IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

AURINIA PHARMACEUTICALS INC., Plaintiff, v. DIFGEN PHARMACEUTICALS LLC, Defendant.	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Aurinia Pharmaceuticals Inc. ("Aurinia") brings this Complaint for patent infringement against Defendant DifGen Pharmaceuticals LLC. ("DifGen") and alleges as follows:

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 DifGen. This action relates to Abbreviated New Drug Application ("ANDA") No. 220332 ("Voclosporin ANDA") filed by DifGen 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®.

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.

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.

4. On information and belief, DifGen is a limited liability company organized under the laws of Delaware, having a principal place of business at 3200 Commerce Parkway, Miramar, Florida 33025.

5. On information and belief, DifGen 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 Delaware.

JURISDICTION AND VENUE

6. Each of the preceding paragraphs 1–5 is re-alleged and re-incorporated 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.

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

9. This Court has personal jurisdiction over DifGen because DifGen is incorporated in the State of Delaware.

10. Additionally, on information and belief, DifGen 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. 220332 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, DifGen directly and/or indirectly will engage in marketing, sale, and distribution of the generic voclosporin products in Delaware upon approval

of its Voclosporin ANDA. On information and belief, such generic voclosporin products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. Additionally, on information and belief, DifGen 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 Delaware and/or purchased by consumers in Delaware.

11. On information and belief, DifGen is subject to personal jurisdiction in this District because it regularly does business or solicits business in Delaware, engages in other persistent courses of conduct in Delaware, derives substantial revenue from services or things used or consumed in Delaware, and/or is incorporated in Delaware, demonstrating that DifGen has continuous and systematic contacts with Delaware.

12. This Court also has personal jurisdiction over DifGen because, based on the activities alleged herein, at least one provision of 10 Del. C. § 3104(c) is satisfied. Upon information and belief, DifGen satisfies at least § 3104(c)(1) ("[t]ransacts any business or performs any character of work or service in the State"), § 3104(c)(2) ("[c]ontracts to supply services or things in this State"), § 3104(c)(3) ("[c]auses tortious injury in the State by an act or omission in this State), and § 3104(c)(4) ("[c]auses tortious injury in the State or outside of the State by an act or omission outside the State if the person regularly does or solicits business, engages in any other persistent course of conduct in the State or derives substantial revenue from services, or things used or consumed in the State").

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

14. On information and belief, venue is proper against DifGen in this judicial district because DifGen is incorporated in Delaware.

PATENTS-IN-SUIT

15. Each of the preceding paragraphs 1-14 is re-alleged and re-incorporated as if fully set forth herein.

16. 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.

17. 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.

18. 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.

DIFGEN’S INFRINGING ACTIVITIES

19. Each of the preceding paragraphs 1–18 is re-alleged and re-incorporated as if fully set forth herein.

20. By letter dated March 17, 2025, addressed to Aurinia (“Notice Letter”), DifGen notified Aurinia that DifGen 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)).

21. The Notice Letter states that DifGen 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 DifGen’s generic voclosporin products that are the same, or substantially the same, as Aurinia’s LUPKYNIS®.

22. On information and belief, DifGen, 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.

23. On information and belief, if the FDA approves DifGen’s Voclosporin ANDA, DifGen, 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.

24. In the Notice Letter, DifGen 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 DifGen’s generic voclosporin product.

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

COUNT I
INFRINGEMENT OF THE ’036 PATENT

26. Each of the preceding paragraphs 1–25 is re-alleged and re-incorporated as if fully set forth herein.

27. DifGen’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).

28. On information and belief, DifGen 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.

29. On information and belief, DifGen had actual knowledge of the ’036 patent at least since its filing of its Voclosporin ANDA and at least since March 17, 2025, the date the Notice Letter was sent to Aurinia.

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

31. On information and belief, DifGen knows, should know, and intends that physicians will prescribe, and patients will take, DifGen’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.

32. On information and belief, DifGen has knowledge of the ’036 patent and, by its proposed package insert for DifGen’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.

33. On information and belief, DifGen 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 DifGen’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.

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

35. On information and belief, DifGen has had and continues to have knowledge that DifGen’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.

36. On information and belief, upon FDA approval of DifGen’s Voclosporin ANDA, DifGen 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.

37. On information and belief, DifGen’s actions relating to the Voclosporin ANDA complained of herein were done by and for the benefit of DifGen.

38. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aurinia and DifGen as to liability for infringement of the ’036 patent claims. DifGen’s actions have created in Aurinia a reasonable apprehension of imminent, irreparable, and substantial harm resulting from DifGen’s threatened imminent actions. If DifGen’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.

COUNT II
INFRINGEMENT OF THE ’991 PATENT

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

40. DifGen’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).

41. On information and belief, DifGen 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.

42. On information and belief, DifGen had actual knowledge of the ’991 patent at least since its filing of its Voclosporin ANDA and at least since March 17, 2025, the date the Notice Letter was sent to Aurinia.

43. Upon information and belief, DifGen’s generic voclosporin products will, if approved and marketed, infringe at least one claim of the ’991 patent.

44. On information and belief, DifGen knows, should know, and intends that physicians will prescribe, and patients will take, DifGen’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.

45. On information and belief, DifGen has knowledge of the ’991 patent and, by its proposed package insert for DifGen’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.

46. On information and belief, DifGen 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 DifGen'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.

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

48. On information and belief, DifGen has had and continues to have knowledge that DifGen'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.

49. On information and belief, upon FDA approval of DifGen's Voclosporin ANDA, DifGen 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.

50. On information and belief, DifGen's actions relating to the Voclosporin ANDA complained of herein were done by and for the benefit of DifGen.

51. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Aurinia and DifGen as to liability for infringement of the '036 patent claims. DifGen's actions have created in Aurinia a reasonable apprehension of imminent, irreparable, and substantial harm resulting from DifGen's threatened imminent actions. If

DifGen'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.

PRAYER FOR RELIEF

WHEREFORE, Aurinia respectfully requests that this Court enter judgment in its favor and against DifGen and grant the following relief:

A. A judgment that the claims of the '036 and '991 patents are not invalid, not unenforceable, and are infringed by DifGen's submission of its Voclosporin ANDA, and that DifGen's making, using, offering to sell, or selling in the United States, or importing into the United States DifGen's generic voclosporin products will infringe the '036 and '991 patents.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of DifGen's Voclosporin ANDA shall be a date which is not earlier than the latest expiration date of the '036 and '991 patents, including any extensions and/or additional periods of exclusivity to which Aurinia is or becomes entitled.

C. An order permanently enjoining DifGen, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States DifGen's generic voclosporin products until after the latest expiration date of the '036 and '991 patents, including any extensions and/or additional periods of exclusivity to which Aurinia is or becomes entitled.

D. Damages or other monetary relief to Aurinia if DifGen engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of DifGen's generic voclosporin products prior to the latest expiration date of the '036 and '991 patents, including any extensions and/or additional periods of exclusivity to which Aurinia is or becomes entitled.

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: May 1, 2025

OF COUNSEL:

Mark J. Feldstein
Danielle A. Duszczyszyn
Emily R. Gabranski
C. Collette Corser
Ryan V. McDonnell
Emma L. Capitanelli
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Ave., N.W.
Washington, DC 20001
(202) 408-4000

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*

Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Maliheh Zare (#7133)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com
mzare@mccarter.com

Attorneys for Plaintiff Aurinia Pharmaceuticals Inc.