IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

BOEHRINGER INGELHEIM PHARMACEUTICALS INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, and BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG, Plaintiffs, v. MYLAN PHARMACEUTICALS INC., MYLAN INC., and MYLAN LABORATORIES LIMITED, Defendants.	Case No. 1:24-cv-82 **REDACTED – PUBLIC VERSION**

AMENDED COMPLAINT

Plaintiffs, Boehringer Ingelheim Pharmaceuticals Inc.; Boehringer Ingelheim International GmbH; and Boehringer Ingelheim Pharma GmbH & Co. KG, by their undersigned attorneys, for their Complaint against Defendants, Defendants Mylan Pharmaceuticals Inc.; Mylan Inc.; and Mylan Laboratories Limited, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Applications ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell a generic version of Plaintiffs' TRADJENTA® (linagliptin) tablets and JENTADUETO® (linagliptin/metformin) tablets prior to the expiration of United States Patent Nos. 11,911,388 and 11,033,552.

THE PARTIES

2. Plaintiff Boehringer Ingelheim Pharmaceuticals Inc. ("BIPI") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 900 Ridgebury Rd., Ridgefield, CT 06877.

3. Plaintiff Boehringer Ingelheim International GmbH ("BII") is a private limited liability company organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

4. Plaintiff Boehringer Ingelheim Pharma GmbH & Co. KG ("BIPKG") is a limited liability partnership organized and existing under the laws of Germany, having a principal place of business at Binger Strasse 173, 55216 Ingelheim, Germany.

5. BIPI, BII, and BIPKG are collectively referred to hereinafter as "Boehringer" or "Plaintiffs."

6. On information and belief, Defendant Mylan Pharmaceuticals Inc. ("Mylan Pharms") is a corporation organized and existing under the laws of the State of West Virginia, having a principal place of business at 3711 Collins Ferry Road, Morgantown, West Virginia 26505.

7. On information and belief, Mylan Pharms is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic pharmaceutical products throughout the United States, including in the State of West Virginia.

8. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, having a principal place of business at Robert J. Coury Global Center, 1000 Mylan Blvd., Canonsburg, Pennsylvania 15317.

9. On information and belief, Defendant Mylan Laboratories Limited ("Mylan Labs") is a corporation organized and existing under the laws of India and has a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

10. On information and belief, Mylan Pharms is a wholly owned subsidiary of Mylan Labs, which, in turn is a wholly owned subsidiary of Mylan Inc.

11. On information and belief, the acts of Mylan Pharms complained of herein were done with the cooperation, participation, and assistance of Mylan Inc. and Mylan Labs.

12. Mylan Pharms, Mylan Labs, and Mylan Inc. are collectively referred to herein as "Mylan."

13. On information and belief, Mylan Inc. is in the business of, among other things, developing, preparing, manufacturing, selling, marketing, and distributing generic drugs, including distributing, selling, and marketing generic drugs throughout the United States, including within the State of West Virginia, through its own actions and through the actions of its agents and subsidiaries, including Mylan Pharms and Mylan Labs, from which Mylan Inc. derives a substantial portion of its revenue.

14. On information and belief, Mylan Inc. acted in concert with Mylan Pharms and Mylan Labs to prepare and submit ANDA No. 208431 (the "Mylan Linagliptin ANDA") for Mylan's 5 mg linagliptin tablets (the "Mylan Linagliptin ANDA Product") and ANDA No. 208430 (the "Mylan Linagliptin/Metformin Hydrochloride ANDA") for Mylan's 2.5 mg linagliptin/500 mg metformin hydrochloride tablets (the "Mylan Linagliptin/Metformin Hydrochloride ANDA Product").

15. On information and belief, Mylan Inc. acted in concert with Mylan Pharms and Mylan Labs to prepare and submit the Mylan Linagliptin ANDA and Mylan

Linagliptin/Metformin Hydrochloride ANDA (collectively, "the Mylan ANDAs") for the Mylan Linagliptin ANDA Product and Mylan Linagliptin/Metformin Hydrochloride ANDA Product (collectively, "the Mylan ANDA Products"), respectively, which was done at the direction of, under the control of, and for the direct benefit of Mylan Inc. Following FDA approval of the Mylan ANDAs, Mylan will manufacture and supply the approved generic products, which will then market and sell the products throughout the United States at the direction, under the control, and for the direct benefit of Mylan Inc.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

17. Venue is proper in this Court because, among other things, Mylan has committed acts of infringement in this district and has a regular and established place of business in this district. 28 U.S.C. § 1400(b). Mylan Labs is a foreign corporation not residing in any United States district and may be sued in any judicial district. 28 U.S.C. § 1391(c). Moreover, Mylan has litigated previous Hatch-Waxman patent infringement disputes in the Northern District of West Virginia, including an ongoing action on the Mylan ANDAs discussed above. *See* Compl. to Mylan, *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 1).

PERSONAL JURISDICTION OVER MYLAN PHARMS

18. Plaintiffs reallege paragraphs 1–17 as if fully set forth herein.

19. On information and belief, Mylan Pharms develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

20. This Court has personal jurisdiction over Mylan Pharms because, *inter alia,* Mylan Pharms, on information and belief: (1) has substantial, continuous, and systematic contacts with this judicial district; (2) is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (3) makes its generic drug products available in this judicial district; (4) intends to market, sell, or distribute Mylan's ANDA Products to residents of this judicial district; (5) maintains a broad distributorship network within this judicial district; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this judicial district.

21. Additionally, on information and belief, Mylan Pharms has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims and by filing suit in the Northern District of West Virginia. This includes an ongoing action between Boehringer and Mylan where Mylan raised counterclaims against Boehringer. *See* Defs.' Answer to Pls.' Compl. and Countercls., *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 48). That ongoing action involves the same Mylan ANDAs discussed herein. *See* Compl. to Mylan, *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 1).

PERSONAL JURISDICTION OVER MYLAN INC.

22. Plaintiffs reallege paragraphs 1–21 as if fully set forth herein.

23. On information and belief, Mylan Inc. develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

24. This Court has personal jurisdiction over Mylan Inc. because, *inter alia,* Mylan Inc., on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this State; (2) controls Defendant Mylan Pharms, which is incorporated in the State

of West Virginia and maintains a principal place of business in this judicial district; (3) makes its generic drug products available in this State through Mylan Pharms, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district; (4) maintains a broad distributorship network within this State; and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

25. Additionally, on information and belief, Mylan Inc. has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims. This includes an ongoing action between Boehringer and Mylan where Mylan raised counterclaims against Boehringer. *See* Defs.' Answer to Pls.' Compl. and Countercls., *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 48). That ongoing action involves the same Mylan ANDAs discussed herein. *See* Compl. to Mylan, *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 1).

PERSONAL JURISDICTION OVER MYLAN LABS

26. Plaintiffs reallege paragraphs 1–25 as if fully set forth herein.

27. On information and belief, Mylan Labs develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

28. This Court has personal jurisdiction over Mylan Labs because, *inter alia,* Mylan Labs, on information and belief: (1) intends to market, sell, or distribute Mylan's ANDA Products to residents of this judicial district; (2) controls Defendant Mylan Pharms, which is incorporated in the State of West Virginia and maintains a principal place of business in this judicial district.

29. Additionally, on information and belief, Mylan Labs has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims. This includes an ongoing

action between Boehringer and Mylan where Mylan raised counterclaims against Boehringer. *See* Defs.' Answer to Pls.' Compl. and Countercls., *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 48). That ongoing action involves the same Mylan ANDAs discussed herein. *See* Compl. to Mylan, *Boehringer Ingelheim Pharmaceuticals Inc. v. Mylan Pharmaceuticals Inc.*, 20-cv-19 (N.D.W. Va.) (No. 1).

30. Alternatively, to the extent the above facts do not establish personal jurisdiction over Mylan Labs, this Court may exercise jurisdiction over Mylan Labs pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Mylan Labs would be a foreign defendant not subject to personal jurisdiction in the courts of any State; and (c) Mylan Labs has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Mylan Labs satisfies due process.

BACKGROUND

U.S. PATENT NO. 11,911,388

31. On February 27, 2024, the United States Patent and Trademark Office duly and legally issued United States Patent No. 11,911,388 (the "'388 patent") entitled Treatment for Diabetes in Patients with Insufficient Glycemic Control Despite Therapy with an Oral or Non-Oral Antidiabetic Drug to inventors Eva Ulrike Graefe-Mody, Thomas Klein, Michael Mark, and Hans-Juergen Woerle. A true and correct copy of the '388 patent is attached as Exhibit 1.

U.S. PATENT NO. 11,033,552

32. On June 15, 2021, The United States Patent and Trademark Office duly and legally issued United States Patent No. 11,033,552 (the "'552 patent") entitled DPP IV Inhibitor

Formulations to inventors Anja Kohlrausch, Patrick Romer, and Gerd Seiffert. A true and correct copy of the '552 patent is attached as Exhibit 2.

TRADJENTA®

33. BIPI is the holder of New Drug Application ("NDA") No. 201280 (the "TRADJENTA® NDA") for linagliptin, for oral use, in 5 mg dosage, which is sold under the trade name TRADJENTA®.

34. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '388 patent is listed in the "Orange Book" with respect to TRADJENTA®.

35. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '552 patent is listed in the "Orange Book" with respect to TRADJENTA®.

36. The '388 patent covers the TRADJENTA® product and the use thereof.

37. The '552 patent covers the TRADEJENTA® product.

JENTADUETO®

38. BIPI is the holder of NDA No. 201281 (the "JENTADUETO® NDA") for linagliptin and metformin hydrochloride, for oral use, in 2.5 mg/500 mg, 2.5 mg/850 mg, and 2.5 mg/1000 mg dosages, which is sold under the trade name JENTADUETO®.

39. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the '388 patent is listed in the "Orange Book" with respect to JENTADUETO®.

40. The '388 patent covers the JENTADUETO® product and the use thereof.

ACTS GIVING RISE TO THIS ACTION

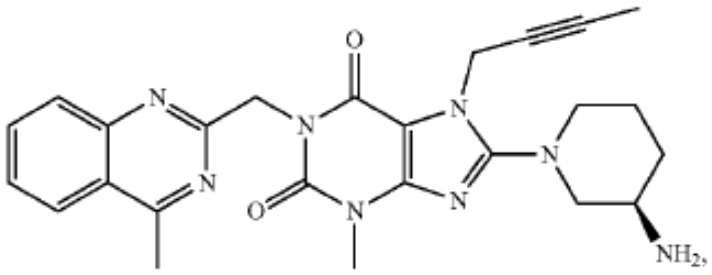
41. Plaintiffs reallege paragraphs 1–40 as if fully set forth herein.

42. On information and belief, Mylan submitted the Mylan ANDAs to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market the Mylan ANDA Products.

43. Mylan has represented that the Mylan ANDAs refer to and rely upon the TRADJENTA® NDA and JENTADUETO® NDA and contain data that, according to Mylan, demonstrate the bioavailability or bioequivalence of the Mylan ANDA Products to TRADJENTA® and JENTADUETO®.

44. Plaintiffs received a letter from Mylan bearing the date December 3, 2021 stating that Mylan had included a certification in the Mylan Linagliptin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '552 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Mylan Linagliptin ANDA Product (the "Mylan '552 Linagliptin Paragraph IV Certification"). Mylan intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Mylan Linagliptin ANDA Product prior to the expiration of the '552 patent.

45. Provided here as a representative claim for exemplary purposes, claim 1 of the '552 patent recites: "1. A solid-form pharmaceutical composition comprising as an active ingredient 5 mg of a DPP IV inhibitor compound of formula



or a salt thereof, a first diluent, a second diluent, a binder, a disintegrant and a lubricant, wherein the first diluent is mannitol, the second diluent is pregelatinized starch, the binder is copovidone, the disintegrant is corn starch, and the lubricant is magnesium stearate; and wherein the DPP IV

inhibitor compound is present in an amount 0.5-7.0% based on the total weight of DPP IV inhibitor compound, first diluent, second diluent, binder, disintegrant and lubricant."

46. The Mylan '552 Linagliptin Paragraph IV Certification, as the sole basis for non-infringement under a theory of literal infringement, asserted that [redacted] Upon information and belief, [redacted] Consequently, the Mylan Linagliptin ANDA Product directly and literally infringes one or more claims of the '552 patent.

47. Plaintiffs received a letter from Mylan bearing the date July 18, 2024 stating that Mylan had included a certification in the Mylan Linagliptin ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '388 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Mylan Linagliptin ANDA Product (the "Mylan '388 Linagliptin Paragraph IV Certification"). Mylan intends to engage in the commercial manufacture, use, offer for sale, and/or sale of the Mylan Linagliptin ANDA Product prior to the expiration of the '388 patent.

48. Plaintiffs received a letter from Mylan bearing the date July 18, 2024 stating that Mylan had included a certification in the Mylan Linagliptin/Metformin Hydrochloride ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the '388 patent are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Mylan Linagliptin/Metformin Hydrochloride ANDA Product (the "Mylan Linagliptin/Metformin Hydrochloride Paragraph IV Certification"). Mylan intends to engage in the commercial

manufacture, use, offer for sale, and/or sale of the Mylan Linagliptin/Metformin Hydrochloride ANDA Product prior to the expiration of the ’388 patent.

49. Provided here as a representative claim for exemplary purposes, claim 1 of the ’388 patent recites: “1. A method for treating metabolic diseases in type 2 diabetes patients with renal impairment and with insufficient glycemic control despite either metformin monotherapy or therapy with metformin in combination with an insulin or an insulin analogue, the method comprising administering a DPP-4 inhibitor which is 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butyn-1-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a pharmaceutically acceptable salt thereof, in an oral daily amount of 5 mg, wherein said 1-[(4-methyl-quinazolin-2-yl)methyl]-3-methyl-7-(2-butynl-yl)-8-(3-(R)-amino-piperidin-1-yl)-xanthine, or a pharmaceutically acceptable salt thereof, is used in combination with either metformin monotherapy or metformin in combination with an insulin or an insulin analogue.”

50. On information and belief, the Mylan ANDA Products, when used in accordance with the instructions provided in the prescribing labels included in the Mylan ANDAs, will cause healthcare providers or clinicians to practice a method of treating metabolic diseases in type 2 diabetes patients with renal impairment and with insufficient glycemic control despite either metformin monotherapy or therapy with metformin in combination with an insulin or an insulin analogue by administering linagliptin.

COUNT I — INFRINGEMENT OF THE ’388 PATENT

51. Plaintiffs reallege paragraphs 1–50 as if fully set forth herein.

52. Mylan has infringed at least one claim of the ’388 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Mylan ANDAs, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Products prior to the expiration of the ’388 patent.

53. Mylan has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan ANDA Products in the event that the FDA approves the Mylan ANDAs. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '388 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

54. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Products in the United States or importation of the Mylan ANDA Products into the United States during the term of the '388 patent would further infringe at least one claim of the '388 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

55. On information and belief, the Mylan ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '388 patent either literally or under the doctrine of equivalents.

56. On information and belief, the use of the Mylan ANDA Products constitutes a material part of at least one of the claims of the '388 patent; Mylan knows that its ANDA Products is especially made or adapted for use in infringing at least one of the claims of the '388 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

57. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products would contributorily infringe at least one of the claims of the '388 patent, either literally or under the doctrine of equivalents.

58. On information and belief, Mylan had knowledge of the '388 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '388 patent, either literally or under the doctrine of equivalents.

59. On information and belief, the offering to sell, sale, and/or importation of the Mylan ANDA Products by Mylan would actively induce infringement of at least one of the claims of the '388 patent, either literally or under the doctrine of equivalents.

60. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '388 patent.

61. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

COUNT II — INFRINGEMENT OF THE '552 PATENT

62. Plaintiffs reallege paragraphs 1–61 as if fully set forth herein.

63. Mylan has infringed at least one claim of the '552 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Mylan ANDAs, by which Mylan seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Mylan ANDA Products prior to the expiration of the '552 patent.

64. Mylan has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Mylan ANDA Products in the event that the FDA approves the Mylan ANDAs. Accordingly, an actual and immediate controversy exists regarding Mylan's infringement of the '552 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

65. Mylan's manufacture, use, offer to sell, or sale of the Mylan ANDA Products in the United States or importation of the Mylan ANDA Products into the United States during the term of the '552 patent would further infringe at least one claim of the '552 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

66. On information and belief, the Mylan ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '552 patent either literally or under the doctrine of equivalents.

67. On information and belief, the use of the Mylan Linagliptin ANDA Product constitutes a material part of at least one of the claims of the '552 patent; Mylan knows that its Linagliptin ANDA Product is especially made or adapted for use in infringing at least one of the claims of the '552 patent, either literally or under the doctrine of equivalents; and its Linagliptin ANDA Product is not a staple article of commerce or commodity of commerce suitable for substantial noninfringing use.

68. On information and belief, the offering to sell, sale, and/or importation of the Mylan Linagliptin ANDA Product would contributorily infringe at least one of the claims of the '552 patent, either literally or under the doctrine of equivalents.

69. On information and belief, Mylan had knowledge of the '552 patent and, by its promotional activities and package inserts for its Linagliptin ANDA Product, knows or should know that they will aid and abet another's direct infringement of at least one of the claims of the '552 patent, either literally or under the doctrine of equivalents.

70. On information and belief, the offering to sell, sale, and/or importation of the Mylan Linagliptin ANDA Product by Mylan would actively induce infringement of at least one of the claims of the '552 patent, either literally or under the doctrine of equivalents.

71. Plaintiffs will be substantially and irreparably harmed if Mylan is not enjoined from infringing the '552 patent.

72. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Boehringer's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that the Court enter judgment against Mylan and for the following relief:

a. A Judgment be entered that Mylan has infringed at least one claim of the '388 patent by submitting the Mylan ANDAs;

b. That Mylan, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '388 patent, and (ii) seeking, obtaining, or maintaining approval of the Mylan ANDAs until the expiration of the '388 patent or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Mylan ANDAs under § 505(j) of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. § 355(j)), shall not be earlier than the expiration date of the '388 patent, including any extensions;

d. That Boehringer be awarded monetary relief if Mylan commercially uses, offers to sell, or sells the Mylan ANDA Products, or any other product that infringes or induces or contributes to the infringement of the '388 patent, within the United States, prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

e. A Judgement be entered that Mylan has infringed at least one claim of the '552 patent by submitting the Mylan Linagliptin ANDA;

f. That Mylan, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the

United States, or importation into the United States, of drugs claimed in the '552 patent, and (ii) seeking, obtaining, or maintaining approval of the Mylan Linagliptin ANDA until the expiration of the '552 patent or such other later time as the Court may determine;

g. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Mylan Linagliptin ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act, (21 U.S.C. § 355(j)), shall not be earlier than the expiration date of the '552 patent, including any extensions;

h. That Boehringer be awarded monetary relief if Mylan commercially uses, offers to sell, or sells the Mylan Linagliptin ANDA Product, or any other product that infringes the '552 patent, within the United States, prior to the expiration of that patent, including any extensions, and that any such monetary relief be awarded to Boehringer with prejudgment interest;

i. A Judgment be entered that this case is exceptional, and that Plaintiffs are entitled to their reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

j. Costs and expenses in this action; and

k. Such other and further relief as the Court deems just and appropriate.

Dated: September 9, 2024

/s/ David R. Pogue

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