**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>ZYDUS LIFESCIENCES LIMITED and ZYDUS PHARMACEUTICALS (USA) INC.,<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 Zydus Lifesciences Limited ("Zydus Lifesciences") and Zydus Pharmaceuticals (USA) Inc. ("Zydus Pharmaceuticals") (collectively, "Zydus" 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 Zydus filing or causing to be filed Abbreviated New Drug Application No. 220636 ("Zydus'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 Zydus's ANDA, Zydus 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 Zydus's current and/or

imminent manufacture, use, sale, offer to sell within the United Sates, and/or importation to the United States of Zydus'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 Zydus Lifesciences, formerly known as Cadila Healthcare Limited, is a corporation organized and existing under the laws of India, Zydus Corporate Park, Scheme No. 63, Survey No. 536, Khoraj (Gandhinagar), Near Vaishnodevi Circle, Sarkhej Gandhinagar Highway, Ahmedabad-382481.

7. On information and belief, Defendant Zydus Lifesciences, 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. Zydus Lifesciences's Integrated Annual Report 2024-25, covering the period between April 1, 2024 and March 31, 2025 ("Zydus 2025 Annual Report") states that it is "a global, innovation drive company, pioneering scientific research and technological innovation" and is the "5th largest generic company in the US in terms of prescriptions." A true and correct copy of the Zydus 2025 Annual Report is attached as Exhibit B.

9. On information and belief, Defendant Zydus Pharmaceuticals is a corporation organized and existing under the laws of the State of New Jersey, having a principal place of business in New Jersey at 73 Route 31 N., Pennington, New Jersey 08534, as indicated on page 1 of its Paragraph IV Notice Letter.

10. On information and belief, Zydus Pharmaceuticals is a wholly-owned subsidiary of Zydus Lifesciences, as indicated on page 1 of its Paragraph IV Notice Letter.

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

13. On information and belief, Zydus Pharmaceuticals, in collaboration with Zydus Lifesciences, intends to commercially manufacture, market, offer for sale, and sell the product described in Zydus's ANDA ("Zydus's ANDA Product") throughout the United States, including in the State of Delaware, in the event the FDA approves Zydus'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 Zydus Lifesciences under 28 U.S.C. § 1391(c)(3) because Zydus Lifesciences is a foreign corporation and may be sued in any judicial district in the United States where Zydus Lifesciences is subject to the court's personal jurisdiction. For reasons set forth below, Zydus Lifesciences is subject to personal jurisdiction in this district.

17. In addition, this Court has personal jurisdiction over Zydus Lifesciences, and venue is proper as to Zydus Lifesciences, at least because on information and belief Zydus Lifesciences: (1) has purposely availed itself of the privilege of doing business in Delaware, directly or indirectly through its subsidiaries, agents, and/or alter egos; (2) maintains pervasive, continuous, and systematic contacts with Delaware, including the marketing, distribution, and/or

sale of generic pharmaceutical products in Delaware; (3) derives substantial revenue from the sale of its products in Delaware; and (4) intends to, directly or indirectly through its subsidiaries, agents, and/or alter egos, market, sell, or distribute Zydus's ANDA Product for which it seeks approval under Zydus's ANDA, including throughout Delaware.

18. This Court has personal jurisdiction over, and venue is proper as to Zydus Lifesciences because, based on information and belief, Zydus Lifesciences distributes over 225 generic products in the United States, including in this judicial district. Exhibit B at 151. According to the Zydus 2025 Annual Report, Zydus Lifesciences crossed $1 billion in revenue in the United States in 2024, representing its largest market at 49% of its consolidated revenues. *Id.* Zydus Lifesciences represents that it ranks #5 amongst generic companies in the United States based on prescriptions, which on information and belief, includes sales in Delaware. *Id.* On information and belief, "Zydus's generic products can be found across the [United States] in most pharmacies both in store as well as mail order," including in Delaware. Exhibit C.

19. This Court has personal jurisdiction over Zydus Lifesciences 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.*, *Calliditas Therapeutics AB v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 1:25-cv-00368 (D. Del.); *Astellas Pharma Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 1:24-cv-01069 (D. Del.); *Pfizer Inc., et al. v. MSN Laboratories Private Limited, et al.*, Docket No. 1:24-cv-00315 (D. Del.); *Azurity Pharmaceuticals, Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al*., Docket No. 1:23-cv-00833 (D. Del.); *Par Pharmaceutical, Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 1:23-cv-00866 (D. Del.); *Astellas Pharma Inc., et al. v . Sandoz Inc., et al.*, No. 1:20-cv-01589 (D. Del.); *ACADIA Pharmaceuticals Inc. v. Zydus Pharmaceuticals (USA) Inc., et*

*al.*, No. 1:20-cv-0121 (D. Del.); *Allergan USA, Inc., et al. v. Aurobindo Pharma Limited, et al.*, No. 1:19-cv-02317 (D. Del.).

20. Alternatively, this Court may exercise jurisdiction over Zydus Lifesciences pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Bayer's claims arise under federal law; (2) Zydus Lifesciences is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Zydus Lifesciences has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting numerous ANDAs to the FDA; has conducted at least one clinical trial throughout the United States; 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 Zydus Lifesciences satisfies due process.

21. Zydus Lifesciences's contacts with the United States as a whole are pervasive, continuous, and systematic. On information and belief, Zydus Lifesciences maintains two business sites, two manufacturing/formulations sites, and one research and development site in the United States. Exhibit D (available at https://www.zyduslife.com/). According to Zydus Lifesciences, it "has a strong presence in the regulated markets of the [United States.]." *Id.* On information and belief, Zydus Lifesciences was a highly active participant in the United States generics market in 2024—it (1) launched 17 generic products in the United States; (2) "received 24 new product approvals" in the United States; and (3) filed 486 ANDAs. Exhibit B at 151.

22. Venue is proper in this Court as to Zydus Pharmaceuticals under 28 U.S.C. § 1400(b) at least because, on information and belief, Zydus Pharmaceuticals will commit acts of infringement giving rise to the claims against it in Delaware upon approval of Zydus's ANDA.

23. On October 9, 2025, Zydus Pharmaceuticals represented that "it will not contest personal jurisdiction and venue in the District of Delaware solely for the limited purpose of Bayer's

claims against" Zydus Pharmaceuticals in this case as they relate to Zydus' proposed ANDA Product.

24. In addition, this Court has personal jurisdiction over Zydus Pharmaceuticals, and venue is proper as to Zydus Pharmaceuticals, because, on information and belief, Zydus Pharmaceuticals: (1) is qualified to do business in Delaware; (2) has customers in Delaware; (3) develops, manufactures, and/or imports generic pharmaceutical versions of branded products for sale and use throughout the United States, including in Delaware; (4) directly or indirectly markets, distributes, and/or sells its generic pharmaceutical products in Delaware; (5) 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; (6) enjoys substantial income from sales of its generic pharmaceutical products in Delaware; and (7) intends to, directly or indirectly through its subsidiary, agent, and/or alter ego, market, sell, or distribute Zydus's ANDA Product in Delaware.

25. On information and belief, Zydus Pharmaceuticals manages the United States operations of and distributes the generic drugs manufactured by Zydus Lifesciences. Exhibit B at 151. On information and belief, Zydus Pharmaceuticals "currently offers more than 500 SKUs to the US market," including in this judicial district. Exhibit E (available https://zydususa.com/overview/). On information and belief, Zydus Pharmaceuticals claims it "has grown tremendously since it entered the US" and "look[s] for new ways to bring value to the US market." *Id.* On information and belief, Zydus Pharmaceuticals has filed at least 145 drug master files, received FDA approval on about 280 ANDAs, and has over 75 ANDAs pending before the FDA. *Id.*

26. According to the Custom, Excise & Service Tax Tribunal of India, Zydus Pharmaceuticals and Zydus Lifesciences have entered into a supply and distribution agreement, in which Zydus Pharmaceuticals is required to coordinate filing of ANDAs with the FDA and obtain necessary approvals for the sale of Zydus Lifesciences's products in the United States. Exhibit F at 2.

27. This Court has personal jurisdiction over Zydus Pharmaceuticals, and venue is proper as to Zydus Pharmaceuticals, because, based on information and belief, Zydus Pharmaceuticals has contracts and collaborates with distributors that service, are licensed to conduct business in, and/or are located in the State of Delaware. Exhibit I. On information and belief, these distributors sell Zydus's products in Delaware. On information and belief, Zydus Pharmaceuticals has availed itself of the legal protections and benefits provided by the State of Delaware by, e.g., appearing in the 2025 Delaware Medicaid Preferred Drug List (PDL).[1]

28. This Court has personal jurisdiction over Zydus 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.*, *ACADIA Pharmaceuticals Inc. v. Zydus Lifesciences Limited, et al*, No. 1:25-cv-00187 (D. Del.); *Astellas Pharma Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 1:24-cv-01069 (D. Del.); *Pfizer Inc., et al. v. MSN Laboratories Private Ltd., et al.*, No. 1:24-cv-00315 (D. Del.) (consolidated); *Azurity Pharmaceuticals, Inc., et al. v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 1:23-cv-00833 (D. Del.); *Biogen Inc., et al. v. Zydus Worldwide DMCC, et al.*, No. 1:23-cv-

[1] National Drug Code numbers representing Zydus's pharmaceutical products are listed as "PDL" in the State of Delaware's Health and Social Services Drug Code Search. *See, e.g.*, Exhibit G (showing Zydus's Acetazolamide ER Capsules with NDC 70710-1591-01 as "Covered" and a "PDL.")

00732 (D. Del.); *Boehringer Ingelheim Pharmaceuticals Inc. et al v. Zydus Pharmaceuticals (USA) Inc., et al.*, No. 1:19-cv-01501 (D. Del.).

29. On information and belief, Zydus Lifesciences and Zydus Pharmaceuticals 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 Zydus's ANDA Product.

30. On information and belief, Zydus Lifesciences and Zydus 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 Zydus's ANDA Product.

31. On information and belief, Zydus Pharmaceuticals, in collaboration and concert with Zydus Lifesciences, filed or caused to be filed Zydus's ANDA with the FDA.

32. On information and belief, Zydus Pharmaceuticals, in collaboration and concert with Zydus Lifesciences, maintains distribution channels for the commercial supply of generic drugs, including on information and belief, Zydus'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 H.

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 H 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 A. 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.

**ZYDUS'S ANDA AND NOTICE LETTER**

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

42. Zydus Pharmaceuticals sent Bayer a letter dated September 4, 2025 ("Zydus's Paragraph IV Notice Letter") providing notice that Zydus'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 Zydus's Paragraph IV Notice Letter on September 5, 2025.

43. The Paragraph IV Certification represents that Zydus Pharmaceuticals 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. Zydus's Paragraph IV Notice Letter purported to contain a "Detailed Factual And Legal Bases in Support of Its Paragraph IV Certification for Finerenone Tablets, 10 mg and 20 mg" ("Detailed Statement").

45. Zydus's purported Detailed Statement alleged that claims 14-26 and 30 of the RE'826 Patent are 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 Zydus's ANDA Product. Zydus'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. Zydus's Paragraph IV Notice Letter purported to include an Offer of Confidential Access ("OCA") to certain Zydus confidential information regarding Zydus's ANDA Product. Plaintiffs requested that Zydus revise its purported OCA on September 19, 2025. Zydus did not agree to Bayer's revisions and the parties came to an impasse on September 26, 2025.

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

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

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

54. Zydus Lifesciences and Zydus Pharmaceuticals are jointly and severally liable for direct infringement of the RE'826 Patent under § 271(e)(2)(A) because, on information and belief, Zydus Lifesciences and Zydus Pharmaceuticals actively and knowingly caused to be submitted, assisted with, participated in, contributed to, and/or directed the submission of Zydus's ANDA and its accompanying Paragraph IV Certification directed to the RE'826 Patent to the FDA. On information and belief, Zydus'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 Zydus's ANDA is approved, Zydus and its affiliates will immediately make, sell, offer for sale, or otherwise distribute Zydus'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. 220636, Zydus will make, use, offer to sell, or sell Zydus's ANDA Product within the United States, or will import Zydus'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, Zydus 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. Zydus's Detailed Statement in Zydus's Paragraph IV Notice Letter lacks sufficient basis to show that Zydus'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 Zydus 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 Zydus, 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 Zydus'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 Zydus'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 Zydus's ANDA is approved, Zydus and its affiliates will immediately make, sell, offer for sale, and/or import Zydus'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 Zydus'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, Zydus knows and intends that health care professionals or patients will use Zydus's ANDA Product in accordance with the labeling sought by Zydus's ANDA and Zydus 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 Zydus 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 Zydus 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 Zydus, 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 Zydus infringes the RE'826 Patent under 35 U.S.C. § 271(e)(2)(A);

B. A declaratory judgment that Zydus's manufacture, use, offer for sale, or sale of Zydus'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 Zydus's manufacture, use, offer for sale, or sale of Zydus'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 Zydus, its affiliates and subsidiaries, and all persons or entities acting in concert with Zydus 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 Zydus's ANDA Product described in ANDA No. 220636;

E. An order pursuant to 35 U.S.C. § 271(e)(4)(A) decreeing that the effective date of any FDA approval of Zydus's ANDA No. 220636 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 Zydus, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with Zydus 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. 220636, 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 Zydus 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 Zydus'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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