IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GRÜNENTHAL GMBH, Plaintiff, v. MSN LABORATORIES PRIVATE LIMITED AND MSN PHARMACEUTICALS INC., Defendants.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

In this patent infringement action, Plaintiff Grünenthal GmbH ("Grünenthal" or "Plaintiff"), for its complaint against Defendants MSN Laboratories Private Limited ("MSN Labs") and MSN Pharmaceuticals Inc. ("MSN Inc.") (collectively, "MSN" or "Defendants"), hereby 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, Title 35, United States Code, § 100 *et. seq.*, including 35 U.S.C. §§ 271 and 281 for infringement of U.S. Patent Nos. 8,536,130 ("the '130 patent") and 11,344,512 ("the '512 patent") (collectively, the "patents-in-suit"). This action relates to MSN's filing of Abbreviated New Drug Application ("ANDA") No. 220864 under Section 505(j) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to manufacture, use, import, offer to sell, and/or sell Tapentadol extended-release tablets, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg ("MSN's generic products"), which are generic versions of NUCYNTA® ER.

2. Plaintiff seeks judgment that MSN has infringed and/or will infringe at least one claim of each of the patents-in-suit, which are listed in the FDA *Approved Drug Products With Therapeutic Equivalence Evaluations* ("Orange Book") as covering NUCYNTA® ER (tapentadol hydrochloride) an extended-release pain medication that is the subject of FDA-approved New Drug Application ("NDA") No. 200533. MSN has infringed at least one claim of each of the patents-in-suit under 35 U.S.C. § 271(e)(2)(A) by filing ANDA No. 220864 and seeking approval to engage in the commercial manufacture, use, and sale of generic versions of NUCYNTA® ER (tapentadol) in 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg dosage strengths before the expiration of the patents-in-suit.

THE PARTIES

3. Plaintiff Grünenthal is a corporation organized and existing under the laws of Germany, having a principal place of business at Zieglerstrasse 6, Aachen, Germany D-52078. Grünenthal is the owner of the patents-in-suit.

4. On information and belief, MSN Labs is a company organized and existing under the laws of India, having a principal place of business at MSN House, Plot No. C-24, Sanath Nagar Industrial Estate, Sanathnagar, Hyderabad, Telangana, India 500018.

5. On information and belief, MSN Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 20 Duke Road, Piscataway, Edison, New Jersey 08854.

6. On information and belief, MSN Inc. is a wholly-owned subsidiary of MSN Labs.

7. On information and belief, MSN is a pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Delaware and throughout the United States.

JURISDICTION AND VENUE

8. This is a civil action for patent infringement and declaratory judgment arising under the patent laws of the United States, 35 U.S.C. § 100, *et seq.*, including 35 U.S.C. § 271 and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

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

10. This Court has personal jurisdiction over MSN Labs because, *inter alia*, MSN Labs, on information and belief, (1) has substantial, continuous, and systematic contacts with Delaware; (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of Delaware; (3) intends to market, sell, and/or distribute its generic products to residents of Delaware; and (4) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

11. This Court also has personal jurisdiction over MSN Labs because it has previously been sued in this District and has not challenged personal jurisdiction and/or has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this District. *See, e.g.*, *Urovant Scis. GmbH, et al. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 25-00420 (D. Del.); *Novartis Pharms. Corp. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 25-00081 (D. Del.); *SK Biopharmaceuticals Co. v. MSN Pharms. Inc., et al.*, Civil Action No. 24-01270 (D. Del.); *Allergan Holdings Unlimited Co., et al. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 24-01187 (D. Del.); *Vanda Pharms. Inc. v. MSN Pharms. Inc., et al.*, Civil Action No. 24-00815 (D. Del.); and *Pfizer Inc., et al. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 24-00624 (D. Del.).

12. On information and belief, MSN Inc. is a United States agent for MSN Labs.

13. This Court has personal jurisdiction over MSN Inc. because, *inter alia*, MSN Inc., on information and belief, is incorporated in the State of Delaware as a domestic corporation under

file number 5454849, and names "United States Corporation Agents, Inc." located at 131 Continental Drive Suite 305, Newark, Delaware 19713, as its registered agent to accept service of process in the State of Delaware.

14. Additionally, this Court has personal jurisdiction over MSN Inc. because, *inter alia*, MSN Inc., on information and belief, (1) has substantial, continuous, and systematic contacts with Delaware; (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of Delaware; (3) intends to market, sell, and/or distribute its generic products to residents of Delaware; and (4) enjoys substantial income from sales of its generic pharmaceutical products in Delaware.

15. On information and belief, MSN Inc. has substantial contacts with and within Delaware and has purposefully conducted and continues to conduct business in this judicial district, including that this judicial district is the likely destination of MSN's generic products. On information and belief, MSN Inc. "develops and manufacture[s] products for MSN" and specializes in the "manufacturing of high-quality generic pharmaceutical products." https://www.msnpi.com/ (last accessed November 3, 2025). On information and belief, MSN Inc.'s "facility is strategically located" and "provides excellent access to New York City and Tri-state region." https://www.msnpi.com/ (last accessed November 3, 2025).

16. This Court also has personal jurisdiction over MSN Inc. because it has previously been sued in this District and has not challenged personal jurisdiction and/or has affirmatively availed itself of the jurisdiction of this Court by filing claims and counterclaims in this District. *See, e.g.*, *Urovant Scis. GmbH, et al. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 25-00420 (D. Del.); *Novartis Pharms. Corp. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 25-00081 (D. Del.); *SK Biopharmaceuticals Co. v. MSN Pharms. Inc., et al.*, Civil Action No. 24-01270 (D.

Del.); *Allergan Holdings Unlimited Co., et al. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 24-01187 (D. Del.); *Vanda Pharms. Inc. v. MSN Pharms. Inc., et al.*, Civil Action No. 24-00815 (D. Del.); and *Pfizer Inc., et al. v. MSN Labs. Priv. Ltd., et al.*, Civil Action No. 24-00624 (D. Del.).

17. This Court has personal jurisdiction over MSN by virtue of, *inter alia*, the fact that it has committed, aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement, and intends a future course of conduct that includes acts of patent infringement in Delaware, that has led and/or will lead to foreseeable harm and injury to Plaintiff.

18. On information and belief, MSN developed its generic products and seeks regulatory approval from FDA to manufacture, market, and sell MSN's generic products throughout the United States, including within Delaware.

19. On information and belief, and consistent with its practice with respect to other generic pharmaceutical products, following FDA approval of ANDA No. 220864, MSN will market, distribute, and sell MSN's generic products throughout the United States, including in Delaware.

20. For these reasons and other reasons that will be presented to the Court if jurisdiction is challenged, the Court has personal jurisdiction over MSN.

21. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), at least because MSN Inc. is incorporated in Delaware.

22. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b), at least because MSN Labs is incorporated in India and may be sued in any judicial district in the United States.

THE PATENTS-IN-SUIT

23. On September 17, 2013, the United States Patent and Trademark Office duly and legally issued the '130 patent, entitled "Use of 1-phenyl-3-dimethylamino-propane Compounds for Treating Neuropathic Pain," naming Thomas Christoph, Elmar Friderichs, Babette-Yvonne Koegel, and Murielle Meen as the inventors. A true and correct copy of the '130 patent is attached hereto as Exhibit A.

24. On May 31, 2022, the United States Patent and Trademark Office duly and legally issued the '512 patent, entitled "Titration of Tapentadol," naming Claudia Lange and Ferdinand Rombout as the inventors. A true and correct copy of the '512 patent is attached hereto as Exhibit B.

25. Plaintiff Grünenthal lawfully owns all right, title, and interest in the patents-in-suit, including the right to sue and to recover for past infringement thereof.

26. Collegium Pharmaceutical, Inc. is the holder of NDA No. 200533 for NUCYNTA® ER, which is indicated for the management of (1) severe and persistent pain in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate, and (2) severe and persistent neuropathic pain associated with diabetic peripheral neuropathy (DPN) in adults that requires an extended treatment period with a daily opioid analgesic and for which alternative treatment options are inadequate. In accordance with 21 U.S.C. § 355(b)(1), the patents-in-suit are listed in the Orange Book in connection with NDA No. 200533 as "patent[s] for which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner of the patent engaged in the manufacture, use, or sale of the drug" NUCYNTA® ER.

THE ANDA

27. On information and belief, MSN submitted ANDA No. 220864 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking FDA approval to engage in the commercial manufacture, use, importation, offer for sale, and/or sale in the United States of generic tapentadol hydrochloride extended-release tablets in dosage strengths of 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg based on the Reference Listed Drug NUCYNTA® ER, which is the subject of approved NDA No. 200533.

28. On information and belief, MSN is seeking FDA approval to engage in the commercial manufacture, use, or sale of MSN's generic products before the expiration date of the '130 and '512 patents listed in the Orange Book.

29. On information and belief, ANDA No. 220864 contains a "Paragraph IV" certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the patents-in-suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of MSN's generic products.

30. MSN sent a letter dated September 19, 2025, with the heading "Re: Notice of Paragraph IV Certification, Tapentadol extended-release tablets, 50 mg, 100 mg, 150 mg, 200 mg, and 250 mg" ("Notice Letter") to Grünenthal.

31. The Notice Letter indicated that ANDA No. 220864 had been filed with the FDA seeking approval to engage in the commercial manufacture, use, or sale of MSN's generic products before the expiration of the '130 and '512 patents.

32. Plaintiff commenced this action within the 45-day period after receiving the September 19, 2025 Notice Letter.

COUNT I (INFRINGEMENT OF THE '130 PATENT)

33. Plaintiff incorporates and realleges paragraphs 1 through 32 above as though fully restated herein.

34. On information and belief, MSN filed ANDA No. 220864 seeking approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '130 patent.

35. On information and belief, MSN 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 that the claims of the '130 patent are invalid, unenforceable, and/or not infringed.

36. On information and belief, in ANDA No. 220864, MSN has represented to the FDA that MSN's generic products are pharmaceutically and therapeutically equivalent to NUCYNTA® ER tablets.

37. MSN has actual knowledge of the '130 patent, as evidenced by the September 19, 2025 Notice Letter.

38. On information and belief, pursuant to 35 U.S.C. § 271(e)(2)(a), MSN has infringed one or more claims of the '130 patent by submitting, or causing to be submitted, ANDA No. 220864 to the FDA, seeking approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products before the expiration of the '130 patent. This infringement entitles Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 220864 be a date that is not earlier than the expiration date of the '130 patent, including any extensions of that date.

39. On information and belief, if ANDA No. 220864 is approved by the FDA, MSN's manufacture, use, importation, offer for sale, and/or sale of MSN's generic products before the expiration of the '130 patent will infringe, contribute to the infringement of, and/or induce the

infringement of one or more claims of the '130 patent under 35 U.S.C. § 271(a)-(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 220864 shall be no earlier than the expiration of the '130 patent and any additional periods of exclusivity.

40. On information and belief, MSN's generic products and their use according to MSN's proposed package insert constitute a material part of the inventions covered by the claims of the '130 patent.

41. On information and belief, MSN knows that MSN's generic products and their use according to MSN's proposed package insert are especially made or especially adapted for use in the infringement of one or more claims of the '130 patent.

42. On information and belief, MSN has had and continues to have knowledge that there is no substantial non-infringing use for MSN's generic products.

43. On information and belief, the administration of MSN's generic products by any healthcare providers, including, but not limited to, doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '130 patent.

44. On information and belief, MSN has knowledge of the '130 patent and, by its proposed package inserts for MSN's generic products, knows or should know that it will induce infringement of one or more claims of the '130 patent, either literally or under the doctrine of equivalents.

45. On information and belief, MSN is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because Healthcare Providers and/or patients will use MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes one or more claims of the '130 patent.

46. On information and belief, if ANDA No. 220864 is approved, MSN intends to and will manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States.

47. On information and belief, MSN's actions relating to ANDA No. 220864 complained of herein were done by and for the benefit of MSN.

48. Unless MSN is enjoined by the Court, Plaintiff will be substantially and irreparably harmed by MSN's infringement of the '130 patent.

49. Plaintiff does not have an adequate remedy at law.

COUNT II (INFRINGEMENT OF THE '512 PATENT)

50. Plaintiff incorporates and realleges paragraphs 1 through 49 above as though fully restated herein.

51. On information and belief, MSN filed ANDA No. 220864 seeking approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '512 patent.

52. On information and belief, MSN 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 that the claims of the '512 patent are invalid, unenforceable, and/or not infringed.

53. On information and belief, in ANDA No. 220864, MSN has represented to the FDA that MSN's generic products are pharmaceutically and therapeutically equivalent to NUCYNTA® ER tablets.

54. MSN has actual knowledge of the '512 patent, as evidenced by the September 19, 2025 Notice Letter.

55. On information and belief, pursuant to 35 U.S.C. § 271(e)(2)(a), MSN has infringed one or more claims of the '512 patent by submitting, or causing to be submitted, ANDA No.

220864 to the FDA, seeking approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products before the expiration of the '512 patent. This infringement entitles Plaintiff to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the effective date of approval for ANDA No. 220864 be a date that is not earlier than the expiration date of the '512 patent, including any extensions of that date.

56. On information and belief, if ANDA No. 220864 is approved by the FDA, MSN's importation, manufacture, use, offer for sale, and/or sale of MSN's generic products before the expiration of the '512 patent will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '512 patent under 35 U.S.C. § 271(a)-(c), unless this Court orders that the effective date of any FDA approval of ANDA No. 220864 shall be no earlier than the expiration of the '512 patent and any additional periods of exclusivity.

57. On information and belief, MSN's generic products and their use according to MSN's proposed package insert constitute a material part of the inventions covered by the claims of the '512 patent.

58. On information and belief, MSN knows that MSN's generic products and their use according to MSN's proposed package insert are especially made or especially adapted for use in the infringement of one or more claims of the '512 patent.

59. On information and belief, MSN has had and continues to have knowledge that there is no substantial non-infringing use for MSN's generic products.

60. On information and belief, the administration of MSN's generic products by any healthcare providers, including, but not limited to doctors, physicians, and nurse practitioners ("Healthcare Providers"), and patients, will directly infringe one or more claims of the '512 patent.

61. On information and belief, MSN has knowledge of the '512 patent and, by its proposed package insert for MSN's generic products, knows or should know that it will induce infringement of one or more claims of the '512 patent, either literally or under the doctrine of equivalents.

62. On information and belief, MSN is aware and/or has knowledge that its proposed package insert will recommend, suggest, encourage, and/or instruct others how to engage in an infringing use because Healthcare Providers and/or patients will use MSN's generic products according to the instructions in the proposed package insert in a way that directly infringes one or more claims of the '512 patent.

63. On information and belief, if ANDA No. 220864 is approved, MSN intends to and will manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States.

64. On information and belief, MSN's actions relating to ANDA No. 220864 complained of herein were done by and for the benefit of MSN.

65. Unless MSN is enjoined by the Court, Plaintiff will be substantially and irreparably harmed by MSN's infringement of the '512 patent.

66. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Adjudging, pursuant to 35 U.S.C. § 271(e)(2)(A), that MSN has infringed, literally or by the doctrine of equivalents, one or more claims of the '130 patent through the submission of ANDA No. 220864 to the FDA seeking approval to manufacture, use, import, offer

to sell, and/or sell MSN's generic products in the United States before the expiration of the '130 patent.

B. Adjudging, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), that MSN's making, using, offering to sell, selling, or importing into the United States MSN's generic products before the expiration of the '130 patent would infringe, literally or by the doctrine of equivalents, induce infringement of, and/or contribute to the infringement of one or more claims of the '130 patent under 35 U.S.C. § 271(a), (b), and/or (c);

C. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 220864 and MSN's generic products described therein, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '130 patent, plus any additional periods of extension or exclusivity attached thereto;

D. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283, and Federal Rule of Civil Procedure 65, MSN and all officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with MSN, and MSN's successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that is the subject of ANDA No. 220864, including MSN's generic products or any other drug product that infringes the '130 patent;

E. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283, and Federal Rule of Civil Procedure 65, MSN and all officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities,

and all other persons acting in concert, participation, or in privity with MSN, and MSN's successors and assigns, from seeking, obtaining, or maintaining approval of ANDA No. 220864 until the expiration of the '130 patent;

F. Adjudging, pursuant to 35 U.S.C. § 271(e)(2)(A), that MSN has infringed, literally or by the doctrine of equivalents, one or more claims of the '512 patent through the submission of ANDA No. 220864 to the FDA seeking approval to manufacture, use, import, offer to sell, and/or sell MSN's generic products in the United States before the expiration of the '512 patent.

G. Adjudging, pursuant to 35 U.S.C. § 271(a), (b), and/or (c) that MSN's making, using, offering to sell, selling, or importing into the United States MSN's generic products before the expiration of the '512 patent would infringe, literally or by the doctrine of equivalents, induce infringement of, and/or contribute to the infringement of one or more claims of the '512 patent under 35 U.S.C. § 271(a), (b), and/or (c);

H. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 220864 and MSN's generic products described therein, under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '512 patent, plus any additional periods of extension or exclusivity attached thereto;

I. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283, and Federal Rule of Civil Procedure 65, MSN and all officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with MSN, and MSN's successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the

United States, or importation into the United States, of any drug product that is the subject of ANDA No. 220864, including MSN's generic products or any other drug product that infringes the '512 patent;

J. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 283, and Federal Rule of Civil Procedure 65, MSN and all officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities, and all other persons acting in concert, participation, or in privity with MSN, and MSN's successors and assigns, from seeking, obtaining, or maintaining approval of ANDA No. 220864 until the expiration of the '512 patent;

K. Declaring this an exceptional case and awarding Plaintiff its attorneys' fees and costs, as provided by 35 U.S.C. §§ 271(e)(4) and 285;

L. Awarding Plaintiff any further appropriate relief under 35 U.S.C. § 271(e)(4); and

M. Awarding Plaintiff such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jeremy A. Tigan

Jeremy A. Tigan (#5239)
Megan E. Dellinger (#5739)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jtigan@morrisnichols.com
mdellinger@morrisnichols.com

Attorneys for Plaintiff

OF COUNSEL:

Anthony C. Tridico
Erin M. Sommers
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, DC 20001
(202) 408-4000

Kathryn R. Judson
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
271 17th St., N.W., Suite 1400
Atlanta, Georgia 30363
(404) 653-6400

November 3, 2025