**IN THE UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF DELAWARE**

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| BAYER HEALTHCARE PHARMACEUTICALS INC.; BAYER PHARMA AKTIENGESELLSCHAFT; and BAYER AKTIENGESELLSCHAFT,<br><br>Plaintiffs,<br><br>v.<br><br>APOTEX INC. and APOTEX CORP.,<br><br>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 Apotex Inc. and Apotex Corp. (collectively, "Apotex" 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 Apotex filing or causing to be filed Abbreviated New Drug Application No. 220684 ("Apotex'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 Apotex's ANDA, Apotex 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 Apotex's current and/or imminent manufacture, use, sale, offer to sell within the United Sates, and/or importation to the

United States of Apotex'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 Apotex Inc. is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

7. On information and belief, Defendant Apotex Inc., 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. According to Apotex Inc.'s website, it is a "leader in Canadian generics pharmaceuticals and top 5 in the United States" and offers approximately 460 generic products. Exhibit B (available at https://www.apotex.com/global/portfolio/generics). Apotex Inc. maintains two sites in the United States, which include warehousing and distribution centers. *See* Exhibit C (available at https://www.apotex.com/global/about-us/global-reach).

9. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware and has a principal place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

10. On information and belief, Apotex Corp. is a wholly-owned subsidiary of Apotex Inc.

11. On information and belief, Apotex Corp. 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, Apotex Inc., in collaboration with Apotex Corp., prepared and submitted Apotex's ANDA and the two entities continue to collaborate in seeking FDA approval of that application.

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

## JURISDICTION AND VENUE

14. 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*.

15. 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.

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

17. In addition, this Court has personal jurisdiction over Apotex Inc., and venue is proper as to Apotex Inc., at least because, upon information and belief, Apotex Inc.: (1) directs and/or controls Apotex Corp., 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

Apotex's ANDA Product for which it seeks approval under Apotex's ANDA, including throughout Delaware.

18. This Court has personal jurisdiction over Apotex 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.*, *Urovant Sciences GmbH, et al. v. Apotex Inc., et al.*, No. 1:25-cv-00372 (D. Del.); *Vifor (International) AG, et al. v. Apotex Inc., et al.*, No. 1:25-cv-00211 (D. Del.); *Otsuka Pharmaceutical Co., Ltd., et al. v. Apotex Inc., et al.*, No. 1:24-cv-01004 (D. Del.); *Vanda Pharmaceuticals Inc. v. Apotex Inc., et al.*, No. 1:24-cv-1344-JLH (D. Del.); *Bayer Intellectual Property GmbH, et al. v. Apotex Inc., et al.*, Case No. 1:23-cv-327-RGA (D. Del.); *Bial-Portela & CA S.A. v. Apotex Inc., et al.*, No. 1:21-cv-187-CFC (D. Del.); *Merck Sharp & Dohme Corp. v. Apotex Inc., et al.*, No. 20-749-RGA; *Gilead Scis., Inc,. et al. v. Lupin Ltd., et al.*, No. 1:21-cv-1621-MN (D. Del.), *Teva Pharms. Int'l GmbH et al. v. Apotex Inc., et al.*, No. 17-cv-1164-CFC (D. Del.).

19. Apotex Inc. has further availed itself of the jurisdiction of Delaware by initiating litigation in this Judicial District. *See, e.g.*, *Apotex Inc. v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.*, No. 1:24-cv-00577-MN (D. Del.); *Apotex Inc. v. Boehringer Ingelheim Pharmaceuticals, Inc., et al.*, No. 1:23-cv-00704-MN (D. Del.); *Apotex Inc., et al. v. Symplmed Pharmaceuticals LLC, et al.*, No. 1:17-cv-00276-CFC-MPT (D. Del.); *Apotex Inc., et al. v. Lupin Ltd., et al.*, No. 1:15-cv-00357-LPS (D. Del.); *Apotex Inc. v. AstraZeneca Pharmaceuticals LP, et al.*, No. 1:08-cv-00358-JJF-LPS (D. Del.).

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

and (3) Apotex Inc. 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 Apotex Inc. satisfies due process.

21. On information and belief, Apotex Inc. conducts operations in the United States through its subsidiary and agent, Apotex Corp. On information and belief, Apotex Inc. has built an infrastructure of "research, manufacturing, and distribution facilities designed to meet the rigorous demands of modern healthcare systems, including the complex needs of the US market." Exhibit D (available at https://www.apotex.com/us/about-us/manufacturing-excellence/our-facilities). According to Apotex Inc., its "US operations play a critical role in warehousing, distribution, and market responsiveness, helping ensure timely delivery to pharmacies, health systems, and patients nationwide." *Id.*

22. On information and belief, Apotex Inc. maintains an operational site in Indianapolis, Indiana and its US-affiliate, Apotex Corp., is headquartered in Weston, Florida.

23. In a previous proceeding, Apotex Inc. admitted that it "seeks FDA approval for and manufactures generic pharmaceutical products that are distributed and sold in the United States, including the state of Delaware, in some cases by Apotex Corp." *See Bayer Intellectual Property GmbH, et al. v. Apotex Inc., et al.*, No. 1:23-cv-00327, D.I. 11 at 3 (D. Del. June 30, 2023).

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

25. In addition, this Court has personal jurisdiction over Apotex Corp., and venue is proper as to Apotex Corp. because, on information and belief, Apotex Corp.: (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 800 North State Street Suite 304, Dover, Delaware 19901; (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 Apotex's ANDA Product in Delaware.

26. On information and belief, Apotex Corp. is "[c]omitted to delivering reliable, affordable medicines across the United States," which includes the State of Delaware. Exhibit E (available at https://www.apotex.com/us/about-us). On information and belief, Apotex Corp. operates a broad pharmaceutical manufacturing network "designed to meet the evolving demands of American healthcare systems, delivering safe, high-quality, and cost effective medicines with consistency and care," including in the State of Delaware. Exhibit F (available at https://www.apotex.com/us/about-us/manufacturing-excellence). On information and belief, Apotex Corp. maintains an active pharmacy wholesale license in the State of Delaware, License No. A4-0001921, which is set to expire September 30, 2026. On information and belief, Apotex

Corp. also maintains an active controlled substances distribution/manufacturing license in the State of Delaware, License No. DM-0008879, which is set to expire on June 30, 2027.

27. This Court has personal jurisdiction over Apotex Corp. 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.*, *Urovant Sciences GmbH, et al. v. Apotex Inc., et al.*, No. 1:25-cv-00372 (D. Del.); *Vifor (International) AG, et al. v. Apotex Inc., et al*., No. 1:25-cv-00211 (D. Del.); *Otsuka Pharmaceutical Co., Ltd., et al. v. Apotex Inc., et al.*, No. 1:24-cv-01004 (D. Del.); *Pfizer Inc., et al. v. Apotex, Inc., et al.*, Docket No. 1:24-cv-00621 (D. Del.); *Mitsubishi Tanabe Pharma Corporation v. Apotex Inc., et al.*, No. 1:24-cv-00549 (D. Del.); *Gilead Sciences, Inc. v. Apotex Inc., et al.*, No. 1:23-cv-00775 (D. Del.); *Merck KGaA, et al. v. Apotex Inc., et al*., Docket No. 1:23-cv-00655 (D. Del.

28. Apotex Corp. has further availed itself of the jurisdiction of this Judicial District by previously initiating litigation in this Judicial District. *See, e.g.*, *Apotex Inc., et al. v. Symplmed Pharmaceuticals, LLC, et al.*, No. 1:17-cv-00276 (D. Del.); *Apotex Inc., et al. v. Allergan Inc.*, No. 1:12-cv-00196 (D. Del.).

29. On information and belief, Apotex Inc. and Apotex Corp. 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 Apotex's ANDA Product.

30. On information and belief, Apotex Inc. and Apotex Corp. 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 Apotex's ANDA Product.

31. On information and belief, Apotex Inc., in collaboration and concert with Apotex Corp., filed or caused to be filed Apotex's ANDA with the FDA.

32. On information and belief, Apotex Inc., in collaboration and concert with Apotex Corp., maintains distribution channels for the commercial supply of generic drugs, including on information and belief Apotex's ANDA Product, throughout the United States, including in Delaware.

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

33. 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®.

34. 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 G.

35. 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 G at Section 11.

36. 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®.

37. 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 G. The RE'826 patent will expire on July 29, 2035.

38. 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.

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

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

**APOTEX'S ANDA AND NOTICE LETTER**

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

42. Apotex Inc. sent Bayer a letter dated September 5, 2025 ("Apotex's Paragraph IV Notice Letter") providing notice that Apotex'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 Apotex Inc.'s Paragraph IV Notice Letter on September 8, 2025.

43. The Paragraph IV Certification represents that Apotex 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.

44. Apotex's Paragraph IV Notice Letter purported to contain a "Detailed Factual And Legal Basis for Apotex's Paragraph IV Certification That U.S. Patent No. RE49,826 E Is Invalid, Unenforceable, And/Or Will Not Be Infringed" ("Detailed Statement").

45. Apotex's purported Detailed Statement alleged that claims 14-30 of the RE'826 Patent will not be infringed by Apotex's ANDA Products. Apotex purported Detailed Statement contains a blanket statement that claims 14-30 of the RE'826 Patent are invalid as inherently anticipated, obvious, and/or under 35 U.S.C. § 112. Apotex'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.

46. Apotex's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain Apotex confidential information regarding Apotex's ANDA Product. Plaintiffs requested that Apotex revise its purported OCA on September 19, 2025. Apotex did not respond to Plaintiffs' request.

47. On information and belief, Apotex Inc., in collaboration with Apotex Corp., has participated in the preparation and submission of Apotex's ANDA, has provided material support to the preparation and submission of Apotex's ANDA, and intends to support the further prosecution of Apotex's ANDA.

48. On information and belief, if the FDA approves Apotex's ANDA, Apotex 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.

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

50. Bayer is commencing this action within 45 days of the date of receipt of Apotex'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**

51. The allegations of paragraphs 1-50 above are repeated and re-alleged as if set forth fully herein.

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

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

54. Apotex Inc. and Apotex Corp. are jointly and severally liable for direct infringement of the RE'826 Patent under § 271(e)(2)(A) because, on information and belief, Apotex Inc. and Apotex Corp. actively and knowingly caused to be submitted, assisted with,

participated in, contributed to, and/or directed the submission of Apotex's ANDA and its accompanying Paragraph IV Certification directed to the RE'826 Patent to the FDA. On information and belief, Apotex's ANDA seeks FDA approval to engage in the commercial manufacture, use or sale of a product claimed in the RE'826 Patent.

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

56. Unless enjoined by this Court, upon approval of ANDA No. 220684, Apotex will make, use, offer to sell, or sell Apotex's ANDA Product within the United States, or will import Apotex'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.

57. On information and belief, Apotex 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.

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

59. Bayer will be irreparably harmed if Apotex 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

Apotex, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

60. The submission of Apotex'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 Apotex'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**

61. The allegations of paragraphs 1-60 above are repeated and re-alleged as if set forth fully herein.

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

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

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

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

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

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

B. A declaratory judgment that Apotex's manufacture, use, offer for sale, or sale of Apotex'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 Apotex's manufacture, use, offer for sale, or sale of Apotex'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 Apotex, its affiliates and subsidiaries, and all persons or entities acting in concert with Apotex 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 Apotex's ANDA Product described in ANDA No. 220684;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of Apotex's ANDA No. 220684 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 Apotex, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with Apotex 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. 220684, 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 Apotex 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 Apotex'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 15, 2025

MCCARTER & ENGLISH, LLP

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