IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

INDIVIOR INC.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
LUPIN INC., LUPIN LIMITED, and LUPIN PHARMACEUTICALS, INC.,	)	
	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Indivior Inc. ("Indivior") files this Complaint against Defendants Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. (collectively "Lupin" or "Defendants") and alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1, *et seq.*, and in particular under 35 U.S.C. § 271, the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, that arises out of Lupin Inc.'s submission of Abbreviated New Drug Application ("ANDA") No. 219264 to the U.S. Food and Drug Administration ("FDA"). Through ANDA No. 219264, Defendants seek approval to market generic versions of OPVEE® (nalmefene) nasal spray ("Lupin's ANDA Product") prior to the expiration of Indivior's U.S. Patent Nos. 11,458,091 ("the '091 Patent") and 12,290,596 ("the '596 Patent") (collectively "Patents-in-Suit").

THE PARTIES

2. Indivior is a Delaware corporation having a principal place of business at 10710 Midlothian Turnpike, Suite 125, North Chesterfield, VA 23235.

3. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. On information and belief, Lupin Inc. is a wholly owned subsidiary of Nanomi B.V., which is a wholly owned subsidiary of Lupin Limited. On information and belief, Lupin Inc. is in the business of, *inter alia*, developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

4. On information and belief, Defendant Lupin Limited is a corporation organized and existing under the laws of India, having a principal place of business at 3rd Floor, Kalpataru Inspire, Off. Western Expressway Highway, Santacruz (East), Mumbai, Maharashtra 400 055, India, and a manufacturing facility at Nagpur 441 108, Maharashtra, India. On information and belief, Lupin Limited is in the business of, *inter alia*, developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 5801 Pelican Bay Boulevard, Suite 500, Naples, Florida 34108. On information and belief, Lupin Pharmaceuticals, Inc. is 97% owned by Lupin Inc., with the remaining 3% interest held by Lupin Limited. On information and belief, Lupin Pharmaceuticals, Inc. is in the business of, *inter alia*, developing, manufacturing, and/or distributing generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

6. On information and belief, Lupin Inc. and Lupin Pharmaceuticals, Inc. act at the direction, and for the benefit, of Lupin Limited, and are controlled and/or dominated by Lupin Limited.

7. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. collaborate with respect to the development, regulatory approval, marketing, sale, and/or distribution of pharmaceutical products. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. are agents of one another and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length.

8. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. caused ANDA No. 219264 ("Lupin's ANDA") to be submitted to the FDA and seek approval of that application to permit Lupin to market a generic version of OPVEE® (nalmefene) nasal spray in the United States.

9. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. acted collaboratively in the preparation and submission of ANDA No. 219264 and continue to act collaboratively in pursuing FDA approval of ANDA No. 219264 and seeking to market the proposed generic nalmefene nasal spray described in that application.

10. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. intend to commercially manufacture, market, offer for sale, and sell the product described in ANDA No. 219264 ("Lupin's ANDA Product") throughout the United States, including in the State of Delaware, in the event the FDA approves Lupin's ANDA.

11. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. rely on material assistance from each other to market, distribute, offer for sale, and/or sell

generic drugs in the U.S. market, including in the State of Delaware. On information and belief, Lupin Inc., Lupin Limited, and Lupin Pharmaceuticals, Inc. intend to act collaboratively to commercially manufacture, market, distribute, offer for sale, and/or sell Lupin's ANDA Product, in the event the FDA approves Lupin's ANDA.

JURISDICTION AND VENUE

12. This civil action for patent infringement arises under the patent laws of the United States, including 35 U.S.C. § 271, and alleges infringement of the Patents-in-Suit. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201, and 2202 and 35 U.S.C. § 1 et seq.

13. This Court has personal jurisdiction over Lupin Inc. and Lupin Pharmaceuticals, Inc. because they are corporations organized and existing under the laws of the State of Delaware.

14. Additionally, this Court has personal jurisdiction over each of Lupin Inc., Lupin Pharmaceuticals, Inc., and Lupin Limited because, on information and belief, each of Lupin Inc., Lupin Pharmaceuticals, Inc., and Lupin Limited, *inter alia*, has continuous and systematic contacts with the State of Delaware; regularly conducts business in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos; has purposefully availed itself of the privilege of doing business in the State of Delaware; and intends to sell Lupin's ANDA Product in the State of Delaware upon approval of Lupin's ANDA.

15. On information and belief, Lupin is licensed to sell pharmaceutical products in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

16. Lupin has committed, or aided, abetted, contributed to, and/or participated in the commission of, acts of infringement of one or more of the Patents-in-Suit that will lead to foreseeable harm and injury to Indivior. On information and belief, Lupin prepared and filed

Lupin's ANDA with the intention of seeking to market Lupin's ANDA Product nationwide, including in Delaware.

17. On information and belief, Lupin plans to sell Lupin's ANDA Product in the State of Delaware, list Lupin's ANDA Product on the State of Delaware's prescription drug formulary, and seek Medicaid reimbursements for sales of Lupin's ANDA Product in the State of Delaware, either directly or through one or more of its wholly owned subsidiaries, agents, and/or alter egos.

18. On information and belief, Lupin knows and intends that Lupin's ANDA Product will be distributed, through its established channels of distribution, and sold in the State of Delaware and will thereby displace sales of OPVEE® (nalmefene), causing injury to Indivior.

19. Lupin has engaged in patent litigation concerning FDA-approved drug products in Delaware and has not contested personal jurisdiction or venue in Delaware in such litigation. *See, e.g.*, *Mitsubishi Tanabe Pharma Corp. v. Lupin Ltd. et al.*, No. 24-1423, D.I. 9 (D. Del. March 7, 2025); *Astellas Pharma Inc. et al. v. Lupin Ltd. et al.*, No. 24-939, D.I. 9 (D. Del. Oct. 14, 2024); *Bayer Pharma AG et al. v. Lupin Ltd. et al.*, No. 24-138, D.I. 10 (D. Del. March 19, 2024); *Harmony Biosciences, LLC et al. v. Lupin Ltd. et al.*, No. 23-1286, D.I. 19 (D. Del. Feb. 26, 2024); *ZS Pharma, Inc. et al. v. Lupin Ltd. et al.*, No. 23-1189, D.I. 9 (D. Del. Nov. 17, 2023); *Amicus Therapeutics US, LLC et al. v. Lupin Ltd. et al.*, No. 23-964, D.I. 9 (D. Del. Sept. 22, 2023); *Actelion Pharms. US, Inc. et al. v. Cipla Ltd. et al.*, No. 22-1450, D.I. 23 (D. Del. May 8, 2023); *Neurocrine Biosciences, Inc. v. Lupin Ltd. et al.*, No. 22-1061, D.I. 6 (D. Del. Sept. 9, 2022); *ZS Pharma, Inc. et al. v. Lupin Ltd. et al.*, No. 22-1055, D.I. 19 (D. Del. Oct. 7, 2022); and *Galderma Labs. L.P. et al. v. Lupin Inc. et al.*, No. 21-1710, D.I. 10 (D. Del. Feb. 7, 2022).

20. This Court also has personal jurisdiction over Lupin Limited because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Indivior's claims arise

under federal law; (b) Lupin Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Limited has sufficient contacts in the United States as a whole, including, but not limited to, participating in the preparation and submission of Lupin's ANDA, and/or manufacturing and/or selling pharmaceutical products throughout the United States including in Delaware, such that this Court's exercise of jurisdiction over Lupin Limited satisfies due process.

21. Venue is proper in this district for Lupin Inc. and Lupin Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391(b), (c), and/or 1400(b) because, *inter alia*, they are corporations organized and existing under the laws of the State of Delaware.

22. Venue is proper in this district for Lupin Limited pursuant to 28 U.S.C. § 1391(c)(3) because, *inter alia*, it is a corporation organized and existing under the laws of the Republic of India and may be sued in any judicial district, and is subject to personal jurisdiction in Delaware.

OPVEE® (NALMEFENE)

23. The United States is facing an ongoing public health crisis related to the widespread abuse of opioids, including both natural and synthetic opioids such as fentanyl. Opioid overdose is a life-threatening condition that can cause respiratory depression, unconsciousness, and death if not treated promptly.

24. On May 22, 2023, in response to the urgent need for rapid-acting, community-accessible overdose reversal agents, the FDA approved OPVEE® (nalmefene), a nasal spray formulation of nalmefene hydrochloride, for the emergency treatment of known or suspected opioid overdose in adults and pediatric patients 12 years of age and older.

25. Nalmefene hydrochloride, the active ingredient in OPVEE® (nalmefene), is an opioid receptor antagonist that works by rapidly displacing opioids from their receptors in the

brain, effectively reversing the effects of opioid toxicity. Its long duration of action and potency make it particularly well-suited to address overdoses involving synthetic opioids.

26. OPVEE® (nalmefene) is the first and only FDA-approved intranasal formulation of nalmefene hydrochloride for emergency opioid overdose treatment. The nasal spray format enables rapid administration without needles or special training, which is critical in community and emergency settings where time and access to medical personnel may be limited.

27. OPVEE® (nalmefene) is not scheduled under the Controlled Substances Act. This distinguishes it from many other treatments in the field and facilitates broader access and distribution in community-based public health programs, schools, clinics, and harm reduction outreach efforts.

28. In recognition of its significant potential to combat the opioid epidemic, OPVEE® (nalmefene) was granted Fast Track designation and received Priority Review by the FDA. These designations reflect OPVEE® (nalmefene)'s value in addressing a pressing public health emergency and helped expedite its availability to patients.

29. OPVEE® (nalmefene) is administered via a single-use nasal spray device, with each spray delivering 2.7 milligrams of nalmefene hydrochloride in 100 microliters of solution. The product is designed for use by laypersons and first responders in the field to immediately reverse life-threatening opioid overdose symptoms and reduce the risk of death.

30. As the opioid crisis continues to claim thousands of lives each year, the availability of innovative, effective, and easy-to-use rescue treatments like OPVEE® (nalmefene) is a critical component in the national effort to reduce overdose deaths and expand emergency response capabilities.

PATENTS-IN-SUIT

31. The ’091 Patent, titled “Compositions and Methods for the Treatment of Opioid Overdose,” was duly and legally issued by the United States Patent and Trademark Office on October 4, 2022. A true and correct copy of the ’091 Patent is attached as Exhibit A.

32. Indivior owns all right, title, and interest in the ’091 Patent.

33. The ’596 Patent, titled “Compositions and Methods for the Treatment of Opioid Overdose,” was duly and legally issued by the United States Patent and Trademark Office on May 6, 2025. A true and correct copy of the ’596 Patent is attached as Exhibit B.

34. Indivior owns all right, title, and interest in the ’596 Patent.

35. OPVEE® (nalmefene) nasal spray containing nalmefene hydrochloride with a strength equivalent to 2.7 milligrams per spray, the method of manufacture, and/or their use are covered by one or more claims of each of the Patents-in-Suit.

36. The Patents-in-Suit are listed in the FDA’s Approved Drug Products with Therapeutic Equivalence Evaluations (“the Orange Book”) for OPVEE® (nalmefene) nasal spray, which are sold by Indivior under New Drug Application (“NDA”) No. 217470.

LUPIN’S ANDA AND LUPIN’S NOTICE LETTER

37. Indivior holds NDA No. 217470 on OPVEE® (nalmefene) nasal spray containing nalmefene hydrochloride with a strength equivalent to 2.7 milligrams per spray (“Indivior’s NDA”).

38. In a letter dated May 8, 2025 (“Lupin’s Notice Letter”), Lupin stated that it had submitted ANDA No. 219264 to the FDA seeking approval to commercially manufacture, use, offer for sale, sell, and/or import Lupin’s ANDA Product prior to the expiration of the ’091 Patent. Lupin’s Notice Letter further stated that ANDA No. 219264 contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“Paragraph IV Certification”) that the ’091 Patent is invalid,

unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's ANDA Product.

39. On information and belief, nalmefene hydrochloride is the active ingredient in Lupin's ANDA Product.

40. On information and belief, Lupin's ANDA refers to and relies on Indivior's NDA and contains data that, according to Lupin, demonstrate the bioequivalence of Lupin's ANDA Product and OPVEE® (nalmefene) nasal spray containing nalmefene hydrochloride with a strength equivalent to 2.7 milligrams per spray. *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

41. On information and belief, Lupin intends to have healthcare providers use Lupin's ANDA Product, if approved, as set forth in Lupin's ANDA Product label. On information and belief, Lupin's ANDA Product label will instruct healthcare providers to prescribe Lupin's ANDA Product in the manner set forth in the label.

42. This action is being filed within forty-five days of Indivior's receipt of Lupin's Notice Letter, pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

COUNT I

INFRINGEMENT OF U.S. PATENT NO. 11,458,091

43. Indivior incorporates by reference and realleges the allegations of the foregoing paragraphs as though fully restated herein.

44. No later than May 8, 2025, Lupin submitted to the FDA the Lupin ANDA seeking authorization to commercially manufacture, use, import, offer to sell, or sell Lupin's ANDA Product in the United States.

45. Lupin's submission of Lupin's ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Product,

prior to the expiration of the '091 Patent, constitutes infringement of at least one or more claims of the '091 Patent under 35 U.S.C. § 271(e)(2).

46. On information and belief, Lupin plans to, intends to, and will manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product immediately upon approval of Lupin's ANDA, *i.e.*, prior to the expiration of the '091 Patent, and will instruct healthcare providers to use Lupin's ANDA Product in accordance with the proposed product labeling.

47. Lupin's commercial manufacture, sale, offer for sale, or use of Lupin's ANDA Product within the United States, or importation of Lupin's ANDA Product into the United States, prior to the expiration of the '091 Patent, would infringe one or more claims of the '091 Patent under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents.

48. On information and belief, Lupin had knowledge of the '091 Patent when it submitted Lupin's ANDA. Lupin's infringement has been, and continues to be, deliberate.

49. Indivior will be substantially and irreparably harmed if Lupin's infringement of the '091 Patent is not enjoined. Indivior does not have an adequate remedy at law.

COUNT II

INFRINGEMENT OF U.S. PATENT NO. 12,290,596

50. Indivior incorporates by reference and realleges the allegations of the foregoing paragraphs as though fully restated herein.

51. No later than May 8, 2025, Lupin submitted to the FDA the Lupin ANDA for Lupin's ANDA Product seeking authorization to commercially manufacture, use, import, offer to sell, or sell Lupin's ANDA Product in the United States.

52. Lupin's submission of Lupin's ANDA under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use, offer to sell, or sale of Lupin's ANDA Product,

prior to the expiration of the '596 Patent, constitutes infringement of one or more claims of the '596 patent under 35 U.S.C. § 271(e)(2).

53. On information and belief, Lupin plans to, intends to, and will manufacture, use, offer for sale, sell, and/or import Lupin's ANDA Product immediately upon approval of Lupin's ANDA, *i.e.*, prior to the expiration of the '596 Patent, and will instruct healthcare providers to use Lupin's ANDA Product in accordance with the proposed product labeling.

54. On information and belief, upon FDA approval of Lupin's ANDA, Lupin will infringe the '596 Patent by making, using, offering to sell, selling, and/or importing Lupin's ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. § 271(b) and/or (c).

55. On information and belief, Lupin had knowledge of the '596 Patent no later than the date of the filing of this Complaint, Lupin knew or should have known that it will induce or contribute to another's direct infringement of the '596 Patent, and Lupin acted with the specific intent to induce or contribute to another's direct infringement of the '596 Patent.

56. Indivior will be substantially and irreparably harmed if Lupin's infringement of the '596 Patent is not enjoined. Indivior does not have an adequate remedy at law.

COUNT III

DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 12,290,596

57. Indivior incorporates by reference and realleges the allegations of the foregoing paragraphs as though fully restated herein.

58. No later than May 8, 2025, Lupin submitted to the FDA the Lupin ANDA for Lupin's ANDA Product seeking authorization to commercially manufacture, use, import, offer to sell, or sell Lupin's ANDA Product in the United States.

59. On information and belief, Lupin will engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Lupin's ANDA Product immediately and imminently upon FDA approval of Lupin's ANDA.

60. On information and belief, Lupin will instruct healthcare providers to use Lupin's ANDA Product in accordance with the proposed product labeling, and the use of Lupin's ANDA Product in accordance with the proposed product labeling constitutes infringement of one or more claims of the '596 Patent.

61. On information and belief, Lupin plans and intends to, and will, actively induce infringement of the '596 Patent under 35 U.S.C. § 271(b) when Lupin's ANDA is approved, and plans and intends to, and will, do so after approval.

62. On information and belief, Lupin knows that Lupin's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '596 Patent and that Lupin's ANDA Product and its proposed labeling are not suitable for substantial non-infringing use. On information and belief, Lupin plans and intends to, and will, contribute to infringement of the '596 Patent under 35 U.S.C. § 271(c) after approval of Lupin's ANDA.

63. Lupin's actions constitute and/or will constitute infringement of the '596 Patent, active inducement of infringement of the '596 Patent, and contribution to the infringement by others of the '596 Patent.

64. On information and belief, Lupin had knowledge of the '596 Patent no later than the date of the filing of this Complaint, and Lupin knew or should have known that its plans to manufacture, use, offer for sale, sell, and/or import into the United States Lupin's ANDA Product will induce or contribute to another's direct infringement of the '596 Patent, and Lupin will act with the specific intent to induce or contribute to another's direct infringement of the '596 Patent.

65. There is a real, substantial, and continuing case or controversy between Indivior and Lupin regarding whether Lupin's manufacture, use, offer for sale, or importation into the United States of Lupin's ANDA Product with its proposed labeling according to Lupin's ANDA will infringe one or more claims of the '596 Patent.

66. Indivior should be granted a declaratory judgment that the making, using, offer for sale, sale, and importation in or into the United States of Lupin's ANDA Product with its proposed labeling would infringe, actively induce the infringement of, and contribute to the infringement by others of the '596 Patent.

67. Lupin should be enjoined from infringing the '596 Patent, actively inducing infringement of the '596 Patent, and contributing to the infringement by others of the '596 Patent; otherwise, Indivior will suffer irreparable injury. Indivior has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Indivior respectfully requests that this Court grant the following relief:

a) Judgment that Lupin's submission of ANDA No. 219264 to the FDA was an act of infringement of one or more claims of the '091 and '596 Patents under 35 U.S.C. § 271(e)(2);

b) Judgment that Lupin's making, using, offering to sell, selling, or importing into the United States of Lupin's ANDA Product prior to the expiration of the '091 and/or '596 Patents, will infringe, will actively induce infringement, and/or will contribute to the infringement of one or more claims of the '091 and/or '596 Patents;

c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 219264 shall be a date that is not earlier than the expiration of the '091 and/or '596 Patents plus any other period of exclusivity to which Indivior is or becomes entitled;

d) An Order permanently enjoining Lupin, their affiliates and subsidiaries, each of their officers, agents, servants and employees, and any person acting in concert with Lupin, from making, using, offering to sell, selling, or importing into the United States Lupin's ANDA Product until after the expiration of the '091 and/or '596 Patents plus any other period of exclusivity to which Indivior is or becomes entitled;

e) An Order granting to Indivior all other relief available to it under 35 U.S.C. § 271(e)(4)(B) and § 271(e)(4)(C) including injunctive relief and damages, should Lupin commercially market its ANDA Product prior to the expiration of the '091 and/or '596 Patents;

f) Judgment declaring that making, using, marketing, offering for sale, selling, distributing, or importing Lupin's ANDA Product, or any other product, the making, using, marketing, offering for sale, sale, distribution, or importation of which infringes the '596 Patent, prior to the expiration date of the '596 Patent will infringe, actively induce infringement of, and/or contribute to the infringement by others of the '596 Patent under 35 U.S.C. §§ 271(a), 271(b) and/or 271(c);

g) A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorneys' fees, expenses, and disbursements of this action;

h) An award of Indivior's reasonable costs and expenses in this action; and

i) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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