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ATTORNEYS FOR PLAINTIFFS
GALDERMA LABORATORIES, L.P.,
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GALDERMA RESEARCH &
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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C., **Plaintiffs,** **v.** **ZYDUS PHARMACEUTICALS (USA) INC.,** **Defendant.**	**CIVIL ACTION NO. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA RESEARCH & DEVELOPMENT, S.N.C. (collectively, "Galderma" or "Plaintiffs") file this Complaint for patent infringement against Defendant ZYDUS PHARMACEUTICALS (USA) INC. ("Zydus" or "Defendant") as follows:

THE PARTIES

1. Galderma Laboratories, L.P. ("GLLP") is a Texas limited partnership with its principal place of business at 14501 North Freeway, Fort Worth, Texas 76177. As Galderma S.A.'s ("GSA") exclusive sub-licensee, GLLP holds the exclusive right to use, manufacture, and sell Galderma's patented products in the United States, including Epiduo® Forte Gel, under FDA approval of New Drug Application ("NDA") No. 207917, approved July 15, 2015. Moreover, GLLP is responsible for seeking regulatory approval of Galderma's products in the United States, and is the sole owner of NDA No. 207917.

2. Galderma S.A. ("GSA") is a Swiss company with its principal place of business at World Trade Center, Avenue de Gratta-Paille 2, 1018 Lausanne, Switzerland. As Galderma Research & Development, S.N.C.'s exclusive licensee, GSA holds exclusive rights to use, manufacture, and sell Galderma's patented products outside of France, including Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3% / 2.5% ("Epiduo® Forte Gel"). GSA's exclusive license also includes the right and authority to grant an exclusive sub-license, which GSA has granted to GLLP as described above.

3. Galderma Research & Development, S.N.C. ("GR&D") is a French corporation with its principal place of business at 2400 Route Des Colles, Les Templiers, Biot, France 06410. GR&D is the current owner of U.S. Patent Nos. 8,936,800 (the "'800 Patent"), 9,814,690 (the "'690 Patent"), 8,785,420 (the "'420 Patent"), 8,703,820 (the "'820 Patent"), 9,387,187 (the

"'187 Patent"), and 8,445,543 (the "'543 Patent"). A copy of the '800 Patent is attached as **Exhibit 1**. A copy of the '690 Patent is attached as **Exhibit 2**. A copy of the '420 Patent is attached as **Exhibit 3**. A copy of the '820 Patent is attached as **Exhibit 4**. A copy of the '187 Patent is attached as **Exhibit 5**. A copy of the '543 Patent is attached as **Exhibit 6.**

4. Zydus is a corporation organized and existing under the laws of the State of New Jersey with its principal place of business at 73 Route 31 North Pennington, New Jersey 08534. Zydus may be served with process by and through its registered agent for service of process, Joseph D. Renner at 73 Route 31 North Pennington, New Jersey 08534.

JURISDICTION

5. This is a complaint for patent infringement. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. This Court has jurisdiction over the subject matter of the claims asserted pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Zydus because Zydus is a New Jersey corporation with a principal place of business in New Jersey.

VENUE

7. Venue in this Court is proper under 28 U.S.C. § 1400(b) because Zydus is a New Jersey corporation with a principal place of business in New Jersey.

BACKGROUND FACTS

A. The ’800 Patent

8. On January 20, 2015, the USPTO issued the ’800 Patent, entitled “Gel composition for treatment of common acne comprising a combination of benzoyl peroxide and adapalene and/or adapalene salt,” to GR&D. GR&D exclusively licensed the ’800 Patent to GSA. GSA exclusively sublicensed its rights under the ’800 Patent in the United States to GLLP.

9. The ’800 Patent is valid, enforceable, and has not expired.

B. The ’690 Patent

10. On November 14, 2017, the USPTO issued the ’690 Patent, entitled “Gel composition for treatment of common acne comprising a combination of benzoyl peroxide and adapalene and/or adapalene salt,” to GR&D. GR&D exclusively licensed the ’690 Patent to GSA. GSA exclusively sublicensed its rights under the ’690 Patent in the United States to GLLP.

11. The ’690 Patent is valid, enforceable, and has not expired.

C. The ’420 Patent

12. On July 22, 2014, the USPTO issued the ’420 Patent, entitled “Combination/association of adapalene and benzoyl peroxide for treating acne lesions,” to GR&D. GR&D exclusively licensed the ’420 Patent to GSA. GSA exclusively sublicensed its rights under the ’420 Patent in the United States to GLLP.

13. The ’420 Patent is valid, enforceable, and has not expired.

D. The ’820 Patent

14. On April 22, 2014, the USPTO issued the ’820 Patent, entitled “Administration of 6-[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders,” to GR&D. GR&D exclusively licensed the ’820 Patent to GSA. GSA exclusively sublicensed its rights under the ’820 Patent in the United States to GLLP.

15. The ’820 Patent is valid, enforceable, and has not expired.

E. The ’187 Patent

16. On July 12, 2016, the USPTO issued the ’187 Patent, entitled “Administration of 6[3-(1-adamantyl)-4-methoxyphenyl]-2-naphthoic acid for the treatment of dermatological disorders,” to GR&D. GR&D exclusively licensed the ’187 Patent to GSA. GSA exclusively sublicensed its rights under the ’187 Patent in the United States to GLLP.

17. The ’187 Patent is valid, enforceable, and has not expired.

F. The ’543 Patent

18. On May 21, 2013, the USPTO issued the ’543 Patent, entitled “Combinations of adapalene and benzoyl peroxide for treating acne lesions,” to GR&D. GR&D exclusively licensed the ’543 Patent to GSA. GSA exclusively sublicensed its rights under the ’543 Patent in the United States to GLLP.

19. The ’543 Patent is valid, enforceable, and has not expired.

G. Epiduo® Forte Gel

20. GLLP is the exclusive owner of NDA No. 207917 giving it sole permission to market and sell Epiduo® Forte Gel in the United States. On July 15, 2015, GLLP obtained FDA approval to market Epiduo® Forte Gel. Epiduo® Forte Gel is a topical ointment prescription drug that combines a retinoid (adapalene) and an antimicrobial (benzoyl peroxide) for the treatment of

acne vulgaris (including severe acne) in people who are at least 12 years old. The ’800 Patent, ’690 Patent, ’420 Patent, ’820 Patent, ’187 Patent and ’543 Patent are listed in the FDA publication entitled, “Approved Drug Products With Therapeutic Equivalence Evaluations” (known as the “Orange Book”), as covering Epiduo® Forte (adapalene and benzoyl peroxide) Gel, 0.3% / 2.5%.

21. GR&D has granted GSA, as exclusive licensee, the exclusive right to use, manufacture, and sell Epiduo® Forte Gel outside of France, including the right to sub-license to GLLP.

22. GR&D and GSA have granted GLLP, as exclusive sub-licensee, the exclusive right to use, manufacture, and sell Epiduo® Forte Gel in the United States.

H. Zydus’ Infringement

23. Zydus is in the business of developing, manufacturing, and marketing generic pharmaceutical products.

24. Prior to September 10, 2020, Zydus decided to file ANDA No. 214553 (the “ANDA”) covering a generic adapalene and benzoyl peroxide gel, 0.3% / 2.5% (the “Accused Product”) seeking FDA approval to market and sell a generic version of Epiduo® Forte Gel.

25. During the process of preparing such application, Zydus reviewed the ’800 Patent, ’690 Patent, ’420 Patent, ’820 Patent, ’187 Patent, and ’543 Patent as well as certain commercial and economic information relating to Epiduo® Forte Gel. On information and belief, the information reviewed by Zydus relating to Epiduo® Forte Gel includes the FDA approved label for that drug product.

26. Zydus submitted the ANDA seeking approval to engage in the commercial manufacture, use, and sale of the Accused Product prior to the expiration of the '800 Patent, '690 Patent, '420 Patent, '820 Patent, '187 Patent and '543 Patent.

27. The Accused Product that is the subject of the ANDA will directly and indirectly infringe one or more claims of the '800 Patent, '690 Patent, '420 Patent, '820 Patent, '187 Patent and '543 Patent.

28. On or about September 10, 2020, Zydus sent the Paragraph IV Certification to GLLP in Fort Worth, Texas as well as to GR&D and GSA. Through the Paragraph IV Certification, Zydus first notified Plaintiffs that Zydus had filed the ANDA with the FDA relating to the Accused Product, and that the ANDA includes a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) that, in Zydus' opinion, the claims of the '800 Patent, '690 Patent, '420 Patent, '820 Patent, '187 Patent and '543 Patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, or importation of the Accused Product.

29. Zydus was aware of the '800 Patent, '690 Patent, '420 Patent, '820 Patent, '187 Patent and '543 Patent when it filed the ANDA and/or sent the Paragraph IV Certification.

30. Plaintiffs have commenced this action within 45 days of the date that they received the Paragraph IV Certification.

31. Zydus intends to continue seeking approval of the ANDA from the FDA, and to engage in the commercial manufacture, marketing, and sale of the Accused Product (including commercial marketing and sale of the Accused Product in the State of New Jersey and this District), in the event that the FDA approves the ANDA.

COUNT I:
INFRINGEMENT OF U.S. PATENT NO. 8,936,800

32. Plaintiffs incorporate paragraphs 1 through 31 above by reference as if fully set forth herein.

33. The ’800 Patent is valid, enforceable, and has not expired.

34. By seeking approval of the ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Zydus’ Accused Product prior to the expiration of the ’800 Patent, Zydus has infringed at least claim 1 of the ’800 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

35. The Accused Product and/or its use as directed infringes one or more of the claims of the ’800 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the ’800 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’800 Patent.

36. Zydus will induce infringement of one or more claims of the ’800 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’800 Patent, including at least claim 1, by users of the Accused Product. The proposed label for the Accused Product must include the same information as the approved label for Epiduo® Forte Gel, including substantially identical dosage and administration information and drug product description.

37. Accordingly, if approved by the FDA, the label for the Accused Product will state that the Accused Product is a gel containing, as active ingredients, 0.3% adapalene and 2.5% benzoyl peroxide.

38. The simplest way to ensure bioequivalence of the Accused Product with Epiduo® Forte Gel is to use the same excipients and concentrations. Epiduo® Forte Gel includes 2% to 5% acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent. On information and belief, the Accused Product contains 2% to 5% acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent.

39. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '800 Patent. Because the proposed label for the Accused Product must mirror the approved label for Epiduo® Forte Gel, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of acne vulgaris and will therefore encourage use of the Accused Product for the treatment of common acne as set forth in one or more claims of the '800 Patent.

40. Zydus intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Zydus and will therefore infringe one or more claims of the '800 Patent under 35 U.S.C. § 271(b).

41. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq*., Zydus' ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iv)].

42. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '800 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '800 Patent.

43. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '800 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '800 Patent.

44. Plaintiffs will be substantially and irreparably harmed by Zydus' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

45. As a result of Zydus' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Zydus and all those in privity or acting in concert with Zydus from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '800 Patent, or from otherwise infringing or inducing the infringement of the '800 Patent.

COUNT II:
INFRINGEMENT OF U.S. PATENT NO. 9,814,690

46. Plaintiffs incorporate paragraphs 1 through 45 above by reference as if fully set forth herein.

47. The '690 Patent is valid, enforceable, and has not expired.

48. By seeking approval of the ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Zydus' Accused Product prior to the expiration of the '690 Patent, Zydus has infringed at least claim 1 of the '690 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

49. The Accused Product and/or its use as directed infringes one or more of the claims of the ’690 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the ’690 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’690 Patent.

50. Zydus will induce infringement of one or more claims of the ’690 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’690 Patent by users of the Accused Product. The proposed label for the Accused Product must include the same information as the approved label for Epiduo® Forte Gel, including substantially identical dosage and administration information and drug product description.

51. Accordingly, if approved by the FDA, the label for the Accused Product will state that the Accused Product is a gel containing, as active ingredients, 0.3% adapalene and 2.5% benzoyl peroxide.

52. The simplest way to ensure bioequivalence of the Accused Product with Epiduo® Forte Gel is to use the same excipients and concentrations. Epiduo® Forte Gel includes 2% to 5% acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent. On information and belief, the Accused Product contains 2% to 5% acrylamide sodium acryloyldimethyltaurate copolymer/isohexadecane/polysorbate 80 gelling agent.

53. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the ’690 Patent. Because the proposed label for the Accused Product must mirror the approved label for Epiduo® Forte Gel, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of acne vulgaris and will therefore encourage

use of the Accused Product for the treatment of common acne as set forth in one or more claims of the ’690 Patent.

54. Zydus intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Zydus and will therefore infringe one or more claims of the ’690 Patent under 35 U.S.C. § 271(b).

55. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq*., Zydus’ ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iv)].

56. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the ’690 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’690 Patent.

57. As a result of Zydus’ infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the ’690 Patent if made, used as directed, sold, offered for sale, or imported during the term of the ’690 Patent.

58. Plaintiffs will be substantially and irreparably harmed by Zydus’ infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

59. As a result of Zydus’ infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Zydus and all those in privity or acting in concert with Zydus

from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the ’690 Patent, or from otherwise infringing or inducing the infringement of the ’690 Patent.

COUNT III:
INFRINGEMENT OF U.S. PATENT NO. 8,785,420

60. Plaintiffs incorporate paragraphs 1 through 59 above by reference as if fully set forth herein.

61. The ’420 Patent is valid, enforceable, and has not expired.

62. By seeking approval of the ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Zydus’ Accused Product prior to the expiration of the ’420 Patent, Zydus has infringed at least claim 1 of the ’420 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

63. The Accused Product and/or its use as directed infringes one or more of the claims of the ’420 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the ’420 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’420 Patent.

64. Zydus will induce infringement of one or more claims of the ’420 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’420 Patent by users of the Accused Product. The proposed label for the Accused Product must include the same information as the approved label for Epiduo® Forte Gel, including substantially identical dosage and administration information and drug product description.

65. Accordingly, if approved by the FDA, the label for the Accused Product will state that the Accused Product contains, as active ingredients, 0.3% adapalene and 2.5% benzoyl peroxide.

66. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '420 Patent. Because the proposed label for the Accused Product must mirror the approved label for Epiduo® Forte Gel, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of acne vulgaris, is for topical use only, and is to be applied to the affected areas once daily. The label for the Accused Product will describe low incidence of adverse reaction(s) and efficacy in treating acne lesions achieved in clinical studies of treatment lasting 12 weeks, including study results showing efficacy resulting in a 33.7% degree of success at week 12, and will therefore encourage using the Accused Product for the treatment of common acne to achieve the efficacy as set forth in one or more claims of the '420 Patent.

67. Zydus intends that physicians will prescribe, and patients will use, the Accused Product in accordance with the indication(s) sought by Zydus and will therefore infringe one or more claims of the '420 Patent under 35 U.S.C. § 271(b).

68. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq*., Zydus' ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iv)].

69. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '420 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '420 Patent.

70. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '420 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '420 Patent.

71. Plaintiffs will be substantially and irreparably harmed by Zydus' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

72. As a result of Zydus' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Zydus and all those in privity or acting in concert with Zydus from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '420 Patent, or from otherwise infringing or inducing the infringement of the '420 Patent.

COUNT IV:
INFRINGEMENT OF U.S. PATENT NO. 8,703,820

73. Plaintiffs incorporate paragraphs 1 through 72 above by reference as if fully set forth herein.

74. The '820 Patent is valid, enforceable, and has not expired.

75. By seeking approval of the ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Zydus' Accused Product prior to the expiration of the '820 Patent, Zydus has infringed at least claim 1 of the '820 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

76. The Accused Product and/or its use as directed infringes one or more of the claims of the '820 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '820 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '820 Patent.

77. Zydus will induce infringement of one or more claims of the '820 Patent—in violation of Plaintiffs' patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the '820 Patent by users of the Accused Product. The proposed label for the Accused Product must include the same information as the approved label for Epiduo® Forte Gel, including substantially identical dosage and administration information and drug product description.

78. Accordingly, if approved, the label for the Accused Product will state that the Accused Product is a gel, that the Accused Product contains, as an active ingredient, 0.3% adapalene and will direct patients to "[a]pply a thin layer of adapalene . . . gel to affected areas of the face . . . once daily" using "a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek)."

79. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '820 Patent. Because the proposed label for the Accused Product must mirror the approved label for Epiduo® Forte Gel, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of acne vulgaris and will therefore encourage use of the Accused Product for the treatment of common acne as set forth in one or more claims of the '820 Patent.

80. Zydus intends that physicians will prescribe, and that patients will use, the Accused Product in accordance with the methods claimed in the '820 Patent under 35 U.S.C. § 271(b).

81. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq*., Zydus' ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iv)].

82. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '820 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '820 Patent.

83. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '820 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '820 Patent.

84. Plaintiffs will be substantially and irreparably harmed by Zydus' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

85. As a result of Zydus' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Zydus and all those in privity or acting in concert with Zydus from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '820 Patent, or from otherwise infringing or inducing the infringement of the '820 Patent.

COUNT V:
INFRINGEMENT OF U.S. PATENT NO. 9,387,187

86. Plaintiffs incorporate paragraphs 1 through 85 above by reference as if fully set forth herein.

87. The ’187 Patent is valid, enforceable, and has not expired.

88. By seeking approval of the ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Zydus’ Accused Product prior to the expiration of the ’187 Patent, Zydus has infringed at least claim 1 of the ’187 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

89. The Accused Product and/or its use as directed infringes one or more of the claims of the ’187 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the ’187 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’187 Patent.

90. Zydus will induce infringement of one or more claims of the ’187 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’187 Patent by users of the Accused Product. The proposed label for the Accused Product must include the same information as the approved label for Epiduo® Forte Gel, including substantially identical dosage and administration information and drug product description.

91. Accordingly, if approved by the FDA, the label for the Accused Product will state that the Accused Product is a gel containing, as an active ingredient, 0.3% adapalene, and will

direct patients to "[a]pply a thin layer of adapalene . . . gel to affected areas of the face . . . once daily" using "a pea-sized amount for each area of the face (e.g., forehead, chin, each cheek)."

92. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '187 Patent. Because the proposed label for the Accused Product must mirror the approved label for Epiduo® Forte Gel, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of acne vulgaris, and will therefore encourage use of the Accused Product for the treatment of common acne as set forth in one or more claims of the '187 Patent. The label for the Accused Product will describe clinical studies in which treatment resulted in 68.7% reduction of inflammatory lesions versus 39.2% reduction using the vehicle alone and 68.3% reduction of non-inflammatory lesions versus 37.4% reduction using the vehicle alone. Epiduo® Forte Gel elicits an early onset of action in treating common acne demonstrated by regression of inflammatory lesions, regression of non-inflammatory lesions or regression of total acne lesions after four weeks of treatment greater than that demonstrated by the vehicle alone by four weeks after treatment begins. Based on the purported bioequivalence, use of the claimed method with the Accused Product will likewise result in the same early onset of action.

93. Zydus intends that physicians will prescribe, and that patients will use, the Accused Product in accordance with the methods claimed in the '187 Patent under 35 U.S.C. § 271(b).

94. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq*., Zydus' ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Epiduo® Forte Gel [21 U.S.C.

§ 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iv)].

95. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '187 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '187 Patent.

96. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '187 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '187 Patent.

97. Plaintiffs will be substantially and irreparably harmed by Zydus' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

98. As a result of Zydus' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Zydus and all those in privity or acting in concert with Zydus from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '187 Patent, or from otherwise infringing or inducing the infringement of the '187 Patent.

COUNT VI:
INFRINGEMENT OF U.S. PATENT NO. 8,445,543

99. Plaintiffs incorporate paragraphs 1 through 98 above by reference as if fully set forth herein.

100. The '543 Patent is valid, enforceable, and has not expired.

101. By seeking approval of the ANDA to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Zydus' Accused Product prior to the expiration of the '543 Patent, Zydus has infringed at least claim 1

of the ’543 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

102. The Accused Product and/or its use as directed infringes one or more of the claims of the ’543 Patent, including at least claim 1, either literally or under the doctrine of equivalents. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the ’543 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’543 Patent.

103. Zydus will induce infringement of one or more claims of the ’543 Patent—in violation of Plaintiffs’ patent rights—if the FDA approves the sale of the Accused Product with instructions and labeling that will result in direct infringement of one or more claims of the ’543 Patent by users of the Accused Product. The proposed label for the Accused Product must include the same information as the approved label for Epiduo® Forte Gel, including substantially identical dosage and administration information and drug product description.

104. Accordingly, if approved by the FDA, the label for the Accused Product will state that the Accused Product contains, as active ingredients, 0.3% adapalene and 2.5% benzoyl peroxide. Epiduo® Forte Gel contains 0.3% adapalene and 2.5% benzoyl peroxide combined at fixed doses in a single formula that delivers said active ingredients together synergistically. If approved by the FDA, the Accused Product will do the same.

105. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the ’543 Patent. Because the proposed label for the Accused Product must mirror the approved label for Epiduo® Forte Gel, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of acne vulgaris, and is “[f]or topical use only,” will direct patients to “[a]pply a thin layer of adapalene . . . gel to affected areas of the

face . . . once daily," and will describe clinical studies in which treatment for 12 weeks resulted 68.3% reduction of non-inflammatory lesions. The label of the Accused Product will therefore encourage topical use of the Accused Product for the treatment of acne lesions to achieve the efficacies as set forth in one or more claims of the '543 Patent.

106. Zydus intends that physicians will prescribe, and that patients will use, the Accused Product in accordance with the methods claimed in the '543 Patent under 35 U.S.C. § 271(b).

107. Pursuant to the Drug Price Competition and Patent Term Restoration Act, 21 U.S.C. § 355 *et seq*., Zydus' ANDA must include information showing that the Accused Product (1) contains the same active ingredients as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Epiduo® Forte Gel [21 U.S.C. § 355(j)(2)(A)(iv)].

108. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '543 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '543 Patent.

109. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '543 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '543 Patent.

110. Plaintiffs will be substantially and irreparably harmed by Zydus' infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

111. As a result of Zydus' infringement, Plaintiffs are entitled to permanent injunctive relief, restraining and enjoining Zydus and all those in privity or acting in concert with Zydus from manufacturing, selling, offering to sell, or importing the Accused Product during the term of the '543 Patent, or from otherwise infringing or inducing the infringement of the '543 Patent.

DEMAND FOR JURY TRIAL

In the event Zydus commercially manufactures, uses, sells, offers to sell, or imports the Accused Product prior to trial, Plaintiffs demand trial by jury of all issues and claims alleged herein.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for the following relief:

(A) A declaration that Zydus' commercial manufacture, use, offer for sale, or sale in, or importation into the United States of the Accused Product prior to the date of the expiration of the '800 Patent, '690 Patent, '420 Patent, '820 Patent,'187 Patent and '543 Patent, including any patent extensions and any additional periods of exclusivity, would constitute infringement of such patents in violation of Plaintiffs' patent rights;

(B) A declaration, pursuant to 35 U.S.C. § 271(e)(2)(A), that Zydus has infringed the '800 Patent, '690 Patent, '420 Patent, '820 Patent, '187 Patent and '543 Patent by submitting the ANDA to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell in, or import into the United States the Accused Product prior to the expiration of such patents, including any patent extensions and any additional periods of exclusivity, and that the Accused Product infringes such patents;

(C) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any approval of the Accused Product described in the ANDA is not to be earlier than the date of the

expiration of the ’800 Patent, ’690 Patent, ’420 Patent, ’820 Patent, ’187 Patent and ’543 Patent, including any patent extensions and any additional periods of exclusivity;

(D) A permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and (D), and 35 U.S.C. § 283, enjoining Zydus and its officers, agents, servants, employees, privies, and others acting for, on behalf of, or in concert with any of them, from commercially manufacturing, using, selling, or offering to sell the Accused Product within the United States; importing the Accused Product into the United States; or otherwise infringing or inducing the infringement of the ’800 Patent, ’690 Patent, ’420 Patent, ’820 Patent, ’187 Patent and ’543 Patent prior to the date of the expiration of such patents, including any patent extensions and any additional periods of exclusivity;

(E) An award to Plaintiffs, pursuant to 35 U.S.C. § 271(e)(4)(C), of damages and other monetary relief, as a result of Zydus’ infringement, to the extent there has been any commercial manufacture, use, offer to sell, or sale within the United States or importation into the United States of the Accused Product prior to the date of the expiration of the ’800 Patent, ’690 Patent, ’420 Patent, ’820 Patent, ’187 Patent and ’543 Patent, including any patent extensions and any additional periods of exclusivity; and

(F) Such other and further relief as this Court may deem just and proper.

Dated: October 22, 2020

Respectfully submitted,

/s/ Sergei Orel

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CERTIFICATION UNDER LOCAL RULE 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any action pending in any court or of any arbitration or administrative proceeding.

By: */s/ Sergei Orel*
Sergei A. Orel

CERTIFICATION UNDER LOCAL RULE 201.1

Pursuant to Local Civil Rule 201.1, I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that Plaintiffs seek, *inter alia*, injunctive relief and the amount in controversy exceeds the $150,000 threshold of interest and costs and any claim for punitive damages.

By: */s/ Sergei Orel*
Sergei A. Orel

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