IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY & CO., INCYTE CORP., and INCYTE HOLDINGS CORP.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
MSN LABORATORIES PRIVATE LIMITED, and MSN PHARMACEUTICALS INC.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly"), Incyte Corporation, and Incyte Holdings Corporation (collectively "Plaintiffs") by their attorneys, hereby allege against Defendants MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals Inc. ("MSN Pharma") (collectively, "MSN" or "Defendants") as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by MSN of Abbreviated New Drug Application ("ANDA") No. 217585 ("the MSN ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, use, import, distribute, offer to sell, and/or sell generic versions of Olumiant® (baricitinib) tablets, 4 mg strength ("MSN's Proposed ANDA Product") prior to the expiration of U.S. Patent Nos. 8,158,616 ("the '616 Patent"). By letters dated September 29, 2023 ("MSN September 2023 Notice Letter") and October 3, 2023 ("MSN October 2023 Notice Letter"), MSN notified Plaintiffs that it had amended the MSN ANDA to include generic versions of Olumiant® in 4 mg strength. Upon information and belief, MSN's Proposed ANDA Product will be marketed as a competing product to Olumiant®

(baricitinib), a product approved for, *inter alia*, the treatment of: COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO; and adult patients with severe alopecia areata.

PARTIES

2. Plaintiff Lilly is a corporation organized and existing under the laws of Indiana, having a place of business at Lilly Corporate Center, Indianapolis, IN 46285.

3. Plaintiff Incyte Corporation is a corporation organized and existing under the laws of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

4. Plaintiff Incyte Holdings Corporation is a corporation organized and existing under the laws of Delaware, having a place of business at 1801 Augustine Cut-Off, Wilmington, DE 19803.

5. Upon information and belief, Defendant MSN Labs is a private limited company organized and existing under the laws of the Republic of India, having a place of business at MSN House, Plot No. C-24, Sanathnagar Industrial Estate, Hyderbad, Telangana 500018, India. Upon information and belief, MSN Labs is in the business of, among other things, manufacturing, selling, importing, and distributing generic versions of branded pharmaceutical drugs through various operating subsidiaries throughout the United States, including in Delaware.

6. Upon information and belief, MSN Pharma is a corporation organized and existing under the laws of Delaware, having its corporate offices and a place of business at 20 Duke Road, Piscataway, NJ 08854. Upon information and belief, MSN Pharma is a wholly owned subsidiary of MSN Labs. Upon information and belief, MSN Pharma is the designated U.S. agent for MSN Labs in accordance with 21 C.F.R. §§ 314.50(a)(5) and 314.94(a)(1). Upon information and belief, MSN Pharma is in the business of, among other things, selling, importing, and distributing generic

versions of branded pharmaceutical drug products throughout the United States, including in Delaware.

7. Upon information and belief, MSN Labs and MSN Pharma collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. Upon further information and belief, MSN Labs and MSN Pharma are agents of each other and/or operate in concert as integrated parts of the same business group.

8. Upon information and belief, MSN Labs and MSN Pharma acted in concert to develop MSN's Proposed ANDA Product that is the subject of the MSN ANDA and to seek regulatory approval from the FDA to market and sell MSN's Proposed ANDA Product throughout the United States, including in Delaware.

9. Upon information and belief, MSN Labs and MSN Pharma intend to benefit directly if the MSN ANDA is approved by participating in the development, regulatory approval, marketing, manufacture, importation, distribution, and/or sale of MSN's Proposed ANDA Product.

10. Upon information and belief, MSN Labs and MSN Pharma intend to act collaboratively to obtain approval for the MSN ANDA, and, in the event the FDA approves that ANDA, to commercially manufacture, use, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United States, including in Delaware.

11. Upon information and belief, MSN Labs and MSN Pharma submitted the MSN ANDA seeking approval to market and sell baricitinib tablets in 4 mg strength.

12. Upon information and belief, MSN Labs and MSN Pharma intend to and will commercially manufacture, use, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United States, including in Delaware, in the event the FDA approves MSN's ANDA.

JURISDICTION AND VENUE

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

14. This Court has personal jurisdiction over MSN Labs because, among other things, on information and belief: (1) MSN Labs and its affiliate MSN Pharma submitted MSN's ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product in the United States, including in Delaware; and (2) upon approval of MSN's ANDA, MSN Labs and its affiliate, agent, and/or alter ego MSN Pharma, themselves and through their affiliates and subsidiaries, will market, distribute, offer for sale, sell, and/or import MSN's Proposed ANDA Product in the United States, including in Delaware, and will derive substantial revenue from the use or consumption of MSN's Proposed ANDA Product in Delaware. On information and belief, upon approval of MSN Pharma Limited's ANDA, MSN's Proposed ANDA Product will, among other things, be marketed, distributed, offered for sale, sold, and/or imported in Delaware; prescribed by physicians practicing in Delaware; dispensed by pharmacies located within Delaware; and/or used by patients in Delaware, all of which would have substantial effects on Delaware.

15. In addition, this Court has personal jurisdiction over MSN Labs because, inter alia, MSN Labs, itself and through its affiliates, subsidiaries, agents, and/or alter egos, including MSN Pharma, has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, MSN Labs, itself and through its affiliates, subsidiaries, agents, and/or alter egos including MSN Pharma, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes a broad range of generic pharmaceutical products throughout the United States, including in Delaware, and

therefore transacts business within Delaware relating to Plaintiffs' claims, and/or has engaged in systematic and continuous business contacts within Delaware.

16. In addition, this Court has personal jurisdiction over MSN Labs because it has committed, aided, abetted, induced, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led and/or will lead to foreseeable harm and injury to Incyte Corporation and Incyte Holdings Corporation, both Delaware corporations.

17. In addition, this Court has personal jurisdiction over MSN Labs because it regularly engages in patent litigation concerning MSN's ANDA products in this District, does not contest personal jurisdiction in this District, and has purposefully availed itself of the rights and benefits of this Court by asserting claims and/or counterclaims in this District. *See, e.g.*, *Otsuka Pharmaceutical Co., Ltd. et al. v. MSN Laboratories Private Ltd., MSN Pharmaceuticals Inc. and MSN Life Sciences Private Ltd.*, C.A. No. 20-1428 (D. Del.); *Intercept Pharmaceuticals, Inc. et al. v. MSN Laboratories Private Ltd., MSN Pharmaceuticals, Inc. and MSN Life Sciences Private Ltd.*, C.A. No. 20-1214 (D. Del.). Furthermore, MSN Labs did not contest this Court's personal jurisdiction in a pending action brought by Plaintiffs in this District concerning the MSN ANDA. *See Eli Lilly & Co. et al. v. MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc.*, C.A. No. 22-1115-CFC, D.I. 19 at 5-7 (D. Del. Nov. 23, 2022).

18. Alternatively, to the extent personal jurisdiction over MSN Labs in Delaware is not held to be proper, then, upon information and belief, MSN Labs is not subject to jurisdiction in any state's courts of general jurisdiction. Therefore, there is personal jurisdiction over MSN Labs in this Court pursuant to Federal Rule of Civil Procedure 4(k)(2) and exercising jurisdiction over it is consistent with the United States Constitution and laws.

19. This Court has personal jurisdiction over MSN Pharma because, on information

and belief, MSN Pharma is a corporation organized and existing under the laws of the Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. Therefore, MSN Pharma has consented to general jurisdiction in Delaware.

20. Because plaintiffs Incyte Corporation and Incyte Holdings Corporation are incorporated and have places of business in Delaware, the injury and consequence of MSN's submission of the MSN ANDA, challenging Plaintiffs' patent rights, are suffered in Delaware. Upon information and belief, MSN knew that it was deliberately challenging the patent rights of Delaware entities and seeking to challenge intellectual property held in Delaware and that the effects of any successful challenge of the '616 Patent would be felt by Plaintiffs in Delaware. Moreover, in an action brought in this District arising out of MSN's submission of the MSN ANDA, MSN did not contest this Court's personal jurisdiction. *See Eli Lilly & Co. et al. v. MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc.*, C.A. No. 22-1115-CFC, D.I. 19 at 5-7 (D. Del. Nov. 23, 2022).

21. For at least the above reasons, it would not be unfair or unreasonable for MSN Labs and MSN Pharma to litigate this action in this District, and MSN Labs and MSN Pharma are subject to personal jurisdiction in this District.

22. Venue is proper in this Court under 28 U.S.C. §§ 1391(c) and/or 1400(b) with respect to MSN Labs at least because, on information and belief, MSN Labs is a foreign corporation that may be sued in any judicial district.

23. Venue is proper in this District under 28 U.S.C. §§ 1391(c) and/or 1400(b) with respect to MSN Pharma at least because, on information and belief, MSN Pharma is a corporation organized and existing under the laws of Delaware and therefore resides in Delaware for purposes of venue.

BACKGROUND

OLUMIANT® (BARICITINIB)

24. On May 31, 2018 and October 8, 2019, the FDA granted Lilly approval to market Olumiant® (baricitinib), 1 mg and 2 mg strengths, for the treatment of moderately to severely active rheumatoid arthritis in adult patients who have an inadequate response to one or more TNF antagonist therapies. On May 10, 2022, the FDA granted Lilly supplemental approval to market Olumiant® (baricitinib), 1 mg, 2 mg, and 4 mg strengths, for the treatment of COVID-19 in hospitalized adults requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or ECMO. On June 13, 2022, the FDA granted Lilly supplemental approval to market Olumiant® (baricitinib), 1 mg, 2 mg, and 4 mg strengths, for the treatment of adult patients with severe alopecia areata.

25. The active pharmaceutical ingredient in Olumiant® is baricitinib. Baricitinib is a Janus kinase (JAK) inhibitor with the chemical name {1-(ethylsulfonyl)-3-[4-(7*H*-pyrrolo[2,3-*d*]pyrimidin-4-yl)-1*H*-pyrazol-1-yl]azetidin-3-yl}acetonitrile. Olumiant® (baricitinib) is FDA approved in 1, 2, and 4 mg dosage strengths. The recommended dosage for the treatment of adult patients with moderately to severely active rheumatoid arthritis is 2 mg once daily, with a modified dosage to 1 mg under certain conditions. The recommended dosage for the treatment of COVID-19 is 4 mg once daily, with modified doses to 1 mg and 2 mg under certain conditions. The recommended dosage for the treatment of severe alopecia areata is 2 mg once daily, with modified doses to 4 mg or 1 mg under certain conditions.

26. Lilly markets Olumiant® (baricitinib) in the United States pursuant to approved New Drug Application ("NDA") No. 207924.

27. Lilly is the holder of approved NDA No. 207924 for Olumiant® (baricitinib).

28. The ’616 Patent is listed for NDA No. 207924 for Olumiant® (baricitinib) in the FDA’s *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the “Orange Book.”

29. The ’616 Patent covers, *inter alia*, baricitinib and pharmaceutical compositions containing baricitinib.

30. The ’616 Patent, titled “Azetidine and Cyclobutane Derivatives as JAK Inhibitors” was duly and legally issued on April 17, 2012. A copy of the ’616 Patent is attached as Exhibit A.

31. Incyte Corporation and Incyte Holdings Corporation are the assignees and owners of the ’616 Patent.

32. Lilly is the exclusive licensee of the ’616 Patent.

33. There is an actual case or controversy between the parties regarding MSN’s liability for its infringement of the ’616 Patent.

MSN’S ANDA

34. By letter dated July 25, 2022 (“MSN July 2022 Notice Letter”), MSN notified Plaintiffs that it had submitted the MSN ANDA, seeking FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of generic versions of Olumiant® (baricitinib) tablets, 1 mg and 2 mg strengths prior to the expiration of the ’616 Patent and U.S. Patent No. 8,420,629 (“the ’629 Patent”). According to the MSN July 2022 Notice Letter, included within the MSN ANDA is a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the ’616 Patent and ’629 Patent are invalid and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of generic versions of Olumiant® (baricitinib) tablets, 1 mg and 2 mg strengths.

35. Within 45 days of receiving the MSN July 2022 Notice Letter, Plaintiffs filed a

complaint asserting patent infringement asserting the '616 Patent and '629 Patent against MSN arising out of MSN's submission of the MSN ANDA. *See Eli Lilly & Co. et al. v. MSN Laboratories Private Ltd. and MSN Pharmaceuticals Inc.*, C.A. No. 22-1115-CFC, D.I. 1 (D. Del. Aug. 24, 2022). That action was consolidated with another action pending before the Court also involving Plaintiffs' assertion of the '616 Patent and '629 Patent against Aurobindo Pharma Limited and Aurobindo Pharma U.S.A., Inc. (collectively "Aurobindo") arising out of Aurobindo's submission of ANDA No. 217542. *See Eli Lilly & Co. et al. v. Aurobindo Pharma Ltd. et al.*, C.A. No. 22-1114-CFC (Lead Case), D.I. 20 (D. Del. Dec. 1, 2022).

36. The MSN September and October 2023 Notice Letters informed Plaintiffs that MSN amended the MSN ANDA to additionally seek FDA approval to engage in the commercial manufacture, use, sale, or offer for sale of generic versions of Olumiant® (baricitinib) tablets, 4 mg strength, prior to the expiration of the '616 Patent. According to the MSN September and October 2023 Notice Letters, included within the MSN ANDA is a Paragraph IV Certification that the '616 Patent is invalid and/or will not be infringed by the commercial manufacture, use, sale, or offer for sale of MSN's Proposed ANDA Product.

37. MSN was aware of the '616 Patent when it amended the MSN ANDA with a Paragraph IV Certification to seek approval of MSN's Proposed ANDA Product.

38. On information and belief, baricitinib is the active ingredient in MSN's Proposed ANDA Product. On information and belief, MSN's Proposed ANDA Product is a pharmaceutical formulation comprising baricitinib oral tablets in 4 mg strength.

39. On information and belief, the MSN ANDA refers to and relies upon the NDA for Olumiant® (baricitinib) and contains data that, according to MSN, demonstrates bioequivalence of MSN's Proposed ANDA Product and Olumiant® (baricitinib), *see* 21 U.S.C. § 355(j)(2); 21 C.F.R.

§ 314.94(a)(7).

40. On information and belief, MSN intends to sell its Proposed ANDA Product with a label that, *inter alia*, instructs and encourages the administration of 4 mg baricitinib tablets.

41. On information and belief, MSN intends that its Proposed ANDA Product be used as set forth in its Proposed ANDA Product label.

42. This action is being filed within 45 days of Plaintiffs' receipt of the MSN September and October 2023 Notice Letters.

COUNT I
(Infringement of the '616 Patent)

43. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

44. Claim 1 of the '616 Patent covers the compound {1-(Ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]azetidin-3-yl}acetonitrile, or a pharmaceutically acceptable salt thereof.

45. Upon information and belief, MSN's Proposed ANDA Product is covered by one or more claims of the '616 Patent, including at least claim 1, because it contains baricitinib, which is a compound with the chemical name {1-(Ethylsulfonyl)-3-[4-(7H-pyrrolo[2,3-d]pyrimidin-4-yl)-1H-pyrazol-1-yl]azetidin-3-yl}acetonitrile.

46. Upon information and belief, the manufacture, use, sale, offer for sale, or importation of MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, will infringe one or more claims of the '616 Patent, including at least claim 1, either literally or under the doctrine of equivalents.

47. Upon information and belief, MSN submitted as part of the MSN ANDA a Paragraph IV Certification, asserting that the claims of the '616 Patent are invalid and/or not infringed by the manufacture, use, offer for sale, or sale of MSN's Proposed ANDA Product.

48. MSN did not contend in the MSN September and October 2023 Notice Letters that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe claims 1 or 3 of the '616 Patent.

49. MSN has no reasonable basis to believe that MSN's Proposed ANDA Product, or the use of MSN's Proposed ANDA Product in accordance with and as directed by MSN's proposed labeling for that product, would not infringe one or more claims of the '616 Patent.

50. The purpose of submitting the MSN ANDA to the FDA was to obtain approval under the Federal Food Drug and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, importation, and/or sale of MSN's Proposed ANDA Product prior to the expiration of the '616 Patent.

51. MSN's submission of the MSN ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, importation, and/or offer for sale of MSN's Proposed ANDA Product prior to the expiration of the '616 Patent was an act of infringement of the '616 Patent under 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, MSN intends to engage in the commercial manufacture, use, sale, importation, and/or offer for sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of the MSN ANDA and any amendments thereto, *i.e.*, prior to the expiration of the '616 Patent.

53. Upon information and belief, MSN has knowledge of the '616 Patent at least because the '616 Patent is listed in the Orange Book for Lilly's Olumiant® (baricitinib) drug product. Notwithstanding this knowledge, MSN continues to assert its intent to engage in the manufacture, use, offer for sale, importation, and/or sale of MSN's Proposed ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of the MSN ANDA and any amendments thereto.

54. Upon information and belief, MSN intends to sell its Proposed ANDA Product with a label that includes instructions to administer 4 mg baricitinib tablets in a manner that will infringe at least claim 1 of the '616 Patent.

55. Upon information and belief, MSN plans and intends to, and will, actively induce infringement of the '616 Patent when the MSN ANDA and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '616 Patent. Further upon information and belief, MSN plans and intends to, and will, do so immediately and imminently upon approval.

56. The foregoing actions by MSN constitute and/or will constitute infringement of the '616 Patent and active inducement of infringement of the '616 Patent, either literally or under the doctrine of equivalents, pursuant to 35 U.S.C. §§ 271(a) and (b).

57. Unless MSN is enjoined from infringing the '616 Patent and actively inducing infringement of the '616 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that MSN has infringed one or more claims of the '616 Patent under

35 U.S.C. § 271(e)(2)(A) by submitting the MSN ANDA to the FDA;

(b) A judgment that MSN's making, using, offering to sell, selling, marketing, distributing, or importing into the United States of MSN's Proposed ANDA Product prior to the expiration of the '616 Patent will infringe, actively induce infringement of, and/or contribute to infringement of one or more claims of the '616 Patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for MSN to make, use, offer for sale, sell, market, distribute, or import MSN's Proposed ANDA Product, or any product the use of which infringes the '616 Patent, be not earlier than the expiration date of the '616 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(d) A preliminary and/or permanent injunction pursuant to 35 U.S.C. § 271(e)(4)(B) restraining and enjoining MSN, MSN's affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in privity or concert with MSN, from making, using, selling, offering to sell, marketing, distributing, or importing MSN's Proposed ANDA Product, or any product the use of which infringes one or more claims of the '616 Patent, prior to the expiration date of the '616 Patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(e) A declaration that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

(f) An award of Plaintiffs' costs and expenses in this action; and

(g) Such further and other relief as this Court may deem just and proper.

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November 8, 2023

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