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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiffs, v. HIKMA PHARMACEUTICALS USA INC., Defendants.	Honorable Jamel K. Semper, U.S.D.J. Civil Action No. 25 CV 2580 (JKS)(AME) **DEFENDANT HIKMA PHARMACEUTICALS USA INC.'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT FOR PATENT INFRINGEMENT**

Defendant Hikma Pharmaceuticals USA Inc. ("Hikma"), 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"). Pursuant to Fed. R. Civ. P. 8(b)(3), Hikma denies all allegations in Plaintiff's Complaint except those admitted specifically below. This pleading is based upon Hikma'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 Hikma. This action relates to Abbreviated New Drug Application ("ANDA") No. 219663 ("Voclosporin ANDA") filed by Hikma 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, Hikma 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. Hikma further admits that Hikma filed ANDA No. 219663 with the United States Food and Drug Administration ("FDA) seeking approval to market and sell voclosporin capsules, 7.9 mg ("Hikma'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"). Hikma 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®. Hikma 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: Hikma 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: Hikma 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, Hikma is a corporation organized under the laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

ANSWER: Hikma admits that Hikma is a corporation organized and existing under the laws of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

5. On information and belief, Hikma 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, Hikma admits that it seeks regulatory approval of and sells generic products in the United States. Hikma 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: Hikma 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, Hikma 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. Hikma 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, Hikma does not contest subject matter jurisdiction for purposes of this case only. Hikma denies the remaining allegations in this paragraph.

9. This Court has personal jurisdiction over Hikma.

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

10. On information and belief, Hikma 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. 219663 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, Hikma 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, Hikma 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, Hikma 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. Hikma denies the remaining allegations in this paragraph.

11. On information and belief, Hikma has engaged in systematic and continuous business contacts within the State of New Jersey. For instance, on information and belief, Hikma maintains a regular and established, physical place of business in the District of New Jersey, at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922. On information and belief, Hikma 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, Hikma 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. Hikma denies the remaining allegations in this paragraph.

12. Further, on information and belief, Hikma 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, Hikma 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. 0100487525. On information and belief, Hikma is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5002130.

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

13. On information and belief, Hikma 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: *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-11118 (D.N.J.); *Axsome Malta Ltd. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-10620 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories Ltd.*, Civil Action No. 24-9209 (D.N.J.); *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-7803 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories, Ltd.*, Civil Action No. 24-4608 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories Ltd.*, Civil Action No. 23-20354 (D.N.J.); *Janssen Pharmaceuticals, Inc. v. Hikma Pharmaceuticals USA, Inc.*, Civil Action No. 23-2942 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21-10398 (D.N.J.); *Corcept Therapeutics, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21-5034 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals International Ltd.*, Civil Action No. 18-13477 (D.N.J.).

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

14. On information and belief, Hikma has previously been sued in this Judicial District and did not challenge personal jurisdiction. *See, e.g.*, *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-11118 (D.N.J.); *Axsome Malta Ltd. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-10620 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories Ltd.*, Civil Action No. 24-9209 (D.N.J.); *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-7803 (D.N.J.); *Axsome Malta Ltd. v. Alkem*

Laboratories, Ltd., Civil Action No. 24-4608 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories Ltd.*, Civil Action No. 23-20354 (D.N.J.); *Janssen Pharmaceuticals, Inc. v. Hikma Pharmaceuticals USA, Inc.*, Civil Action No. 23-2942 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21-10398 (D.N.J.); *Corcept Therapeutics, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21-5034 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals International Ltd.*, Civil Action No. 18-13477 (D.N.J.).

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

16. On information and belief, venue is proper against Hikma 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, Hikma does not contest that venue is proper in this judicial district for purposes of this case only. Hikma denies the remaining allegations in this paragraph.

17. Hikma did not contest venue in this judicial district in at least the following actions: *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-11118 (D.N.J.); *Axsome Malta Ltd. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-10620 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories Ltd.*, Civil Action No. 24-9209 (D.N.J.); *American Regent, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 24-7803 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories, Ltd.*, Civil Action No. 24-4608 (D.N.J.); *Axsome Malta Ltd. v. Alkem Laboratories Ltd.*, Civil Action No. 23-20354 (D.N.J.); *Janssen Pharmaceuticals, Inc. v. Hikma Pharmaceuticals USA, Inc.*, Civil Action No. 23-2942 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21-10398 (D.N.J.); *Corcept Therapeutics, Inc. v. Hikma Pharmaceuticals USA Inc.*, Civil Action No. 21-5034 (D.N.J.); *Celgene Corporation v. Hikma Pharmaceuticals International Ltd.*, Civil Action No. 18-13477 (D.N.J.).

ANSWER: This paragraph contains conclusions of law for which no response is required. To the extent that a response is required, Hikma does not contest that venue is proper in this judicial district for purposes of this case only. Hikma 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, Hikma admits that on its face, the '036 patent bears an issuance date of May 14, 2019, and is titled "Protocol for the Treatment of Lupus Nephritis." Hikma admits that a purported copy of the '036 patent is attached to the Complaint as Exhibit 1. Hikma specifically denies that the '036 patent was duly and legally issued. Hikma further admits that, according to the records of the U.S. Patent and Trademark Office ("USPTO"), Aurinia is the assignee of the '036 patent. Hikma 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, Hikma admits that on its face, the '991 patent bears an issuance date of April 11, 2023, and is titled "Protocol for the Treatment of Lupus Nephritis." Hikma admits that a purported copy of the '991 patent is attached to the Complaint as Exhibit 2. Hikma specifically denies that the '991 patent was duly and legally issued. Hikma further admits that, according to the records of the USPTO, Aurinia is the assignee of the '991 patent. Hikma 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: Hikma 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. Hikma further admits that, according to the records of the FDA, the FDA approved NDA No. 213716 on January 22, 2021. Hikma also admits that the '036 and '991 patents are listed in the FDA's Orange Book in connection with NDA No. 213716. Hikma 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.

HIKMA'S INFRINGING ACTIVITIES

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

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

22. By letter dated February 24, 2025, addressed to Aurinia ("Notice Letter"), Hikma notified Aurinia that Hikma 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: Hikma admits that it sent Aurinia a letter dated February 24, 2025 ("Hikma's Notice Letter"), pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, providing notice that Hikma submitted ANDA No. 219663 to the FDA. Hikma denies the remaining allegations in this paragraph.

23. The Notice Letter states that Hikma 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 Hikma’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, Hikma admits that Hikma’s Notice Letter notified Aurinia that Hikma submitted ANDA No. 219663 to the FDA seeking approval to manufacture, use, or sell Hikma’s ANDA Product in the United States before the expiration of the ’036 and ’991 patents. Hikma denies the remaining allegations in this paragraph.

24. On information and belief, Hikma, 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, Hikma admits that Hikma submitted ANDA No. 219663 to the FDA seeking approval to manufacture, use, or sell Hikma’s ANDA Product in the United States. Hikma denies the remaining allegations in this paragraph.

25. On information and belief, if the FDA approves Hikma’s Voclosporin ANDA, Hikma, 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, Hikma admits that Hikma submitted ANDA No. 219663 to the FDA seeking approval to manufacture, use, or sell Hikma’s ANDA Product in the United States. Hikma denies the remaining allegations in this paragraph.

26. In the Notice Letter, Hikma 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 Hikma’s generic voclosporin product.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Hikma admits that Hikma’s Notice Letter notified Aurinia that

Hikma's ANDA No. 219663 includes a Paragraph IV certification to the '036 and '991 patents. Hikma 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, Hikma admits that the Complaint was filed on April 10, 2025, which was within forty-five days of receipt of Hikma's Notice Letter. Hikma 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: Hikma incorporates by reference its responses to paragraphs 1-27 as if fully set forth herein.

29. Hikma'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, Hikma denies the allegations in this paragraph.

30. On information and belief, Hikma 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: Hikma admits that Hikma's Notice Letter notified Aurinia that Hikma's ANDA No. 219663 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 Hikma's ANDA Product. Hikma denies the remaining allegations in this paragraph.

31. On information and belief, Hikma had actual knowledge of the '036 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, Hikma admits that it was aware of the '036 patent at the time of filing Hikma's ANDA No. 219663. Hikma denies the remaining allegations in this paragraph.

32. On information and belief, Hikma concedes infringement of at least one claim of the '036 patent because Hikma'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, Hikma denies the allegations in this paragraph.

33. On information and belief, Hikma'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, Hikma denies the allegations in this paragraph.

34. On information and belief, Hikma knows, should know, and intends that physicians will prescribe, and patients will take, Hikma'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, Hikma denies the allegations in this paragraph.

35. On information and belief, Hikma has knowledge of the '036 patent and, by its proposed package insert for Hikma'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, Hikma denies the allegations in this paragraph.

36. On information and belief, Hikma 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 Hikma'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, Hikma denies the allegations in this paragraph.

37. On information and belief, Hikma 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, Hikma denies the allegations in this paragraph.

38. On information and belief, Hikma has had and continues to have knowledge that Hikma'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, Hikma denies the allegations in this paragraph.

39. On information and belief, upon FDA approval of Hikma's Voclosporin ANDA, Hikma 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, Hikma denies the allegations in this paragraph.

40. If Hikma'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, Hikma 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: Hikma incorporates by reference its responses to paragraphs 1-40 as if fully set forth herein.

42. Hikma'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, Hikma denies the allegations in this paragraph.

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

ANSWER: This paragraph contains conclusions of law for which no response is required. Hikma admits that Hikma's Notice Letter notified Aurinia that Hikma's ANDA No. 219663 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 Hikma's ANDA Product. Hikma denies the remaining allegations in this paragraph.

44. On information and belief, Hikma 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, Hikma admits that it was aware of the '991 patent at the time of filing Hikma's ANDA No. 219663. Hikma denies any remaining allegations in this paragraph.

45. On information and belief, Hikma concedes infringement of at least one claim of the '991 patent because Hikma'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, Hikma denies the allegations in this paragraph.

46. Upon information and belief, Hikma'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, Hikma denies the allegations in this paragraph.

47. On information and belief, Hikma knows, should know, and intends that physicians will prescribe, and patients will take, Hikma'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, Hikma denies the allegations in this paragraph.

48. On information and belief, Hikma has knowledge of the '991 patent and, by its proposed package insert for Hikma'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, Hikma denies the allegations in this paragraph.

49. On information and belief, Hikma 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 Hikma'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, Hikma denies the allegations in this paragraph.

50. On information and belief, Hikma 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, Hikma denies the allegations in this paragraph.

51. On information and belief, Hikma has had and continues to have knowledge that Hikma'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, Hikma denies the allegations in this paragraph.

52. On information and belief, upon FDA approval of Hikma's Voclosporin ANDA, Hikma 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, Hikma denies the allegations in this paragraph.

53. If Hikma'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, Hikma 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, Hikma denies that Plaintiff is entitled to any remedy or relief.

AFFIRMATIVE DEFENSES

Hikma 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. Hikma 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 Hikma'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 Hikma’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

Hikma 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

Hikma 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 Hikma Pharmaceuticals USA Inc. ("Hikma") states as follows:

PARTIES

1. Hikma is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 200 Connell Drive, 4th Floor, Berkeley Heights, New Jersey 07922.

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 THE ACTION

3. Hikma 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. Hikma submitted Abbreviated New Drug Application (“ANDA”) No. 219663

("Hikma'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 ("Hikma's ANDA Product") within the United States.

17. Hikma'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 Hikma's ANDA Product.

18. By letter dated February 24, 2025, Hikma sent written notice of Hikma's Paragraph IV Certifications to Aurinia pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95 ("Hikma's Notice Letter"). Hikma's Notice Letter asserted that the claims of the '036 and '991 patents are invalid, unenforceable, and/or will not be infringed by Hikma's ANDA or the product or activities described therein.

19. Hikma's Notice Letter included a detailed statement of the legal and factual basis for the Paragraph IV Certifications included in Hikma'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 Hikma on April 10, 2025, alleging infringement of the '036 and '991 patents.

21. As a consequence of the foregoing, there is an actual and justiciable controversy between Hikma, 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 Hikma's ANDA No. 219663 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. Hikma 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 Hikma alleging infringement of the '036 patent.

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

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

29. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma'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 Hikma 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. Hikma 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 Hikma 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.

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, substantial, continuing, and justiciable controversy between

Hikma and Plaintiff regarding, *inter alia*, the validity of all claims of the '036 patent.

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

39. Hikma 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-crated bases for invalidity and unenforceability.

40. This case is an exceptional one, and Hikma 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. Hikma 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 Hikma alleging infringement of the '991 patent.

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

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

48. Hikma is entitled to a declaration that the manufacture, use, or sale of Hikma'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 Hikma 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. Hikma 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 Hikma 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.

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, substantial, continuing, and justiciable controversy between Hikma and Plaintiff regarding, *inter alia*, the validity of all claims of the '991 patent.

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

58. Hikma 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-crated bases for invalidity and unenforceability.

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

PRAYER FOR RELIEF

WHEREFORE, Counterclaim-Plaintiff Hikma 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 Hikma'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 Hikma'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 Hikma its costs and expenses in this action;

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

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

MIDLIGE RICHTER LLC
Attorneys for Defendant,
Hikma Pharmaceuticals USA Inc

By: s/ James S. Richter
James S. Richter
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Dated: June 20, 2025

OF COUNSEL:

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Jovial Wong (*pro hac vice* forthcoming)
Sharon Lin McIntosh (*pro hac vice* forthcoming)
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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. DR. REDDY'S LABORATORIES, INC. et al Civil Action No. 2:25-cv-03693-JKS-AME
- AURINIA PHARMACEUTICALS INC. v. SANDOZ INC. Civil Action No. 2:25-cv-03986-JKS-AME

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

s/ James S. Richter
James S. Richter

Dated: June 20, 2025

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, Defendant Hikma Pharmaceuticals USA 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/ James S. Richter
James S. Richter

Dated: June 20, 2025

CERTIFICATION OF SERVICE

I certify that on June 20, 2025, a true and correct copy of the foregoing Defendant Hikma Pharmaceuticals USA 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.

s/ James S. Richter
James S. Richter

Dated: June 20, 2025