IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER PHARMA AKTIENGESELLSCHAFT; and BAYER AKTIENGESELLSCHAFT, Plaintiffs, v. MACLEODS PHARMACEUTICALS LTD. and MACLEODS PHARMA USA, INC., 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 Macleods Pharmaceuticals Limited ("Macleods Ltd.") and Macleods Pharma USA, Inc. ("Macleods USA") (collectively, "Macleods" 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 Macleods filing or causing to be filed Abbreviated New Drug Application No. 220747 ("Macleods'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 Macleods's ANDA, Macleods 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 Macleods's current and/or imminent manufacture, use, sale, offer to sell within the United Sates, and/or importation to the United States of Macleods'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 Macleods Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at Atlanta Arcade, Church Road, Near Leela Hotel, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India, as indicated on page 1 of its Paragraph IV Notice Letter.

7. On information and belief, Defendant Macleods Ltd., 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 information and belief, Macleods Ltd. is engaged in "developing, manufacturing, and marketing a wide range of formulations across several major therapeutic areas." Exhibit B (available at https://www.macleodspharma.com/about/). Macleods Ltd. distributes its pharmaceutical products globally, and, on information and belief, including the United States and the State of Delaware. *Id.*

9. On information and belief, Defendant Macleods USA is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business in New Jersey at 103 College Road East, Second Floor, Princeton, New Jersey 08540.

10. On information and belief, Macleods USA is a wholly-owned subsidiary of Macleods Ltd.

11. On information and belief, Macleods USA 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. According to Macleods Ltd.'s website, "[t]he formation of Macleods Pharma USA, Inc. in 2011, marked the commencement of our pharmaceutical business operations in the United States." Exhibit C (available at https://www.macleodspharma.com/usa/#about). As of August 31, 2023, Macleods filed 185 ANDAs with the FDA, including 100 approvals. *Id.*

13. On information and belief, Macleods Ltd., in collaboration with Macleods USA, prepared and submitted Macleods's ANDA and the two Macleods entities continue to collaborate in seeking FDA approval of that application.

14. On information and belief, Macleods Ltd., in collaboration with Macleods USA, intends to commercially manufacture, market, offer for sale, and sell the product described in Macleods's ANDA ("Macleods's ANDA Product") throughout the United States, including in the State of Delaware, in the event the FDA approves Macleods's ANDA.

JURISDICTION AND VENUE

15. 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*.

16. 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.

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

18. In addition, this Court has personal jurisdiction over Macleods Ltd., and venue is proper as to Macleods Ltd., at least because, upon information and belief, Macleods Ltd.: (1) directs and/or controls Macleods USA, 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 Macleods's ANDA Product for which it seeks approval under Macleods's ANDA, including throughout Delaware.

19. This Court has personal jurisdiction over Macleods Ltd. 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.*, *Bayer Pharma AG, et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:25-cv-00719 (D. Del.); *Bayer Pharma AG, et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:23-cv-00665 (D. Del.); *ZS Pharma, Inc., et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:22-cv-01100 (D. Del.); *Anacor Pharmaceuticals, Inc., et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:21-cv-01350 (D. Del.); *Novartis Pharmaceuticals Corp. v. Torrent Pharma Inc., et al.*, No. 1:21-cv-01330 (D. Del.); *Otsuka Pharmaceutical Co., Ltd., et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:21-cv-00316 (D. Del.).

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

and (3) Macleods Ltd. 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 Macleods Ltd. satisfies due process.

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

22. In addition, this Court has personal jurisdiction over Macleods USA, and venue is proper as to Macleods USA because, on information and belief, Macleods USA: (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 131 Continental Drive Suite 301, Newark, Delaware 19713; (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 Macleods's ANDA Product in Delaware.

23. On information and belief, Macleods USA distributes and/or imports oral and topical pharmaceutical products in the United States, including in the State of Delaware. Exhibit D (available at https://www.macleodspharma.com/wp-content/uploads/2025/03/Macleods-Product-List-finalMANUFACTURING-UNIT_V31_06022025.pdf). On information and belief, Macleods Ltd. manufactures pharmaceutical products that are sold and distributed in the United States, including in Delaware, by Macleods USA. *See, e.g.*, Exhibit E (available at https://www.macleodspharma.com/wp-content/uploads/2024/06/Lacosamide-Medguide-PM00398801-W.pdf).

24. This Court has personal jurisdiction over Macleods USA 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.*, *Bayer Pharma AG, et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:25-cv-00719 (D. Del.); *Bayer Pharma AG, et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:23-cv-00665 (D. Del.); *ZS Pharma, Inc., et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:22-cv-01100 (D. Del.); *Anacor Pharmaceuticals, Inc., et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:21-cv-01350 (D. Del.); *Novartis Pharmaceuticals Corp. v. Torrent Pharma Inc., et al.*, No. 1:21-cv-01330 (D. Del.); *Otsuka Pharmaceutical Co., Ltd., et al. v. Macleods Pharmaceuticals Ltd., et al.*, No. 1:21-cv-00316 (D. Del.).

25. On information and belief, Macleods Ltd. and Macleods USA 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 Macleods's ANDA Product.

26. On information and belief, Macleods Ltd. and Macleods USA 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 Macleods's ANDA Product.

27. On information and belief, Macleods Ltd., in collaboration and concert with Macleods USA, filed or caused to be filed Macleods's ANDA with the FDA.

28. On information and belief, Macleods Ltd. in collaboration and concert with Macleods USA maintains distribution channels for the commercial supply of generic drugs, including on information and belief Macleods's ANDA Product, throughout the United States, including in Delaware.

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

29. 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®.

30. 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 F.

31. 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 F at Section 11.

32. 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®.

33. 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." Ex. A. The RE'826 patent will expire on July 29, 2035.

34. 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.

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

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

MACLEODS'S ANDA AND NOTICE LETTER

37. On information and belief, Macleods 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 Macleods's ANDA Product as a purported generic version of KERENDIA® before the expiration of the RE'826 Patent.

38. Macleods Ltd. sent Bayer a letter dated September 9, 2025 ("Macleods's Paragraph IV Notice Letter") providing notice that Macleods'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 AG received Macleods's Paragraph IV Notice Letter on September 12, 2025.

39. The Paragraph IV Certification represents that Macleods Ltd. 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.

40. Macleods's Paragraph IV Notice Letter purported to contain a "Factual and Legal Basis for Non-infringement, Invalidity and/or Unenforceability of the Orange Book-Listed Patents" ("Detailed Statement").

41. Macleods's purported Detailed Statement alleged that claims 14-30 of the RE'826 Patent will not be infringed by the commercial manufacture, use, or sale of Macleods's ANDA Product, that the RE'826 Patent is improperly listed in the Orange Book considering process claims such that no certification is required as to claims 27-30, that claims 14-26 are invalid for lack of enablement, and that claims 14-30 are invalid as obvious and/or invalid as inherently anticipated. Macleods's Paragraph IV Notice Letter did not allege that any other claims of the RE'826 Patent are invalid or that any other claims of the RE'826 Patent will not be infringed.

42. Macleods's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain Macleods confidential information regarding Macleods's

ANDA Product. Plaintiffs requested that Macleods revise its purported OCA on September 19, 2025. Macleods failed to respond to Bayer's correspondence.

43. On information and belief, Macleods Ltd., in collaboration with Macleods USA, has participated in the preparation and submission of Macleods's ANDA, has provided material support to the preparation and submission of Macleods's ANDA, and intends to support the further prosecution of Macleods's ANDA.

44. On information and belief, if the FDA approves Macleods's ANDA, Macleods 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.

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

46. Bayer is commencing this action within 45 days of the date of receipt of Macleods'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

47. The allegations of paragraphs 1-46 above are repeated and re-alleged as if set forth fully herein.

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

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

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

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

52. Unless enjoined by this Court, upon approval of ANDA No. 220747, Macleods will make, use, offer to sell, or sell Macleods's ANDA Product within the United States, or will import Macleods'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.

53. On information and belief, Macleods 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.

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

55. Bayer will be irreparably harmed if Macleods 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 Macleods, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

56. The submission of Macleods'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 Macleods'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

57. The allegations of paragraphs 1-56 above are repeated and re-alleged as if set forth fully herein.

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

59. On information and belief, if Macleods's ANDA is approved, Macleods and its affiliates will immediately make, sell, offer for sale, and/or import Macleods'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 Macleods'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).

60. On information and belief, Macleods knows and intends that health care professionals or patients will use Macleods's ANDA Product in accordance with the labeling sought by Macleods's ANDA and Macleods 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).

61. As a result of the foregoing facts, there is a real, substantial, and continuing justiciable controversy between Bayer and Macleods 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.

62. Bayer will be irreparably harmed if Macleods 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 Macleods, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

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

B. A declaratory judgment that Macleods's manufacture, use, offer for sale, or sale of Macleods'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 Macleods's manufacture, use, offer for sale, or sale of Macleods'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 Macleods, its affiliates and subsidiaries, and all persons or entities acting in concert with Macleods 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 Macleods's ANDA Product described in ANDA No. 220747;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of Macleods's ANDA No. 220747 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 Macleods, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with Macleods 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. 220747, 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 Macleods 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 Macleods'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

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