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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

AURINIA PHARMACEUTICALS INC., Plaintiff, v. LOTUS PHARMACEUTICAL CO., LTD., Defendant.	Civil Action No. 25-2613 **(Document Filed Electronically)**

DEFENDANT LOTUS PHARMACEUTICAL CO., LTD.'S ANSWER, DEFENSES, AND COUNTERCLAIMS

Defendant Lotus Pharmaceutical Co., Ltd. ("Lotus"), by its undersigned attorneys, for its Answer to the Complaint for Patent Infringement filed by Plaintiff Aurinia Pharmaceuticals Inc.

("Plaintiff" or "Aurinia"), states as follows. Pursuant to Fed. R. Civ. P. 8(b)(3), Lotus denies all allegations in Plaintiff's Complaint except those expressly 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 Lotus. This action relates to Abbreviated New Drug Application ("ANDA") No. 220206 ("Voclosporin ANDA") filed by Lotus 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 of the Complaint contains legal conclusions to which no answer is required. To the extent an answer is required, Lotus admits that Plaintiff's Complaint purports to assert an action for patent infringement based on Lotus's filing of an Abbreviated New Drug Application ("ANDA") seeking approval from the U.S. Food and Drug Administration ("FDA") to commercially market a generic version of LUPKYNIS® prior to the expiration of U.S. Patent Nos. 10,286,036 and 11,622,921. Lotus is without sufficient information with which to form a belief as to the truth or accuracy of the remaining allegations of Paragraph 1 of the Complaint and therefore denies them.

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: Lotus is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 2 of the Complaint and, therefore, denies all allegations.

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: Lotus is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 3 of the Complaint and, therefore, denies all allegations.

4. On information and belief, Lotus is a corporation organized under the laws of Taiwan, having a principal place of business at 17F, No. 277, Song Den Road, Xin Yi District, Taipei City 110, Taiwan.

ANSWER: Admitted.

5. On information and belief, Lotus 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: 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: Lotus incorporates its answers to the preceding paragraphs 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 to which no answer is required. To the extent an answer is required, Lotus admits that Plaintiff's Complaint purports to assert an action for patent infringement under the patent laws of the United States, including 35 U.S.C. §§ 100, *et. seq*. Solely for purposes of this action, Lotus does not contest that this Court has subject matter jurisdiction over this action. Lotus denies any remaining allegations contained 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 to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest that this Court has subject matter jurisdiction over this action. Lotus denies any remaining allegations contained in Paragraph 8 of the Complaint.

9. This Court has personal jurisdiction over Lotus.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest that this Court has personal jurisdiction over Lotus. Lotus denies any remaining allegations contained in Paragraph 9 of the Complaint.

10. This Court has personal jurisdiction over Lotus because, on information and belief, Lotus 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, Lotus

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 to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest that this Court has personal jurisdiction over Lotus. Lotus denies any remaining allegations contained in Paragraph 10 of the Complaint.

11. Further, on information and belief, Lotus directly and/or indirectly has established distribution channels for its generic drug products in the United States, including in New Jersey, and derives substantial revenue from the sale of drug products in the United States, including in New Jersey. For example, on information and belief, Lotus has partnered with Alvogen Pharma US, Inc. ("Alvogen US"), a privately owned US-based pharmaceutical company headquartered at 44 Whippany Road, Suite 300, Morristown, New Jersey 07960. Lotus has stated that "Alvogen US has been one of the most important business partners for Lotus since 2015" and, as of 2022, Lotus and Alvogen companies were "partnering on 8 generic pipeline products for the US market." https://www.lotuspharm.com/newsroom/lotus-increases-equity-stake-in-alvogen-us. On information and belief, Lotus has made significant financial investment in Alvogen US to "gain significant influence over Alvogen US." *See id.* Further, on information and belief, an affiliate of Alvogen US, Alvogen PB Research and Development LLC, headquartered at 44 Whippany Road, Suite 300, Morristown, New Jersey 07960, has served as the U.S. Agent for Lotus with respect to at least two ANDA products.

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest that this

Court has personal jurisdiction over Lotus. Lotus denies any remaining allegations contained in Paragraph 11 of the Complaint.

12. On information and belief, Lotus has previously been sued in this judicial district and did not challenge personal jurisdiction, and Lotus 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: *Celgene Corporation v. Lotus Pharmaceutical Co., Ltd.*, Civil Action No. 18-11518; *Celgene Corporation v. Lotus Pharmaceutical Co., Ltd.*, Civil Action No. 17-6842.

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest that this Court has personal jurisdiction over Lotus. Lotus denies any remaining allegations contained in Paragraph 12 of the Complaint.

13. In the alternative, this Court has personal jurisdiction over Lotus pursuant to Federal Rule of Civil Procedure 4(k)(2) because, *inter alia*, (a) Aurinia's claims arise under federal law; (b) Lotus is a foreign corporation not subject to general personal jurisdiction in the courts of any state; and (c) Lotus has sufficient contacts with the United States as a whole, including, but not limited to participating in the preparation and submission of the Voclosporin ANDA and/or manufacturing, importing, offering for sale, and selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lotus satisfies due process.

ANSWER: Paragraph 13 contains legal conclusions to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest that this Court has personal jurisdiction over Lotus. Lotus denies any remaining allegations contained in Paragraph 13 of the Complaint.

14. 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 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest the propriety of venue in this District. Lotus denies all remaining allegations of Paragraph 14.

15. Venue is proper in the District of New Jersey for Lotus because it is a Taiwanese corporation not resident in the United States, and thus venue is proper in any judicial district that has personal jurisdiction, including the District of New Jersey.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest the propriety of venue in this District. Lotus denies all remaining allegations of Paragraph 15.

16. Lotus did not contest venue in this judicial district in at least the following action: *Celgene Corporation v. Lotus Pharmaceutical Co., Ltd.*, Civil Action No. 18-11518.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, solely for purposes of this action, Lotus does not contest the propriety of venue in this District. Lotus denies all remaining allegations of Paragraph 16.

PATENTS-IN-SUIT

17. 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: Paragraph 17 contains legal conclusions to which no answer is required. To the extent an answer is required, Lotus admits that the '036 patent is entitled "Protocol for the Treatment of Lupus Nephritis," that a purported copy of the '036 patent is attached as Exhibit 1, and that the issue date on the cover of the '036 patent is May 14, 2019. Lotus denies that the '036 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 17.

18. 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: Paragraph 18 contains legal conclusions to which no answer is required. To the extent an answer is required, Lotus admits that the '991 patent is entitled "Protocol for the Treatment of Lupus Nephritis," that a purported copy of the '991 patent is attached as Exhibit 2, and that the issue date on the cover of the '991 patent is April 11, 2023. Lotus denies that the '991 patent was "duly and lawfully issued," and further denies any remaining allegations of Paragraph 18.

19. 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: Paragraph 19 contains legal conclusions to which no answer is required. To the extent an answer is required, Lotus admits that NDA No. 213716 was approved by the Food

and Drug Administration ("FDA") for the sale and manufacture of LUPKYNIS®. Lotus admits that the electronic FDA publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," otherwise known as the electronic "Orange Book," identifies the Patents-in-Suit in connection with the NDA for LUPKYNIS®. Lotus denies the remaining allegations of Paragraph 19 of the Complaint.

LOTUS'S INFRINGING ACTIVITIES

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

ANSWER: Lotus incorporates its answers to the preceding paragraphs as if fully set forth herein.

21. By letter dated February 26, 2025, addressed to Aurinia ("Notice Letter"), Lotus notified Aurinia that Lotus 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: Lotus admits that its February 26, 2025 letter speaks for itself. Lotus denies the remaining allegations of Paragraph 21 of the Complaint.

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

ANSWER: Lotus admits that its February 26, 2025 letter speaks for itself. Lotus denies the remaining allegations of Paragraph 22 of the Complaint.

23. On information and belief, Lotus, 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: Denied.

24. On information and belief, if the FDA approves Lotus's Voclosporin ANDA, Lotus, 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: Denied.

25. In the Notice Letter, Lotus 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 Lotus's generic voclosporin product.

ANSWER: Lotus admits that its February 26, 2025 letter speaks for itself. Lotus denies the remaining allegations of Paragraph 25 of the Complaint.

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

ANSWER: Lotus is without sufficient information with which to form a belief as to the truth or accuracy of the allegations in Paragraph 26 of the Complaint and, therefore, denies all allegations.

COUNT I
INFRINGEMENT OF THE '036 PATENT

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

ANSWER: Lotus incorporates its answers to the preceding paragraphs as if fully set forth herein.

28. Lotus'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: Denied.

29. On information and belief, Lotus 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: Admitted.

30. On information and belief, Lotus had actual knowledge of the '036 patent at least since its filing of its Voclosporin ANDA and at least since February 26, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

33. On information and belief, Lotus knows, should know, and intends that physicians will prescribe, and patients will take, Lotus'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.

34. On information and belief, Lotus has knowledge of the '036 patent and, by its proposed package insert for Lotus'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.

35. On information and belief, Lotus 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 Lotus'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.

36. On information and belief, Lotus 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.

37. On information and belief, Lotus has had and continues to have knowledge that Lotus'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.

38. On information and belief, upon FDA approval of Lotus's Voclosporin ANDA, Lotus 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.

39. If Lotus'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

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

ANSWER: Lotus incorporates its answers to the preceding paragraphs as if fully set forth herein.

41. Lotus'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: Denied.

42. On information and belief, Lotus 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: Admitted.

43. On information and belief, Lotus had actual knowledge of the '991 patent at least since its filing of its Voclosporin ANDA and at least since February 26, 2025, the date the Notice Letter was sent to Aurinia.

ANSWER: Denied.

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

ANSWER: Denied.

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

ANSWER: Denied.

46. On information and belief, Lotus knows, should know, and intends that physicians will prescribe, and patients will take, Lotus'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.

47. On information and belief, Lotus has knowledge of the '991 patent and, by its proposed package insert for Lotus'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.

48. On information and belief, Lotus 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 Lotus'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.

49. On information and belief, Lotus 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.

50. On information and belief, Lotus has had and continues to have knowledge that Lotus'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.

51. On information and belief, upon FDA approval of Lotus's Voclosporin ANDA, Lotus 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.

52. If Lotus'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.

GENERAL DENIAL AND RESPONSE TO PRAYER FOR RELIEF

To the extent not specifically admitted above, Lotus hereby denies all allegations in the Complaint. Lotus further denies that Plaintiff is entitled to any relief whatsoever. Lotus denies that Plaintiff is entitled to the judgment or other relief prayed for in Paragraphs A-E of the Complaint under the heading PRAYER FOR RELIEF.

LOTUS'S DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted, and without undertaking any of the burdens imposed by law on Plaintiff, Lotus avers and asserts the following separate defenses to the Complaint:

FIRST SEPARATE DEFENSE
(INVALIDITY OF THE '036 PATENT)

One or more claims of the '036 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '036 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220206 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '036 Patent.

THIRD SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '036 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220206 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '036 Patent.

FOURTH SEPARATE DEFENSE
(INVALIDITY OF THE '991 PATENT)

One or more claims of the '991 Patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, *et seq.* including, *inter alia*, §§ 101, 102, 103, and/or 112, or under other judicially-created bases for invalidation.

FIFTH SEPARATE DEFENSE
(NO DIRECT INFRINGEMENT OF THE '991 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220206 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '1991 Patent.

SIXTH SEPARATE DEFENSE
(NO INDIRECT INFRINGEMENT OF THE '991 PATENT)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 220206 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '991 Patent.

SEVENTH SEPARATE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiff's Complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

EIGHTH SEPARATE DEFENSE
(LACK OF SUBJECT MATTER JURISDICTION)

Plaintiff's Complaint lacks subject matter jurisdiction over any and all claims asserted under 35 U.S.C. § 271(a), (b), and/or (c).

NINTH SEPARATE DEFENSE
(PROSECUTION HISTORY ESTOPPEL)

By virtue of the prosecution proceedings before the United States Patent and Trademark Office of the patent applications leading to the '036 and '991 patents, Plaintiff is estopped from maintaining that any valid or enforceable claim of the '036 and '991 patents is infringed by the product that is the subject of ANDA No. 220206.

RESERVATION OF ADDITIONAL SEPARATE DEFENSES

Lotus reserves the right to plead additional separate defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

LOTUS'S COUNTERCLAIMS

For its counterclaims against Counterclaim-Defendant Aurinia Pharmaceuticals Inc. ("Counterclaim-Defendant" or "Plaintiff"), Counterclaim-Plaintiff Lotus Pharmaceutical Co., Ltd. ("Lotus" or "Counterclaim-Plaintiff"), states as follows:

THE PARTIES

1. On information and belief, Counterclaim-Defendant Aurinia Pharmaceuticals Inc. 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.

2. Counterclaim-Plaintiff Lotus Pharmaceutical Co., Ltd. is a corporation organized under the laws of Taiwan, having a principal place of business at 17F, No. 277, Song Den Road, Xin Yi District, Taipei City 110, Taiwan.

NATURE OF THE ACTION

3. Lotus 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 jurisdiction over these counterclaims under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

5. This Court has personal jurisdiction over Plaintiff because, among other reasons, Plaintiff subjected itself to the jurisdiction of this Court by filing its complaint here.

6. Venue is proper in this Court under 28 U.S.C. §§ 1391(b) and 1400(b), and by Plaintiff's choice of forum.

7. There is an actual and justiciable controversy between the parties as to the infringement and invalidity of the Patents-in-Suit.

BACKGROUND

A. FDA Approval of New Brand Name Drugs

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

9. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

10. An NDA must include, among other things, the number of any patent that allegedly 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 unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b)(1), (c)(2).

11. Upon approval of the NDA, the FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." 21 C.F.R. § 314.53(e).

12. FDA's duties with respect to the Orange Book are purely ministerial. If the NDA holder submits a patent to the FDA for listing in the Orange Book, the patent is listed in the Orange Book. *See* 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.53(e)-(f). FDA does not substantively review the submitted patent information to ensure that it is accurate or that the NDA holder properly submitted it in connection with the NDA drug (or "reference listed drug"), but instead relies on the NDA holder to properly list the patents.

B. FDA Approval of New Generic Drugs

13. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments, to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)). Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition.

14. Under the Hatch-Waxman Amendments, a generic manufacturer submits to the FDA what is called an Abbreviated New Drug Application ("ANDA").

15. Among other things, an ANDA must also contain a "certification" to each patent that the NDA holder has submitted to the FDA for listing in the Orange Book in connection with the reference listed drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

16. A "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, the applicant seeks FDA approval

of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); *see also* 21 C.F.R. § 314.94(a)(12)(i)(A)(4).

17. An applicant submitting an ANDA containing a paragraph IV certification must notify both the patent holder and NDA holder of each of its paragraph IV certifications. *See* 21 U.S.C. § 355(j)(2)(B).

18. Upon receiving notice of the paragraph IV certifications, the patent holder has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

19. Patent holders have a significant strategic incentive to file suit within 45 days of receiving notice of the paragraph IV certifications because doing so, regardless of merit, prevents the FDA from approving the generic maker's ANDA for a period of 30 months, absent certain exceptions requiring court actions. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

20. If the court hearing the infringement action decides the patent is valid, enforceable, and would be infringed by the proposed product in the ANDA, the FDA will not approve the ANDA until the patent expires. *Id.* If, however, the court hearing the infringement action rules before the expiration of the 30-month period that the patent is invalid, unenforceable, or not infringed, the FDA may approve the ANDA effective on the date when the court enters the judgment. *Id.*

C. Lotus's ANDA and Plaintiff's Complaint

21. Lotus submitted Abbreviated New Drug Application ("ANDA") No. 220206 ("Lotus's ANDA") to obtain FDA approval to engage in the commercial manufacture, use, and sale of generic voclosporin products ("Lotus's ANDA Product").

22. On information and belief, Plaintiff holds approved New Drug Application ("NDA") No. 213716 for LUPKYNIS® under Section 505(b) of the Federal Food Drug and

Cosmetic Act ("FFDCA").

23. Lotus's ANDA shows that Lotus's ANDA Products are bioequivalent to the products that are the subject of NDA No. 213716.

24. On information and belief, Plaintiff caused the Patents-in-Suit to be listed in the publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly called the "Orange Book," as patents that purportedly claim the drug listed in, and/or purportedly claim a method of using the drug for which Plaintiff submitted, NDA No. 213716.

25. The '036 patent is entitled "Protocol for the Treatment of Lupus Nephritis"; the issue date identified on the cover of the '036 patent is May 14, 2019; and Aurinia is identified as the assignee of the '036 patent.

26. The '991 patent is entitled "Protocol for the Treatment of Lupus Nephritis"; the issue date identified on the cover of the '991 patent is April 11, 2023; and Aurinia is identified as the assignee of the '991 patent.

27. Lotus's ANDA contains "Paragraph IV" certifications under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Lotus's ANDA Product.

28. On February 26, 2025 Lotus sent Plaintiff written notice of Lotus's Paragraph IV Certifications ("Lotus's Notice Letter") pursuant to 21 U.S.C. § 355(j)(2)(B). Lotus's Notice Letter asserted that the claims of the Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by Lotus's ANDA or the products or activities described therein.

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

30. On April 11, 2025, Plaintiff filed the present lawsuit alleging infringement of the Patents-in-Suit. There has been and now is an actual and justiciable controversy between Lotus and Plaintiff as to whether Lotus's ANDA Products infringe, induce infringement, or contribute to the infringement of any valid and enforceable claim of the Patents-in-Suit.

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

31. Lotus incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

32. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Lotus regarding whether the filing of Lotus's ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lotus's ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the '036 patent.

33. Lotus incorporates by reference Lotus's Notice Letter, which contains exemplary and nonlimiting explanations that the '036 patent is not infringed by Lotus's ANDA or the products or activities described therein.

34. Lotus is entitled to a declaration that it 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 such infringement.

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

35. Lotus incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

36. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Lotus regarding whether the claims of the '036 patent are invalid.

37. Lotus incorporates by reference Lotus's Notice Letter, which contains exemplary

and nonlimiting explanations that the claims of the ’036 patent are invalid.

38. Lotus is entitled to a declaration that all claims of the ’036 patent are invalid under 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.

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

39. Lotus incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

40. There is an actual, substantial, continuing, and justiciable controversy between Plaintiff and Lotus regarding whether the filing of Lotus’s ANDA and/or the manufacture, use, offer to sell, sale, and/or importation into the United States of Lotus’s ANDA Products infringe, have infringed, and/or will infringe any valid and enforceable claim of the ’991 patent.

41. Lotus incorporates by reference Lotus’s Notice Letter, which contains exemplary and nonlimiting explanations that the ’991 patent is not infringed by Lotus’s ANDA or the products or activities described therein.

42. Lotus is entitled to a declaration that it 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 such infringement.

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

43. Lotus incorporates by reference the allegations in the foregoing paragraphs of its counterclaims.

44. There is an actual, substantial, continuing and justiciable controversy between Plaintiff and Lotus regarding whether the claims of the ’991 patent are invalid.

45. Lotus incorporates by reference Lotus’s Notice Letter, which contains exemplary

and nonlimiting explanations that the claims of the '991 patent are invalid.

46. Lotus is entitled to a declaration that all claims of the '991 patent are invalid under 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.

PRAYER FOR RELIEF

WHEREFORE, Lotus respectfully requests that this Court enter a judgment in its favor and against Plaintiff as follows:

(a) Dismissing the Complaint with prejudice and entering judgment for Lotus;

(b) Declaring that no valid claim of the Patents-in-Suit would be infringed by the manufacture, use, sale, offer for sale, and/or importation of Lotus's ANDA Products pursuant to ANDA No. 220206;

(c) Declaring that the claims of the Patents-in-Suit are invalid;

(d) Entering judgment for Lotus on its affirmative defenses and any and all additional defenses and counterclaims that discovery may reveal;

(e) Enjoining Counterclaim-Defendant, its officers, agents, servants, employees, attorneys and any person who acts in concert or participation with Counterclaim-Defendant from threatening to assert or otherwise attempting to enforce the Patents-in-Suit against Lotus, its customers, suppliers, or anyone in privity with Lotus;

(f) Declaring that this case is exceptional pursuant to 35 U.S.C. § 285 and awarding Lotus its reasonable attorneys' fees and costs incurred in this action;

(g) Awarding Lotus its costs and expenses incurred in this action; and

(h) Awarding Lotus such other and further relief as this Court may deem proper.

Dated: June 10, 2025

By: */s/ Rebekah R. Conroy*

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Counsel for Defendant Lotus Pharmaceutical Co., Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2

Pursuant to Local Civil Rule 11.2, Defendant Lotus Pharmaceutical Co., Ltd., by and through its undersigned counsel, hereby certifies that the matter in controversy is not subject to any other action pending in any court, or any pending arbitration or administrative proceeding known to Defendant.

Respectfully Submitted,

Dated: June 10, 2025

/s/ Rebekah R. Conroy

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Counsel for Defendant Lotus Pharmaceutical Co., Ltd.

CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

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

Respectfully Submitted,

Dated: June 10, 2025

/s/ Rebekah R. Conroy

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