against Counterclaim Plaintiffs for infringement of the '991 patent, Counterclaim Defendant has created a case or controversy regarding the validity of the '991 patent for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting.

29. The claims of the '991 patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, 112, and/or obviousness-type double patenting.

PRAYER FOR RELIEF

WHEREFORE, Counterclaim Plaintiffs respectfully request that the Court enter judgment against Counterclaim Defendant as follows:

A. A declaration that Counterclaim Plaintiffs have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '036 patent;

B. A declaration that the claims of the '036 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

C. A declaration that Counterclaim Plaintiffs have not and will not directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '991 patent;

D. A declaration that the claims of the '991 patent are invalid for failure to comply with one or more of the provisions of 35 U.S.C. §§ 100 *et seq.*, including §§ 101, 102, 103 and/or 112, and/or obviousness-type double patenting;

E. A declaration that Counterclaim Defendant take nothing by its Complaint;

F. A dismissal of Counterclaim Defendant's Complaint with prejudice;

G. An award to Counterclaim Plaintiffs of their reasonable costs and attorneys' fees incurred in this action pursuant to 35 U.S.C. § 285; and

H. An award of any other and further relief that this Court may deem just and proper.

Dated: July 8, 2025

By: *s/ Theodora McCormick*

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Attorneys for Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding, except that the same Plaintiff has asserted at least some of the patents-in-suit in this case in the following pending matters in this Judicial District: *Aurinia Pharmaceuticals Inc. v. Sandoz Inc.*, C.A. No. 2:25-cv-03986-JKS-AME (D.N.J.); *Aurinia Pharmaceuticals Inc. v. Dr. Reddy's Laboratories, Inc. et al.*, C.A. No. 2:25-cv-03693-JKS-AME (D.N.J.); *Aurinia Pharmaceuticals Inc. v. DifGen Pharmaceuticals LLC*, C.A. No. 2:25-cv-03533-JKS-AME (D.N.J.); *Aurinia Pharmaceuticals Inc. v. Teva Pharmaceuticals, Inc. et al.*, C.A. No. 2:25-cv-03267-JKS-AME (D.N.J.); *Aurinia Pharmaceuticals Inc. v. Galenicum Health S.L.U.*, C.A. No. 2:25-cv-02807-JKS-AME (D.N.J.); *Aurinia Pharmaceuticals Inc. v. Lotus Pharmaceutical Co., Ltd.*, C.A. No. 2:25-cv-02613-JKS-AME (D.N.J.); and *Aurinia Pharmaceuticals Inc. v. Hikma Pharmaceuticals USA Inc.*, C.A. No. 2:25-cv-02580-JKS-AME (D.N.J.). Defendants are not aware of any other action pending in any court or any pending arbitration or administrative proceeding related to this matter.

Dated: July 8, 2025

By: *s/ Theodora McCormick*
Theodora McCormick

LOCAL CIVIL RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the parties seek, *inter alia*, declaratory relief in their respective pleadings.

I hereby certify under penalty of perjury that the foregoing is true and correct.

Dated: July 8, 2025

By: *s/ Theodora McCormick*
Theodora McCormick

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Zydus Pharmaceuticals (USA) Inc. and Zydus Lifesciences Limited's answer, affirmative defenses, and counterclaims to Plaintiff's complaint was filed via ECF and served on all counsel of record by electronic mail on July 8, 2025.

Dated: July 8, 2025

By: *s/ Theodora McCormick*
Theodora McCormick