IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER PHARMA AKTIENGESELLSCHAFT; and BAYER AKTIENGESELLSCHAFT, Plaintiffs, v. MSN PHARMACEUTICALS INC.; MSN LABORATORIES PRIVATE LIMITED; and MSN LIFE SCIENCES PRIVATE LIMITED, Defendants.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT AND FOR DECLARATORY JUDGMENT OF PATENT INFRINGEMENT

Plaintiffs Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma Aktiengesellschaft ("Bayer Pharma AG"), and Bayer Aktiengesellschaft ("Bayer AG") (collectively, "Bayer" or "Plaintiffs"), for their Complaint against Defendants MSN Pharmaceuticals Inc. ("MSN Pharmaceuticals"), MSN Laboratories Private Limited ("MSN Laboratories"), and MSN Life Sciences Private Limited ("MSN Life Sciences") (collectively, "MSN" or "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement and for a declaratory judgment of patent infringement of United States Patent No. RE49,826 (the "RE'826 Patent"). This action arises out of MSN filing or causing to be filed Abbreviated New Drug Application No. 220821 ("MSN's ANDA") with the United States Food and Drug Administration ("FDA") for approval to market a generic version of Bayer's KERENDIA®, (finerenone) drug product. Through MSN's ANDA,

MSN seeks approval to market a generic version of the pharmaceutical product KERENDIA® before the expiration of the RE'826 Patent. This action also arises out of MSN's current and/or imminent manufacture, use, sale, offer to sell within the United Sates, and/or importation to the United States of MSN's generic version of the pharmaceutical product KERENDIA®. A true and correct copy of the RE'826 Patent is attached as Exhibit A. Plaintiffs seek injunctive relief precluding infringement, attorneys' fees, costs and expenses, and any other relief the Court deems just and proper.

THE PARTIES

2. Plaintiff Bayer HealthCare Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 100 Bayer Blvd., Whippany, NJ 07981.

3. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of Germany and has a principal place of business at Müllerstrasse 178, 13353 Berlin, Germany.

4. Plaintiff Bayer AG is a corporation organized and existing under the laws of Germany and has a principal place of business at Kaiser-Wilhelm-Allee 1, 51368 Leverkusen, Germany. Bayer HealthCare Pharmaceuticals Inc. and Bayer Pharma AG are wholly owned subsidiaries of Bayer AG.

5. Bayer is a pioneering pharmaceutical company that aims to develop therapies and treatments that can help prevent, treat, or potentially cure diseases. Bayer is committed to the discovery and development of new therapies that improve the health of millions of patients around the world. Guided by science and Bayer's commitment to patients, Bayer strives to address the individual needs of patients in order to achieve improved and sustainable health for all. By unlocking previously undruggable targets and applying breakthrough technologies, Bayer is

challenging the limitations of medical treatment. Through this approach, Bayer has become a global leader in treating and preventing cardiovascular disease.

6. On information and belief, Defendant MSN Laboratories is a private limited company organized and existing under the laws of India, having a principal place of business at MSN House, Plot No: C-24, Industrial Estate, Sanathnagar, Hyderabad – 18 Telangana, India, 500018.

7. On information and belief, Defendant MSN Laboratories, directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, markets, distributes, imports, offers for sale, and/or sells generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

8. On its website, MSN Laboratories states that it has "achieved 30+ first-to-launch generics and 900+ national and international patents filed" to date, and its "growing portfolio consists of 1330+ DMFs, 2400+ dossiers and 170+ ANDAs registered." Exhibit B (available at https://www.msnlabs.com/r-and-d.html). The website also states that MSN Laboratories has "17 API and 8 finished dosage facilities established across India[,] USA, Indonesia & UAE." Exhibit C (available at https://www.msnlabs.com/who-we-are.html).

9. On information and belief, Defendant MSN Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business in New Jersey at 20 Duke Road, Piscataway, New Jersey 08854, as indicated on page 1 of its Paragraph IV Notice Letter.

10. On information and belief, MSN Pharmaceuticals is a wholly-owned subsidiary of MSN Laboratories.

11. On information and belief, MSN Pharmaceuticals develops, manufactures, markets, distributes, imports, offers for sale, and/or sells, generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

12. On information and belief, Defendant MSN Life Sciences is a private limited company organized and existing under the laws of India, having a principal place of business at Sy No – 21/A & 21AA, Mambapur (Village), Gummadidala (Mandal), Sangareddy (District) – 502313, Telangana, India.

13. On information and belief, MSN Life Sciences is a subsidiary, agent, and/or affiliate of MSN Laboratories. On information and belief, MSN Life Sciences is a wholly-owned subsidiary of MSN Laboratories.

14. On information and belief, both MSN Life Sciences and MSN Laboratories list Dr. Manne Satyanarayana Reddy and Manne Laxmi Prasuna as Ultimate Beneficial Owners.

15. On information and belief, MSN Life Sciences, directly or through one or more of its subsidiaries, agents, and/or affiliates, develops, manufactures, markets, distributes, imports, offers for sale, and/or sells, generic versions of branded pharmaceutical products throughout the United States, including in Delaware.

16. On information and belief, MSN Pharmaceuticals, in collaboration and concert with MSN Laboratories and MSN Life Sciences, prepared and submitted MSN's ANDA and the three MSN entities continue to collaborate in seeking FDA approval of that application.

17. On information and belief, MSN Pharmaceuticals, in collaboration and concert with MSN Laboratories and MSN Life Sciences, intends to commercially manufacture, market, offer for sale, and sell the product described in MSN's ANDA ("MSN's ANDA Product")

throughout the United States, including in the State of Delaware, in the event the FDA approves MSN's ANDA.

JURISDICTION AND VENUE

18. This is a civil action for patent infringement and declaratory judgment of infringement of U.S. Patent No. RE49,826. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

19. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201-02, and 35 U.S.C. § 271.

20. Venue is proper in this Court as to MSN Laboratories under 28 U.S.C. § 1391(c)(3) because MSN Laboratories is a foreign corporation and may be sued in any judicial district in the United States where MSN Laboratories is subject to the court's personal jurisdiction. For reasons set forth below, MSN Laboratories is subject to personal jurisdiction in this district.

21. In addition, this Court has personal jurisdiction over MSN Laboratories, and venue is proper as to MSN Laboratories, at least because, upon information and belief, MSN Laboratories: (1) directs and/or controls MSN Pharmaceuticals, which is incorporated in Delaware; (2) has purposely availed itself of the privilege of doing business in Delaware, directly or indirectly through its subsidiaries, agents, and/or alter egos; (3) maintains pervasive, continuous, and systematic contacts with Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical products in Delaware; (4) derives substantial revenue from the sale of its products in Delaware; and (5) intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute MSN's ANDA Product for which it seeks approval under MSN's ANDA, including throughout Delaware.

22. This Court has personal jurisdiction over MSN Laboratories, and thus venue is proper, for at least the additional reason that it has availed itself of the legal protections of Delaware by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Adverio Pharma GmbH, et al. v. Changzhou Pharmaceutical Factory, et al.*, No. 1:25-cv-00479 (D. Del.); *Sumitomo Pharma Switzerland GmbH, et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:25-cv-00345 (D. Del.); *Novartis Pharmaceuticals Corp. v. MSN Pharmaceuticals Inc., et al.*, No. 1:25-cv-00081 (D. Del.); *Allergan Holdings Unlimited Co. et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:23-cv-00794 (D. Del.); *AbbVie Inc., et al. v. Alkem Laboratories Ltd., et al*., No. 1:22-cv-01423 (D. Del.); *Novartis Pharmaceuticals Corp. v. Alembic Pharmaceuticals Ltd., et al.*, No. 1:22-cv-01395 (D. Del.); *Exelixis, Inc. v. MSN Laboratories Private Ltd., et al.*, No. 1:22-cv-00228 (D. Del.); *Allergan USA, Inc., et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:22-cv-00181 (D. Del.); *Allergen USA Inc., et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:21-cv-01064 (D. Del.); *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 1:19-cv-02053 (D. Del.); *Exelixis, Inc. v. MSN Laboratories Private Ltd., et al.*, No. 1:19-cv-02017 (D. Del.); *Genentech Inc., et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:19-cv-00205 (D. Del.); *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc., et al.*, No. 1:19-cv-00926 (D. Del.); *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc., et al.*, No. 1:18-cv-00690 (D. Del.); *H. Lundbeck A/S, et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:18-cv-00114 (D. Del.); *Biogen International GmbH v. MSN Laboratories Private Ltd., et al.*, No. 1:18-cv-00337 (D. Del.).

23. Alternatively, this Court may exercise jurisdiction over MSN Laboratories pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Bayer's claims arise under federal law; (2) MSN Laboratories is a foreign defendant not subject to personal jurisdiction in any state's court of

general jurisdiction; and (3) MSN Laboratories has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting numerous ANDAs to the FDA and manufacturing, importing, offering to sell, or selling generic pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over MSN Laboratories satisfies due process.

24. Venue is proper in this Court as to MSN Pharmaceuticals under 28 U.S.C. § 1400(b) at least because MSN Pharmaceuticals is incorporated in Delaware. MSN Pharmaceuticals will also commit acts of infringement giving rise to the claims against it in Delaware upon approval of MSN's ANDA.

25. In addition, this Court has personal jurisdiction over MSN Pharmaceuticals, and venue is proper as to MSN Pharmaceuticals because, on information and belief, MSN Pharmaceuticals: (1) is a corporation organized and existing under the laws of the State of Delaware; (2) is qualified to do business in Delaware and has appointed a registered agent for service of process in Delaware located at 300 Delaware Avenue, Suite 210-A, Wilmington, Delaware 19801; (3) has customers in Delaware; (4) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in Delaware; (5) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical products in Delaware; (6) directly or indirectly maintains pervasive, continuous, and systematic contacts with Delaware, including through a network of wholesalers and distributors, for the purposes of marketing, distributing, and/or selling generic pharmaceutical products in Delaware; (7) enjoys substantial income from sales of its generic pharmaceutical products in Delaware; and (8) intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute MSN's ANDA Product in Delaware.

26. This Court has personal jurisdiction over MSN Pharmaceuticals for at least the additional reason that it has availed itself of the legal protections of Delaware by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Adverio Pharma GmbH, et al. v. Changzhou Pharmaceutical Factory, et al.*, No. 1:25-cv-00479 (D. Del.); *Sumitomo Pharma Switzerland GmbH, et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:25-cv-00345 (D. Del.); *Novartis Pharmaceuticals Corp. v. MSN Pharmaceuticals Inc., et al.*, No. 1:25-cv-00081 (D. Del.); *AbbVie Inc., et al. v. Alkem Laboratories Ltd., et al.*, No. 1:22-cv-01423 (D. Del.); *Allergan Holdings Unlimited Co. et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:23-cv-00794 (D. Del.); *Novartis Pharmaceuticals Corp. v. Alembic Pharmaceuticals Ltd., et al.*, No. 1:22-cv-01395 (D. Del.); *Exelixis, Inc. v. MSN Laboratories Private Ltd., et al.*, No. 1:22-cv-00228 (D. Del.); *Allergan USA, Inc., et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:22-cv-00181 (D. Del.); *Allergen USA Inc., et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:21-cv-01064 (D. Del.); *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 1:19-cv-02053 (D. Del.); *Exelixis, Inc. v. MSN Laboratories Private Ltd., et al.*, No. 1:19-cv-02017 (D. Del.); *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc., et al.*, No. 1:19-cv-00926 (D. Del.); *Vanda Pharmaceuticals Inc. v. MSN Pharmaceuticals Inc., et al.*, No. 1:18-cv-00690 (D. Del.); *H. Lundbeck A/S, et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:18-cv-00114 (D. Del.); *Biogen International GmbH v. MSN Laboratories Private Ltd., et al.*, No. 1:18-cv-00337 (D. Del.).

27. Venue is proper in this Court as to MSN Life Sciences under 28 U.S.C. § 1391(c)(3) because MSN Life Sciences is a foreign corporation and may be sued in any judicial district in the United States where MSN Life Sciences is subject to the court's personal jurisdiction. For reasons set forth below, MSN Life Sciences is subject to personal jurisdiction in this district.

28. This Court has personal jurisdiction over MSN Life Sciences, and venue is proper as to MSN Life Sciences, at least because, upon information and belief, MSN Life Sciences: (1) either directly or indirectly through MSN Laboratories, directs and/or controls MSN Pharmaceuticals, which is incorporated in Delaware; (2) has purposely availed itself of the privilege of doing business in Delaware, directly or indirectly through its subsidiaries, agents, and/or alter egos; (3) maintains pervasive, continuous, and systematic contacts with Delaware, including the marketing, distribution, and/or sale of generic pharmaceutical products in Delaware; (4) derives substantial revenue from the sale of its products in Delaware; and (5) intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute MSN's ANDA Product for which it seeks approval under MSN's ANDA, including throughout Delaware.

29. This Court has personal jurisdiction over MSN Life Sciences, and thus venue is proper, for at least the additional reason that it has availed itself of the legal protections of Delaware by previously consenting to personal jurisdiction and asserting counterclaims in this Judicial District. *See, e.g.*, *Novartis Pharmaceuticals Corp. v. MSN Pharmaceuticals Inc., et al.*, No. 1:25-cv-00081 (D. Del.); *AbbVie Inc., et al. v. Alkem Laboratories Ltd., et al.*, No. 1:22-cv-01423 (D. Del.); *Novartis Pharmaceuticals Corp. v. Alembic Pharmaceuticals Ltd., et al.*, No. 1:22-cv-01395 (D. Del.); *Novartis Pharmaceuticals Corp. v. Dr. Reddy's Laboratories, Inc., et al.*, No. 1:19-cv-02053 (D. Del.).

30. Alternatively, this Court may exercise jurisdiction over MSN Life Sciences pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Bayer's claims arise under federal law; (2) MSN Life Sciences is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) MSN Life Sciences has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting numerous DMFs and ANDAs to the

FDA and manufacturing, importing, offering to sell, or selling generic pharmaceutical products distributed throughout the United States, either directly or indirectly through its subsidiaries, agents or affiliates, including MSN Laboratories and MSN Pharmaceuticals, such that this Court's exercise of jurisdiction over MSN Life Sciences satisfies due process.

31. On information and belief, MSN Pharmaceuticals, MSN Laboratories, and MSN Life Sciences are agents of each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to MSN's ANDA Product.

32. On information and belief, MSN Life Sciences, MSN Laboratories, and MSN Pharmaceuticals are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing, and/or selling pharmaceutical products throughout the United States, and will do the same with respect to MSN's ANDA Product.

33. On information and belief, MSN Pharmaceuticals, in collaboration and concert with MSN Laboratories and MSN Life Sciences, filed or caused to be filed MSN's ANDA with the FDA.

34. On information and belief, MSN Pharmaceuticals in collaboration and concert with MSN Laboratories and MSN Life Sciences maintains distribution channels for the commercial supply of generic drugs, including on information and belief MSN's ANDA Product, throughout the United States, including in Delaware.

BAYER'S APPROVED KERENDIA® AND THE RE'826 PATENT

35. Bayer HealthCare Pharmaceuticals Inc. holds New Drug Application ("NDA") No. 215341 on KERENDIA®, which the FDA approved on July 9, 2021. The FDA also granted five years of regulatory exclusivity on KERENDIA® for a new chemical entity pursuant to 21

C.F.R. § 314.108, which regulatory exclusivity expires on July 9, 2026. Bayer markets and sells products that are the subject of NDA No. 215341 in the United States under the brand name KERENDIA®.

36. KERENDIA® (finerenone) is a non-steroidal mineralocorticoid receptor antagonist (nsMRA) indicated to reduce the risk of: sustained estimated glomerular filtration rate (eGFR) decline, end stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2DM); and cardiovascular death, hospitalization for heart failure, and urgent heart failure visits in adult patients with heart failure with left ventricular ejection fraction (LVEF) ≥40%. A true and correct copy of the prescribing information for KERENDIA® is attached as Exhibit D.

37. The prescribing information for KERENDIA® instructs that each KERENDIA® tablet contains "10 mg, 20 mg, or 40 mg of finerenone" which "is a white to yellow crystalline powder." Exhibit D at Section 11.

38. Pursuant to 21 U.S.C. § 355(b)(1), the RE'826 Patent is listed in the FDA's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (commonly referred to as the "Orange Book") as covering KERENDIA®.

39. The RE'826 Patent was duly and legally issued by the United States Patent and Trademark Office ("USPTO") on February 6, 2024, and is titled "Method for the preparation of (4S)-4-(4-cyano-2-methoxyphenyl)-5-ethoxy-2,8-dimethyl-1,4-dihydro-1-6-naphthyridine-3-carboxamide and the purification thereof for use as an active pharmaceutical ingredient." Exhibit A. The RE'826 patent will expire on July 29, 2035.

40. RE'826 Patent is a reissue of U.S. Patent No. 10,336,749 ("'749 Patent"), originally issued on July 2, 2019, with the same title as the RE'826 Patent. The RE'826 Patent comprises claims 14-30; claims 1-13 of the original '749 Patent do not form a part of the RE'826 Patent.

41. Bayer Pharma AG is the assignee of the RE'826 Patent.

42. Bayer AG holds an exclusive license to the RE'826 Patent.

MSN'S ANDA AND NOTICE LETTER

43. On information and belief, MSN submitted its ANDA to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of MSN's ANDA Product as a purported generic version of KERENDIA® before the expiration of the RE'826 Patent.

44. MSN Pharmaceuticals sent Bayer a letter dated September 8, 2025 ("MSN's Paragraph IV Notice Letter") providing notice that MSN's ANDA contains a certification with respect to the RE'826 Patent under the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification"). Bayer HealthCare Pharmaceuticals Inc. received MSN's Paragraph IV Notice Letter on September 15, 2025.

45. The Paragraph IV Certification represents that MSN filed its ANDA seeking approval from the FDA to commercially manufacture, use, market, or sell its generic finerenone tablets, 10 mg and 20 mg, in the United States before the expiration of the RE'826 Patent.

46. MSN's Paragraph IV Notice Letter purported to contain a "Detailed Statement of the Factual And Legal Bases for MSN's Opinion that United States Patent No. RE49826 Is Invalid, Unenforceable, and/or Will Not Be Infringed" ("Detailed Statement").

47. MSN's purported Detailed Statement alleged that claims 14-26 of the RE'826 Patent are invalid as inherently anticipated or obvious, and that claims 27-30 of the RE'826 Patent will not be infringed by the commercial manufacture, use, or sale of MSN's ANDA Product. MSN's Paragraph IV Notice Letter did not allege any other claims of the RE'826 Patent are invalid or that any other claims of the RE'826 Patent will not be infringed.

48. MSN's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain MSN confidential information regarding MSN's ANDA Product. Plaintiffs requested that MSN revise its purported OCA on October 6, 2025. MSN failed to respond to Bayer's correspondence.

49. On information and belief, MSN Pharmaceuticals, in collaboration and concert with MSN Laboratories and MSN Life Sciences, has participated in the preparation and submission of MSN's ANDA, has provided material support to the preparation and submission of MSN's ANDA, and intends to support the further prosecution of MSN's ANDA.

50. On information and belief, MSN Life Sciences is the holder of FDA Drug Master File ("DMF") No. 41150 for finerenone.

51. On information and belief, if the FDA approves MSN's ANDA, MSN will manufacture, offer for sale, or sell its ANDA Product within the United States, including within Delaware, or will import its ANDA Product into the United States, including Delaware.

52. On information and belief, if the FDA approves MSN's ANDA, MSN will actively induce or contribute to the manufacture, use, offer for sale, or sale of its ANDA Product.

53. Bayer is commencing this action within 45 days of the date of receipt of MSN's Paragraph IV Notice Letter in accordance with the time frame for filing such a suit established by the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CAUSE OF ACTION
INFRINGEMENT OF THE RE'826 PATENT

54. The allegations of paragraphs 1-53 above are repeated and re-alleged as if set forth fully herein.

55. On information and belief, MSN has submitted or caused the submission of MSN's ANDA to FDA, and continues to seek FDA approval of the MSN ANDA.

56. MSN has infringed the RE'826 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting MSN's ANDA with a Paragraph IV certification and seeking FDA approval of MSN's ANDA before the expiration of the RE'826 Patent.

57. MSN Laboratories, MSN Pharmaceuticals, and MSN Life Sciences are jointly and severally liable for direct infringement of the RE'826 Patent under § 271(e)(2)(A) because, on information and belief, MSN Laboratories, MSN Pharmaceuticals, and MSN Life Sciences actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of MSN's ANDA and its accompanying Paragraph IV Certification directed to the RE'826 Patent to the FDA. On information and belief, MSN's ANDA seeks FDA approval to engage in the commercial manufacture, use or sale of a product claimed in the RE'826 Patent.

58. On information and belief, if MSN's ANDA is approved, MSN and its affiliates will immediately make, sell, offer for sale, or otherwise distribute MSN's ANDA Product in the United States, including in Delaware, thereby directly infringing one or more claims of the RE'826 Patent.

59. Unless enjoined by this Court, upon approval of ANDA No. 220821, MSN will make, use, offer to sell, or sell MSN's ANDA Product within the United States, or will import

MSN's ANDA Product into the United States, and will thereby actively contribute to the infringement of and/or induce the infringement of one or more claims of the RE'826 Patent.

60. On information and belief, MSN has acted with full knowledge of the RE'826 Patent and without a reasonable basis for believing that the manufacture, use or sale of its generic product would not infringe and, likewise, lacks any reasonable basis for believing that its generic product is a staple article or commodity of commerce suitable for substantial non-infringing use.

61. MSN's Detailed Statement in MSN's Paragraph IV Notice Letter lacks sufficient basis to show that MSN's ANDA Product will not infringe, contribute to the infringement of, or induce the infringement of the RE'826 Patent.

62. Bayer will be irreparably harmed if MSN is not enjoined from infringing, and from actively inducing or contributing to the infringement of the RE'826 Patent. Bayer does not have an adequate remedy at law, and considering the balance of hardships between Bayer and MSN, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

63. The submission of MSN's ANDA to obtain FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or import into the United States of MSN's ANDA Product before the expiration of the RE'826 Patent also entitles Bayer to fees under 35 U.S.C. § 271(e)(4) and § 285.

SECOND CAUSE OF ACTION
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE RE'826 PATENT

64. The allegations of paragraphs 1-63 above are repeated and re-alleged as if set forth fully herein.

65. Bayer's claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

66. On information and belief, if MSN's ANDA is approved, MSN and its affiliates will immediately make, sell, offer for sale, and/or import MSN's ANDA Product in the United States, including in Delaware, thereby directly infringing one or more claims of the RE'826 Patent under at least 35 U.S.C. §§ 271 (a). Additionally, on information and belief, health care professionals or patients who use MSN's ANDA product will directly infringe one or more claims of the RE'826 Patent under one or more of 35 U.S.C. §§ 271 (a), (f) and (g).

67. On information and belief, MSN knows and intends that health care professionals or patients will use MSN's ANDA Product in accordance with the labeling sought by MSN's ANDA and MSN will therefore contribute to the infringement of and/or induce the infringement of one or more claims of the RE'826 Patent under one or more of 35 U.S.C. §§ 271 (b) and (c).

68. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Bayer and MSN concerning liability for the infringement of the RE'826 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

69. Bayer will be irreparably harmed if MSN is not enjoined from infringing, and from actively inducing or contributing to the infringement of the RE'826 Patent. Bayer does not have an adequate remedy at law, and considering the balance of hardships between Bayer and MSN, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

70. This case is exceptional, and Bayer is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Bayer requests that the Court grant the following relief:

A. A judgment that MSN infringes the RE'826 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A declaratory judgment that MSN's manufacture, use, offer for sale, or sale of MSN's ANDA Product in the United States, or importation into the United States, will directly infringe one or more claims of the RE'826 Patent under 35 U.S.C. §§ 271(a), (f), and/or (g);

C. A declaratory judgment that MSN's manufacture, use, offer for sale, or sale of MSN's ANDA Product in the United States, or importation into the United States, will induce and/or contribute to the infringement of one or more claims of the RE'826 Patent under 35 U.S.C. §§ 271 (b) and/or (c);

D. A permanent injunction pursuant to 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining MSN, its affiliates and subsidiaries, and all persons or entities acting in concert with MSN from commercially manufacturing, using, offering for sale, selling, or importing any product that infringes the RE'826 Patent by the commercial manufacture, use, provision, offer for sale, or sale within the United States, and/or importation into the United States, including MSN's ANDA Product described in ANDA No. 220821;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of MSN's ANDA No. 220821 be a date that is not earlier than the expiration date of the RE'826 Patent, or any later expiration of any patent term extension or exclusivity for the RE'826 Patent to which Bayer is or becomes entitled;

F. A declaration under 28 U.S.C. § 2201 that if MSN, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to

act in active concert or participation with MSN or acting on its behalf, engages in the commercial manufacture, use, offer for sale, sale and/or importation of the product described in ANDA No. 220821, it will constitute an act of direct and/or indirect infringement of the RE'826 Patent;

G. An award of damages or other relief pursuant to 35 U.S.C. § 271(e)(4)(C) to the extent MSN commercially manufactures, uses, provides, offers to sell, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the RE'826 Patent within the United States before the expiration of the RE'826 Patent, including any later expiration of any patent term extension or exclusivity for the RE'826 Patent to which Bayer is or becomes entitled, and that any such monetary relief be awarded to Bayer with prejudgment interest;

H. The entry of judgment declaring that MSN's acts render this case an exceptional case, and awarding Bayer its attorneys' fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

I. An award of Bayer's costs and expenses in this action; and

J. Such other and further relief as the Court may deem just and proper.

Dated: October 20, 2025

MCCARTER & ENGLISH, LLP

/s/ *Daniel M. Silver*
Daniel M. Silver (#4758)
Alexandra M. Joyce (#6423)
Renaissance Centre
405 N. King Street, 8th Floor
Wilmington, Delaware 19801
(302) 984-6300
dsilver@mccarter.com
ajoyce@mccarter.com

Attorneys for Plaintiffs
Bayer HealthCare Pharmaceuticals Inc., Bayer Pharma AG, and Bayer AG

Of Counsel:

Deborah Fishman
ARNOLD & PORTER KAYE SCHOLER LLP
3000 El Camino Real,
Five Palo Alto Square, Suite 500
Palo Alto, CA 94306-3807
(650) 319-4500
deborah.fishman@arnoldporter.com

Jeremy Cobb
ARNOLD & PORTER KAYE SCHOLER LLP
601 Massachusetts Ave, NW
Washington, DC 20001-3743
(202) 942-5000
jeremy.cobb@arnoldporter.com

Abigail Struthers
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 10019-9710
(212) 836-8000
abigail.struthers@arnoldporter.com