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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC.,	:	Honorable Jamel K. Semper, U.S.D.J.
Plaintiff,	:	Civil Action No. 25 CV 3533 (JKS)(AME)
v.	:	
	:	**DEFENDANT, DIFGEN PHARMACEUTICALS LLC'S ANSWER, SEPARATE DEFENSES, AND COUNTERCLAIMS TO PLAINTIFF'S COMPLAINT**
DIFGEN PHARMACEUTICALS LLC,	:	
Defendant.	:	

Defendant DifGen Pharmaceuticals LLC ("DifGen"), by and through its counsel, hereby answers and responds to each of the allegations of the Complaint of Plaintiff Aurinia Pharmaceuticals Inc. ("Aurinia" or "Plaintiff") and asserts its separate defenses and counterclaims as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), DifGen denies all allegations in Plaintiff's Complaint except those specifically admitted below.

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®.

ANSWER: Paragraph 1 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that Plaintiff's Complaint purports to be a civil action alleging infringement pursuant to Title 35 of the United States Code. DifGen denies all remaining allegations of 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: DifGen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 2 of the Complaint, and on that basis, 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: DifGen lacks sufficient knowledge or information to form a belief as to the truth of the allegations of Paragraph 3 of the Complaint, and on that basis, denies them.

4. On information and belief, DifGen is a limited liability company organized under the laws of Delaware.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that it is a limited liability company organized under the laws of the State of Delaware. DifGen denies any remaining allegations contained in Paragraph 4 not expressly admitted.

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 New Jersey.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, denied.

JURISDICTION AND VENUE

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

ANSWER: DifGen incorporates its Answer 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: Paragraph 7 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that Plaintiff's Complaint purports to be a civil action pursuant to Title 35 of the United States Code. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 7 of the Complaint.

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

ANSWER: Paragraph 8 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen does not dispute the Court's subject matter jurisdiction under 28 U.S.C. ¶¶ 1331 and 1338(a) for purposes of this litigation only, and expressly reserves the right to contest subject matter jurisdiction in any other case as to any party, including Plaintiff. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 8 of the Complaint.

9. This Court has personal jurisdiction over DifGen.

ANSWER: Paragraph 9 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen does not contest personal jurisdiction in New Jersey for purposes of this action only and expressly reserves the right to

contest personal jurisdiction in any other case as to any party, including Plaintiff. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 9 of the Complaint.

10. This Court has personal jurisdiction over DifGen because, on information and belief, DifGen directly and/or indirectly will engage in marketing, sale, and distribution of the generic voclosporin products throughout the United States, including in the State of 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, 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 New Jersey and/or purchased by consumers in New Jersey.

ANSWER: Paragraph 10 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen does not contest personal jurisdiction in New Jersey for purposes of this action only and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 10 of the Complaint.

11. Further, on information and belief, DifGen directly and/or indirectly has established distribution channels for its generic drug products in the United States, including New Jersey, and will derive substantial revenue from the sale of drug products in United States, including New Jersey. For example, on information and belief, DifGen only recently "relocated its corporate headquarters from Princeton, New Jersey to the Miramar Park of Commerce," after DifGen had developed and submitted its ANDA to FDA. *See DifGen Pharmaceuticals Relocates Corporate Headquarters from New Jersey to Miramar Park of Commerce*, South Florida Hospital News, (Feb. 10, 2025) https://southfloridahos__pitalnews.com/difgen-pharmaceuticals-relocates-corporate-headquarters-from-new-jersey-to-miramar-park-of-commerce/. Further, on information and belief, DifGen remains registered with the State of New Jersey's Division of Revenue and Enterprise Services as a foreign limited liability company operating in New Jersey under Business ID No. 0450834642.

ANSWER: Paragraph 11 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen does not contest personal jurisdiction in New Jersey for purposes of this action only, and expressly reserves the right to contest personal jurisdiction in any other case as to any party, including Plaintiff. DifGen further admits that its corporate headquarters are located in Florida and not in New Jersey. DifGen admits

that it had previously registered with the State of New Jersey's Division of Revenue and Enterprise Services as a foreign limited liability company under Business ID No. 0450834642. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 11 of the Complaint.

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

ANSWER: Paragraph 12 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen does not contest venue in this judicial district for the purposes of this action only and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 12 of the Complaint.

13. On information and belief, venue is proper in the District of New Jersey for DifGen 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. For example, on information and belief, 57 Winterset Drive Morris Plains, New Jersey has been maintained as a regular and established place of business for DifGen and for its founder and co-chief executive officer.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen does not contest venue in this judicial district for the purposes of this action only and expressly reserves the right to contest venue in any other case as to any party, including Plaintiff. DifGen denies that it maintains a regular and established place of business in New Jersey and denies any allegations of infringement including within the state of New Jersey. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 13 of the Complaint.

PATENTS-IN-SUIT

14. 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: DifGen admits that Plaintiff purports to attach a copy of the '036 patent to the Complaint as Exhibit 1. DifGen further admits that on its face, the '036 patent is titled "Protocol for Treatment of Lupus Nephritis," and indicates that it issued on May 14, 2019, to assignee Aurinia Pharmaceuticals Inc. DifGen denies that the '036 patent was duly and legally issued or is valid or enforceable. DifGen lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in Paragraph 14 and, on that basis, denies them.

15. 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: DifGen admits that Plaintiff purports to attach a copy of the '991 patent to the Complaint as Exhibit 2. DifGen further admits that on its face, the '991 patent is titled "Protocol for Treatment of Lupus Nephritis," and indicates that it issued on April 11, 2023, to assignee Aurinia Pharmaceuticals Inc. DifGen denies that the '991 patent was duly and legally issued or is valid or enforceable. DifGen lacks sufficient knowledge and information to form a belief as to the truth of the remaining allegations contained in Paragraph 15, and on that basis, denies them.

16. 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: DifGen admits that Aurinia Pharmaceuticals Inc. is listed in the FDA's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") as the holder of New Drug Application ("NDA") No. 213716. DifGen further admits that the Orange Book indicates an approval date of January 22, 2021, for NDA No. 213716 and that the products subject to NDA No. 213716 are marketed under the trade name "LUPKYNIS®." DifGen admits that the '036 and '991 patents are listed in the Orange Book in

connection with NDA No. 213716. DifGen lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations contained in Paragraph 16 and, on that basis, denies them.

DIFGEN'S INFRINGING ACTIVITIES

17. Each of the preceding paragraphs 1–16 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: DifGen incorporates its Answer to paragraphs 1-16 as if fully set forth herein.

18. 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)).

ANSWER: DifGen admits that it mailed a Notice Letter on March 17, 2025, notifying Plaintiff that it had submitted ANDA No. 220332 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)). To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 18 of the Complaint.

19. 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®.

ANSWER: DifGen admits that it submitted ANDA No. 220332 seeking FDA approval for voclosporin capsules 7.9 mg. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 19 of the Complaint.

20. 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.

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that it submitted ANDA No.

220332 FDA approval for voclosporin capsules 7.9 mg. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 20 of the Complaint.

21. 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.

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that it submitted ANDA No. 220332 FDA approval for voclosporin capsules 7.9 mg. To the extent not expressly admitted, DifGen denies the remaining allegations in Paragraph 21 of the Complaint.

22. 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.

ANSWER: DifGen admits that it mailed a Notice Letter on March 17, 2025, notifying Plaintiff that it had submitted ANDA No. 220332 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and that the Notice Letter included a Notice of Certification for ANDA No. 220332 under 37 C.F.R. § 314.95(c)(6) as to the '036 and '991 patents. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 22 of the Complaint.

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

ANSWER: Admitted.

COUNT I
INFRINGEMENT OF THE '036 PATENT

24. Each of the preceding paragraphs 1–23 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: DifGen incorporates its Answer to paragraphs 1-23 as if fully set forth herein.

25. 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).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that it filed ANDA No. 220332 seeking FDA approval for voclosporin capsules 7.9 mg. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 25 of the Complaint.

26. 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.

ANSWER: DifGen admits that it mailed a Notice Letter on March 17, 2025, notifying Plaintiff that it had submitted ANDA No. 220332 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and that the Notice Letter included a Notice of Certification for ANDA No. 220332 under 37 C.F.R. § 314.95(c)(6) as to the '036 patent. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 26 of the Complaint.

27. 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.

ANSWER: DifGen admits that it mailed a Notice Letter on March 17, 2025, notifying Plaintiff that it had submitted ANDA No. 220332 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and that the Notice Letter included a Notice of Certification for ANDA No. 220332 under 37 C.F.R. § 314.95(c)(6) as to the '036 patent. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 27 of the Complaint.

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

ANSWER: Denied.

29. 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.

ANSWER: Denied.

30. 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.

ANSWER: Denied.

31. 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.

ANSWER: Denied.

32. 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.

ANSWER: Denied.

33. 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.

ANSWER: Denied.

34. 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.

ANSWER: Denied.

35. 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.

ANSWER: Denied.

COUNT II
INFRINGEMENT OF THE '991 PATENT

36. Each of the preceding paragraphs 1–35 is re-alleged and re-incorporated as if fully set forth herein.

ANSWER: DifGen incorporates its Answer to paragraphs 1-35 as if fully set forth herein.

37. 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).

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, DifGen admits that it filed ANDA No. 220332 seeking FDA approval for voclosporin capsules 7.9 mg. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 37 of the Complaint.

38. 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.

ANSWER: DifGen admits that it mailed a Notice Letter on March 17, 2025, notifying Plaintiff that it had submitted ANDA No. 220332 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and that the Notice Letter included a Notice of Certification for ANDA No. 220332 under 37 C.F.R. § 314.95(c)(6) as to the '991 patent. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 38 of the Complaint.

39. 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.

ANSWER: DifGen admits that it mailed a Notice Letter on March 17, 2025, notifying Plaintiff that it had submitted ANDA No. 220332 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) and that the Notice Letter included a Notice of Certification for ANDA No. 220332 under 37 C.F.R. § 314.95(c)(6) as to the '991 patent. To the extent not expressly admitted, DifGen denies the remaining allegations contained in Paragraph 39 of the Complaint.

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

ANSWER: Denied.

41. 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.

ANSWER: Denied.

42. 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.

ANSWER: Denied.

43. 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.

ANSWER: Denied.

44. 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.

ANSWER: Denied.

45. 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.

ANSWER: Denied.

46. 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.

ANSWER: Denied.

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

ANSWER: Denied.

RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

All remaining allegations not specifically admitted are herein denied. It is further denied that Plaintiff is entitled to the relief requested in the Complaint or to any other relief whatsoever.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, DifGen asserts the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST SEPARATE DEFENSE

The Complaint fails to state a cause of action under 35 U.S.C. § 271(a), (b), and/or (c) against DifGen because Plaintiff has not pleaded with particularity facts regarding any post ANDA approval activities.

SECOND SEPARATE DEFENSE

Plaintiff has failed to state a claim upon which relief can be granted.

THIRD SEPARATE DEFENSE

The claims of the '036 and '991 patents are unenforceable and/or invalid for failure to satisfy one or more of the conditions for patentability contained in 35 U.S.C. §§ 101, 102, 103, 112, 116, double patenting, and/or other judicially created bases for invalidity and/or unenforceability, and the rules, regulations and laws pertaining thereto, for at least for the reasons set forth in the Detailed Statement of the factual and legal bases included with DifGen's March 17, 2025, Notice Letter to Plaintiff.

FOURTH SEPARATE DEFENSE

DifGen has not directly or indirectly infringed any claims of the '036 and '991 patents. The filing of DifGen's ANDA No. 220332, and the manufacture, use, offer for sale, sale, and/or importation of the products that are the subject of DifGen's ANDA No. 220332 does not and would not infringe any valid or enforceable claim of the '036 and '991 patents, either literally or under the doctrine of equivalents.

FIFTH SEPARATE DEFENSE

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

SIXTH SEPARATE DEFENSE

DifGen reserves all defenses, at law or equity, which may now exist or in the future be available on discovery and further factual investigation in this case.

COUNTERCLAIMS

For its counterclaims against Plaintiff/Counterclaim-Defendant Aurinia Pharmaceuticals, Inc. ("Aurinia"), Defendant/Counterclaim-Plaintiff DifGen Pharmaceuticals LLC ("DifGen") states as follows:

NATURE OF THE ACTION

1. This action arises 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 and 2202, seeking declaratory judgment 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.

PARTIES

2. DifGen is a corporation organized and existing under the laws of the State of Delaware, having a principle place of business at 3200 Commerce Pkway, Miramar, Florida 33025-3907.

3. 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.

JURISDICTION AND VENUE

4. This action is for declaratory judgment that DifGen has not, does not, and will not infringe any valid and enforceable claim of the patents-in-suit.

5. This Court has subject matter jurisdiction over these counterclaims pursuant to 28 U.S.C. §§ 1331 and 1338(a) because these counterclaims involve substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 100 *et seq*.

6. 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.

7. Venue is proper in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400 for purposes of this action only, and by Aurinia's choice of forum.

8. There is an actual and justiciable controversy between the parties as to the non-infringement and invalidity of the patents-in-suit.

FACTUAL BACKGROUND

9. On information and belief, on or about May 14, 2019, the United States Patent and Trademark Office ("USPTO") issued the '036 patent, titled "Protocol for Treatment of Lupus Nephritis." According to the information on the face of the '036 patent, it is assigned to Aurinia.

10. On information and belief, on or about April 11, 2023, the USPTO issued the '991 patent, titled "Protocol for Treatment of Lupus Nephritis." According to the information on the face of the '991 patent, it is assigned to Aurinia.

11. On information and belief, Aurinia is the holder of NDA No. 213716, which purportedly covers LUPKYNIS®, voclosporin capsules 7.9 mg.

12. On information and belief, Aurinia caused the FDA to list the patents-in-suit in the FDA's publication, Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book") in connection with NDA No. 213716.

13. DifGen filed ANDA No. 220332 seeking FDA approval for voclosporin capsules 7.9 mg ("DifGen's ANDA Product").

14. Aurinia has alleged that DifGen infringes claims of the patents-in-suit in connection with ANDA No. 220332.

COUNT I: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '036 PATENT

15. DifGen repeats and realleges the allegations in paragraphs 1-14 of its counterclaims as if fully set forth herein.

16. DifGen denies infringement of any valid, enforceable, properly construed claim of the '036 patent and alleges that DifGen has not, and does not, infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the '036 patent, including for at least the reasons set forth in the detailed statement including with DifGen's Notice Letter.

17. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of DifGen's ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the '036 patent.

18. DifGen is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of DifGen's ANDA Product does not, and would not if marketed, infringe any valid and/or enforceable claim of the '036 patent.

19. Unless Aurinia is enjoined, DifGen believes that Aurinia will continue to assert DifGen's ANDA Product is infringing the claims of the '036 patent, and will continue to interfere with DifGen's business with respect to DifGen's ANDA Product and its manufacture, use, offer for sale and sale.

20. DifGen will be irreparably harmed if Aurinia is not enjoined from continuing to assert the '036 patent and from interfering with DifGen's business.

21. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the non-infringement of the '036 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

22. DifGen is entitled to a declaratory judgment that the claims of the '036 patent are not infringed.

COUNT II: DECLARATORY JUDGMENT OF INVALIDITY OF THE '036 PATENT

23. DifGen repeats and realleges the allegations in paragraphs 1-21 of its counterclaims as if fully set forth herein.

24. DifGen denies infringement of the claims of the '036 patent and alleges that the claims of the '036 patent are invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 100 *et seq*., including without limitation §§ 101, 102, 103, 112, and/or double patenting, and including for at least the reasons set forth in the detailed statement included with DifGen's Notice Letter.

25. 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 no 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.

26. The claims of the '036 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '036 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or 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.

27. The claims of the ’036 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112. Further, the ’036 patent fails to enable one of ordinary skill in the art to make and use the full scope of the alleged invention without undue experimentation, as required by 35 U.S.C. § 112.

28. Unless Aurinia is enjoined, DifGen believes that Aurinia will continue to assert that DifGen’s ANDA Product is infringing the claims of the ’036 patent, and will continue to interfere with DifGen’s business with respect to DifGen’s ANDA Product and its manufacture, use, offer for sale and sale.

29. DifGen will be irreparably harmed if Aurinia is not enjoined from continuing to assert the ’036 patent and from interfering with DifGen’s business.

30. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the ’036 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

31. DifGen is entitled to a declaratory judgment that the claims of the ’036 patent are invalid.

COUNT III: DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE ’991 PATENT

32. DifGen repeats and realleges the allegations in paragraphs 1-31 of its counterclaims as if fully set forth herein.

33. DifGen denies infringement of any valid, enforceable, properly construed claim of the ’991 patent and alleges that DifGen has not, and does not, infringe (either literally or under the

doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid, enforceable, properly construed claim of the ’991 patent, including for at least the reasons set forth in the detailed statement including with DifGen’s Notice Letter.

34. The manufacture, use, sale, or offer for sale within, and/or importation into, the United States of DifGen’s ANDA Product will not constitute infringement (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), of any valid, enforceable, properly construed claim of the ’991 patent.

35. DifGen is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, and/or importation of DifGen’s ANDA Product does not, and would not, if marketed, infringe any valid and/or enforceable claim of the ’991 patent.

36. Unless Aurinia is enjoined, DifGen believes that Aurinia will continue to assert DifGen’s ANDA Product is infringing the claims of the ’991 patent, and will continue to interfere with DifGen’s business with respect to DifGen’s ANDA Product and its manufacture, use, offer for sale and sale.

37. DifGen will be irreparably harmed if Aurinia is not enjoined from continuing to assert the ’991 patent and from interfering with DifGen’s business.

38. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the non-infringement of the ’991 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

39. DifGen is entitled to a declaratory judgment that the claims of the ’991 patent are not infringed.

COUNT IV: DECLARATORY JUDGMENT OF INVALIDITY OF THE ’991 PATENT

40. DifGen repeats and realleges the allegations in paragraphs 1-39 of its counterclaims as if fully set forth herein.

41. DifGen denies infringement of the claims of the '991 patent and alleges that the claims of the '991 patent are invalid for failure to meet one or more of the statutory requirements for patentability set forth in 35 U.S.C. §§ 100 *et seq*., including without limitation §§ 101, 102, 103, 112, and/or double patenting, and including for at least the reasons set forth in the detailed statement included with DifGen's Notice Letter.

42. The alleged invention of the '991 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement over the prior art set forth in the '991 patent is no more than the predictable use of prior art elements according to their established functions. A person of skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '991 patent and would have had a reasonable expectation of success in doing so.

43. The claims of the '991 patent are invalid at least under 35 U.S.C. §§ 102 and/or 103 in view of the prior art. The differences between the subject matter claimed in the '991 patent and the prior art are such that the subject matter as a whole was either fully anticipated by the prior art or would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains.

44. The claims of the '991 patent do not inform those skilled in the art about the scope of the invention with reasonable certainty, and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112. Further, the '991

patent fails to enable one of ordinary skill in the art to make and use the full scope of the alleged invention without undue experimentation, as required by 35 U.S.C. § 112.

45. Unless Aurinia is enjoined, DifGen believes that Aurinia will continue to assert that DifGen's ANDA Product is infringing the claims of the '991 patent, and will continue to interfere with DifGen's business with respect to DifGen's ANDA Product and its manufacture, use, offer for sale and sale.

46. DifGen will be irreparably harmed if Aurinia is not enjoined from continuing to assert the '991 patent and from interfering with DifGen's business.

47. There is a definite and concrete, real and substantial, justiciable, and continuing case or controversy existing between the parties regarding the invalidity of the '991 patent that is of sufficient immediacy and reality to warrant the issuance of a Declaratory Judgment.

48. DifGen is entitled to a declaratory judgment that the claims of the '991 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, DifGen respectfully requests entry of judgment in its favor and judgment against Aurinia providing the following relief:

a) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is subject to ANDA No. 220332 has not infringed, does not infringe, and would not infringe any valid or enforceable claim of the patents-in-suit, either literally or under the doctrine of equivalents;

b) Declaring that the manufacture, use, sale, offer for sale, or importation of the drug product that is the subject of ANDA No. 220332 has not infringed, does not infringe,

and would not induce the infringement of or contributorily infringe any valid or enforceable claim of the patents-in-suit;

c) Declaring the claims of the patents-in-suit invalid;

d) Ordering that Aurinia's Complaint be dismissed with prejudice and judgment entered in favor of DifGen;

e) Declaring that Aurinia is not entitled to any declaratory or injunctive relief or any alleged damages for alleged patent infringement by DifGen;

f) Declaring this case exceptional and awarding DifGen its reasonable attorney's fees and costs pursuant to 35 U.S.C. § 285; and

g) Awarding DifGen such other and further relief as the Court may deem just and proper.

MIDLIGE RICHTER LLC
Attorneys for Defendant,
DifGen Pharmaceuticals LLC

By: *s/ James S. Richter*
James S. Richter
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Dated: July 2, 2025

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify, to the best of my knowledge, the same drug and patents are at issue in the following 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. HIKMA PHARMACEUTICALS USA, INC. Civil Action No. 2:25-cv-2580-JKS-AME
- AURINIA PHARMACEUTICALS INC. v. DR. REDDY'S LABORATORIES, INC. et al Civil Action No. 2:25-cv-03693-JKS-AME
- AURINIA PHARMACEUTICALS INC. v. SANDOZ INC. Civil Action No. 2:25-cv-03986-JKS-AME

Difgen 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: July 2, 2025

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.

s/ James S. Richter
James S. Richter

Dated: July 2, 2025

CERTIFICATE OF SERVICE

The undersigned attorney certifies that a copy of Difgen's foregoing Answer, Separate Defenses, and Counterclaims was filed via ECF and served on all counsel of record by electronic mail on July 2, 2025.

s/James S. Richter
James S. Richter

Dated: July 2, 2025