IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER PHARMA AKTIENGESELLSCHAFT; and BAYER AKTIENGESELLSCHAFT, Plaintiffs, v. TEVA PHARMACEUTICALS, INC.; TEVA PHARMACEUTICALS USA, INC.; and TEVA PHARMACEUTICAL INDUSTRIES LIMITED, Defendants.	Case No. 1:25-cv-01247-UNA

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 Teva Pharmaceuticals, Inc. ("Teva Inc."), Teva Pharmaceuticals USA, Inc. ("Teva USA"), and Teva Pharmaceutical Industries Limited ("Teva Ltd.") (collectively, "Teva" 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 Teva filing or causing to be filed Abbreviated New Drug Application No. 220737 ("Teva'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 Teva's ANDA,

Teva 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 Teva's current and/or imminent manufacture, use, sale, offer to sell within the United Sates, and/or importation to the United States of Teva'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 Teva Ltd. is a corporation organized and existing under the laws of Israel, having a principal place of business at 124 Dvora HaNevi'a St. Tel Aviv 6944020, Israel.

7. On information and belief, Defendant Teva 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. Teva Ltd.'s Securities and Exchange Commission Form 10-K filing for the fiscal year ending December 31, 2024 ("Teva Ltd. 10-K") states that it is "one of the leading generic pharmaceutical companies in the United States" and "market[s] approximately 500 generic prescription products in more than 1,400 dosage strengths, packaging sizes and forms." A true and correct copy of Teva Ltd. 10-K is attached as Exhibit B.

9. On information and belief, Defendant Teva Inc. 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 400 Interpace Parkway, Parsippany, New Jersey 07054, as indicated on page 4 of its Paragraph IV Notice Letter.

10. On information and belief, Teva Inc. is a wholly-owned subsidiary of Teva Ltd.

11. On information and belief, Teva Inc. 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 Teva 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 400 Interpace Parkway, Parsippany, New Jersey 07054.

13. On information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd.

14. On information and belief, Teva 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.

15. On information and belief, Teva Inc., in collaboration with Teva Ltd. and Teva USA, prepared and submitted Teva's ANDA and the three Teva entities continue to collaborate in seeking FDA approval of that application.

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

JURISDICTION AND VENUE

17. 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*.

18. 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.

19. Venue is proper in this Court as to Teva Ltd. under 28 U.S.C. § 1391(c)(3) because Teva Ltd. is a foreign corporation and may be sued in any judicial district in the United

States where Teva Ltd. is subject to the court's personal jurisdiction. For reasons set forth below, Teva Ltd. is subject to personal jurisdiction in this district.

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

21. This Court has personal jurisdiction over Teva 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., Amicus Therapeutics US, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 1:22-cv-01461 (D. Del.).

22. Teva Ltd. has further availed itself of the jurisdiction of Delaware by initiating litigation in this Judicial District. *See, e.g., Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, No. 1:17-cv-00992 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 1:17-cv-00693 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc.*, No. 1:17-cv-00597 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 1:17-cv-00390 (D. Del.); *Teva Pharmaceuticals USA,*

Inc., et al. v. Mylan Pharmaceuticals Inc., et al., No. 1:17-cv-00249 (D. Del.); *In Re: Copaxone 775 Patent Litigation*, No. 1:16-cv-01267 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Biocon Ltd., et al.*, No. 1:16-cv-00278 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories Ltd., et al.*, No. 1:15-cv-00306 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC*, No. 1:15-cv-00124 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 1:14-cv-01419 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, No. 1:14-cv-01278 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Dr Reddy's Laboratories Ltd., et al.*, No. 1:14-cv-01172 (D. Del.); *In Re Copaxone 40 MG Consolidated Cases*, No. 1:14-cv-01171 (D. Del.); *Teva Pharmaceutical Industries Ltd., et al. v. Torrent Pharmaceuticals Ltd., et al.*, No. 1:07-cv-00332 (D. Del.).

23. Alternatively, this Court may exercise jurisdiction over Teva Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Bayer's claims arise under federal law; (2) Teva Ltd. is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Teva 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 Teva Ltd. satisfies due process.

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

25. In addition, this Court has personal jurisdiction over Teva Inc., and venue is proper as to Teva Inc. because, on information and belief, Teva Inc.: (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 251 Little Falls Drive, Wilmington, Delaware 19808; (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 Teva's ANDA Product in Delaware.

26. This Court has personal jurisdiction over Teva Inc. 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.*, *Amicus Therapeutics US, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 1:24-cv-00696 (D. Del.); *Pfizer Inc., et al. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:24-cv-00627 (D. Del.); *UroGen Pharma Ltd., et al. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:24-cv-00417 (D. Del.); *Azurity Pharmaceuticals, Inc., et al. v. Teva Pharmaceuticals, Inc.*, No. 1:23-cv-01080 (D. Del.); *Celgene Corporation et al. v. Teva Pharmaceuticals, Inc.*, No. 1:23-cv-01008 (D. Del.); *Array BioPharma Inc. v. Teva Pharmaceuticals, Inc.*, No. 1:23-cv-00625 (D. Del.); *AbbVie, Inc. v. Teva Pharmaceuticals, Inc.*, No. 1:23-cv-00374 (D. Del.); *Amicus Therapeutics US, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al*, No. 1:22-cv-01461 (D. Del.); *Journey Medical Corporation et al. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:22-cv-00288 (D. Del.); *Neurocrine Biosciences,*

Inc. v. Teva Pharmaceuticals, Inc., et al., No. 1:22-cv-00965 (D. Del.); *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:22-cv-00513 (D. Del.).

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

28. In addition, this Court has personal jurisdiction over Teva USA, and venue is proper as to Teva USA because, on information and belief, Teva 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 251 Little Falls Drive, Wilmington, Delaware 19808; (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 Teva's ANDA Product in Delaware.

29. This Court has personal jurisdiction over Teva 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.*, *Amicus Therapeutics US, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 1:24-cv-00696 (D. Del.); *Pfizer Inc., et al. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:24-cv-00627 (D. Del.); *UroGen*

Pharma Ltd., et al. v. Teva Pharmaceuticals, Inc., et al., No. 1:24-cv-00417 (D. Del.); *Bayer Pharma AG, et al. v. Teva Pharmaceuticals USA, Inc.*, No. 1:23-cv-00551 (D. Del.); *Amicus Therapeutics US, LLC, et al. v. Teva Pharmaceuticals USA, Inc., et al.*, No. 1:22-cv-01461 (D. Del.); *Neurocrine Biosciences, Inc. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:22-cv-00965 (D. Del.); *Otsuka Pharmaceutical Co., Ltd. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:22-cv-00513 (D. Del.); *Journey Medical Corporation et al. v. Teva Pharmaceuticals, Inc., et al.*, No. 1:22-cv-00288 (D. Del.); *Novartis Pharmaceuticals Corporation v. Teva Pharmaceuticals USA, Inc.*, No. 1:22-cv-00083 (D. Del.) *Teva Pharmaceuticals USA, Inc., et al. v. Biocon Ltd., et al.*, No. 1:16-cv-00278 (D. Del.).

30. Teva USA has further availed itself of the jurisdiction of this Judicial District by previously initiating litigation in this Judicial District. *See, e.g., Teva Branded Pharmaceutical Products R&D LLC, et al. v. Armstrong Pharmaceuticals, Inc., et al.*, No. 1:24-cv-00869 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.*, No. 1:17-cv-00992 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, No. 1:17-cv-00693 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Sandoz Inc.*, No. 1:17-cv-00597 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 1:17-cv-00390 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Mylan Pharmaceuticals Inc., et al.*, No. 1:17-cv-00249 (D. Del.); *In Re: Copaxone 775 Patent Litigation*, No. 1:16-cv-01267 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Biocon Ltd., et al.*, No. 1:16-cv-00278 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Doctor Reddy's Laboratories Ltd., et al.*, No. 1:15-cv-00306 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC*, No. 1:15-cv-00124 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Synthon Pharmaceuticals, Inc., et al.*, No. 1:14-cv-01419 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Mylan*

Pharmaceuticals Inc., et al., No. 1:14-cv-01278 (D. Del.); *Teva Pharmaceuticals USA, Inc., et al. v. Dr Reddy's Laboratories Ltd., et al.*, No. 1:14-cv-01172 (D. Del.); *In Re Copaxone 40 MG Consolidated Cases*, No. 1:14-cv-01171 (D. Del.); *Teva Pharmaceutical Industries Ltd., et al. v. Torrent Pharmaceuticals Ltd., et al.*, No. 1:07-cv-00332 (D. Del.).

31. On information and belief, Teva Ltd., Teva Inc., and Teva 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 Teva's ANDA Product.

32. On information and belief, Teva Ltd., Teva Inc., and Teva 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 Teva's ANDA Product.

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

34. On information and belief, Teva Inc. in collaboration and concert with Teva Ltd. and Teva USA maintains distribution channels for the commercial supply of generic drugs, including on information and belief Teva'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 C.

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 C 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." Ex. 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.

TEVA'S ANDA AND NOTICE LETTER

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

44. Teva Inc. sent Bayer a letter dated August 26, 2025 ("Teva's Paragraph IV Notice Letter") providing notice that Teva'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 Teva's Paragraph IV Notice Letter on August 27, 2025.

45. The Paragraph IV Certification represents that Teva Inc. 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. Teva's Paragraph IV Notice Letter purported to contain a "Detailed Factual And Legal Bases for Its Paragraph IV Certification that the Claims of U.S. Patent No. RE49,826 E Are Invalid, Unenforceable and/or Not Infringed" ("Detailed Statement").

47. Teva's purported Detailed Statement alleged that claims 14-27 of the RE'826 Patent are invalid as inherently anticipated, claim 30 of the RE'826 Patent is invalid as

obvious, and that claims 27-29 of the RE'826 Patent will not be infringed by the commercial manufacture, use, or sale of Teva's ANDA Product. Teva'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.

48. Teva's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain Teva confidential information regarding Teva's ANDA Product. Plaintiffs requested that Teva revise its purported OCA on September 8, 2025. Bayer and Teva came to an agreement as to the terms of an OCA on September 15, 2025. Bayer requested access to Teva's ANDA on September 15, 2025. Teva provided access to Modules 1, 2, and 3 of Teva's ANDA on September 16, 2025.

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

50. On information and belief, if the FDA approves Teva's ANDA, Teva 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.

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

52. Bayer is commencing this action within 45 days of the date of receipt of Teva'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

53. The allegations of paragraphs 1-52 above are repeated and re-alleged as if set forth fully herein.

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

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

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

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

58. Unless enjoined by this Court, upon approval of ANDA No. 220737, Teva will make, use, offer to sell, or sell Teva's ANDA Product within the United States, or will import Teva'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.

59. On information and belief, Teva 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.

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

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

62. The submission of Teva'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 Teva'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

63. The allegations of paragraphs 1-62 above are repeated and re-alleged as if set forth fully herein.

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

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

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

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

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

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

B. A declaratory judgment that Teva's manufacture, use, offer for sale, or sale of Teva'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 Teva's manufacture, use, offer for sale, or sale of Teva'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 Teva, its affiliates and subsidiaries, and all persons or entities acting in concert with Teva 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 Teva's ANDA Product described in ANDA No. 220737;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of Teva's ANDA No. 220737 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 Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with Teva 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. 220737, 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 Teva 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 Teva'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 9, 2025

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

Abigal Struthers
ARNOLD & PORTER KAYE SCHOLER LLP
250 West 55th Street
New York, NY 100190-9710
(212) 836-8000
abigail.struthers@arnoldporter.com

MCCARTER & ENGLISH, LLP

/s/ Daniel M. Silver

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

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