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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA HOLDING, S.A., Plaintiffs, v. ZYDUS PHARMACEUTICALS (USA) INC., Defendant.	Civil Action No. 1:20-19578 (RMB)(KMW) *Document Electronically Filed*

DEFENDANT ZYDUS PHARMACEUTICALS (USA) INC.'S ANSWER AND AFFIRMATIVE DEFENSES TO PLAINTIFFS' COMPLAINT FOR PATENT INFRINGEMENT

Zydus Pharmaceuticals (USA) Inc. ("Zydus" or "Defendant") for its Answer and Affirmative Defenses to the Complaint of Galderma Laboratories, L.P., Galderma S.A., and Galderma Holding S.A. (collectively, "Plaintiffs") state as follows:

All averments not expressly admitted are denied.

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. GLLP holds the exclusive right to use, manufacture, and sell Galderma's patented products in the United States, including Soolantra® (ivermectin) Cream 1%, under FDA approval of New Drug Application

("NDA") No. 206255, approved December 19, 2014. Moreover, GLLP is responsible for seeking regulatory approvals of Galderma's products in the United States and is the sole owner of NDA No. 206255. Soolantra® (Ivermectin) Cream, 1% is indicated for the treatment of inflammatory lesions of rosacea.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first, second and third sentences of paragraph 1 and therefore denies them. Zydus admits that the Food and Drug Administration's ("FDA's") Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"), lists GLLP as the Applicant Holder and Soolantra as the Proprietary Name in connection with NDA No. 206255. Zydus admits that the prescribing information for Soolantra® (Ivermectin) Cream, 1%, dated April 19, 2018, available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/206255s004lbl.pdf, states in part that "SOOLANTRA cream is indicated for the treatment of inflammatory lesions of rosacea." Zydus denies all other allegations in paragraph 1.

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. GSA is an exclusive licensee of the Asserted Patents. GSA has granted GLLP exclusive rights under the Asserted Patents to GLLP.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in paragraph 2 and therefore denies them.

3. Galderma Holding S.A. ("GSHSA") is a Swiss company with its principal place of business at Avenue Gratta-Paille 2, CH-1018 Lausanne, Switzerland. GSHSA is the owner of U.S. Patent No. 9,089,587 (the "'587 Patent"), U.S. Patent No. 9,233,117 (the "'117 Patent"), U.S. Patent No. 9,233,118 (the "'118 Patent"), U.S. Patent No. 9,782,425 (the "'425 Patent"), and U.S. Patent No. 10,206,939 (the "'939 Patent") (collectively, the "Asserted Patents"). A copy of the '587 Patent is attached as Exhibit A. A copy of the '117 Patent is attached as Exhibit B. A copy of the '118 Patent is attached as Exhibit C. A copy of the '425 Patent is attached as Exhibit D. A copy of the '939 Patent is attached as Exhibit E.

ANSWER: Zydus lacks knowledge or information sufficient to form a belief about the truth of the allegations in the first sentence of paragraph 3 and therefore denies them. Zydus admits on information and belief that what purports to be a copy of the '587 Patent is attached to the

Complaint as Exhibit A; what purports to be a copy of the '117 Patent is attached to the Complaint as Exhibit B; what purports to be a copy of the '118 Patent is attached to the Complaint as Exhibit C; what purports to be a copy of the '425 Patent is attached to the Complaint as Exhibit D; and what purports to be a copy of the '939 Patent is attached to the Complaint as Exhibit E. Zydus denies all other allegations in paragraph 3.

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.

ANSWER: Zydus admits the allegations in the first sentence of paragraph 4. The allegations in the second sentence state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest service of Plaintiffs' Complaint. Zydus denies all other allegations in paragraph 4.

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).

ANSWER: The allegations in paragraph 5 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that Plaintiffs' Complaint purports to be a civil action alleging patent infringement. Zydus does not contest subject matter jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 215210. Zydus denies all other allegations in paragraph 5.

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

ANSWER: The allegations in paragraph 6 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest personal jurisdiction in this Court solely for the purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 215210. Zydus denies all other allegations in paragraph 6.

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.

ANSWER: The allegations in paragraph 7 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus does not contest venue in this Court solely for the purposes of Plaintiffs' claims against Zydus in this case and solely as they apply to the proposed product described in ANDA No. 215210. Zydus denies all other allegations in paragraph 7.

BACKGROUND FACTS

A. The '587 Patent

8. On July 28, 2015, the USPTO issued the '587 Patent, entitled "Treatment of Papulopustular Rosacea with Ivermectin," to GSA.

ANSWER: Zydus admits that the '587 Patent is titled "Treatment of Papulopustular Rosacea with Ivermectin" and lists January 28, 2015 as the issue date of the '587 Patent. Zydus further admits that GSA is listed as the assignee on the face of the '587 Patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 8 and therefore denies them.

9. The '587 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

B. The ’117 Patent

10. On January 12, 2016, the USPTO issued the ’117 Patent, entitled “Treatment of Inflammatory Lesions of Rosacea with Ivermectin,” to GSA.

ANSWER: Zydus admits that the ’117 Patent is titled “Treatment of Inflammatory Lesions of Rosacea with Ivermectin” and lists January 12, 2016 as the issue date of the ’117 Patent. Zydus further admits that GSA is listed as the assignee on the face of the ’117 Patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 10 and therefore denies them.

11. The ’117 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

C. The ’118 Patent

12. On January 12, 2016, the USPTO issued the ’118 Patent, entitled “Treatment of Papulopustular Rosacea with Ivermectin,” to GSA.

ANSWER: Zydus admits that the ’118 Patent is titled “Treatment of Papulopustular Rosacea with Ivermectin” and lists January 12, 2016 as the issue date of the ’118 Patent. Zydus further admits that GSA is listed as the assignee on the face of the ’118 Patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 12 and therefore denies them.

13. The ‘118 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

D. The ‘425 Patent

14. On October 10, 2017, the USPTO issued the ’425 Patent, entitled “Treatment of Papulopustular Rosacea with Ivermectin,” to GSA.

ANSWER: Zydus admits that the ’425 Patent is titled “Treatment of Papulopustular Rosacea with Ivermectin” and lists October 10, 2017 as the issue date of the ’425 Patent. Zydus further admits that GSA is listed as the assignee on the face of the ’425 Patent. Zydus lacks

knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 14 and therefore denies them.

15. The ’425 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

E. The ’939 Patent

16. On February 19, 2019, the USPTO issued the ’939 Patent, entitled “Treatment of Papulopustular Rosacea with Ivermectin,” to GSA

ANSWER: Zydus admits that the ’939 Patent is titled “Treatment of Papulopustular Rosacea with Ivermectin” and lists February 19, 2019 as the issue date of the ’939 Patent. Zydus further admits that GSA is listed as the assignee on the face of the ’939 Patent. Zydus lacks knowledge or information sufficient to form a belief about the truth of all other allegations in paragraph 16 and therefore denies them.

17. The ’939 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

F. Soolantra® (Ivermectin) Cream, 1%

18. GLLP is the exclusive owner of NDA No. 206255 giving it sole permission to market and sell Soolantra® (Ivermectin) Cream, 1% in the United States. On December 19, 2014, GLLP obtained FDA approval to market Soolantra® (ivermectin) Cream, 1%. The ’587 Patent, ’117 Patent, ’118 Patent, ’425 Patent, and ’939 Patent are listed in the FDA publication entitled, “Approved Drug Products with Therapeutic Equivalence Evaluations” (known as the “Orange Book”) as covering Soolantra® (ivermectin) Cream, 1%.

ANSWER: Zydus admits that FDA’s Orange Book lists GLLP as the Applicant Holder, Soolantra as the Proprietary Name, and December 19, 2014 as the Approval Date in connection with NDA No. 206255. Zydus further admits that FDA’s Orange Book lists the ’587 Patent, the ’117 Patent, the ’118 Patent, the ’425 Patent, and the ’939 Patent in connection with NDA No. 206255. Zydus lacks knowledge or information sufficient to form a belief about all other allegations in paragraph 18 and therefore denies them.

G. Zydus' Infringement

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

ANSWER: Zydus admits that it sells products, including generic pharmaceutical products, in the United States. Zydus denies all other allegations of paragraph 19.

20. Prior to November 2, 2020, Zydus decided to file ANDA No. 215210 (the "ANDA") covering a generic version of Soolantra® (Ivermectin) Cream, 1% (the "Accused Product") seeking FDA approval to market and sell a generic version of Soolantra® (Ivermectin) Cream, 1%.

ANSWER: Zydus admits that it submitted ANDA No. 215210 to FDA prior to November 2, 2020 to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and importation of ivermectin cream, 1%. Zydus admits that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the Reference Listed Drug ("RLD"). Zydus denies all other allegations of paragraph 20.

21. During the process of preparing such application, Zydus reviewed the '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent as well as certain commercial and economic information relating to Soolantra® (Ivermectin) Cream 1%. On information and belief, the information reviewed by Zydus relating to Soolantra® (Ivermectin) Cream 1% includes the FDA approved label for that drug product.

ANSWER: Zydus admits that ANDA No. 215210 includes a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to the '587 Patent, the '117 Patent, the '118 Patent, the '425 Patent, and the '939 Patent; that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the RLD; and that ANDA No. 215210 includes a proposed label for the proposed product described in ANDA No. 215210. Zydus denies all other allegations in paragraph 21.

22. 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 '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent.

ANSWER: Zydus admits that it submitted ANDA No. 215210 under 21 U.S.C. § 355(j) to FDA to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and importation of ivermectin cream, 1%, and that ANDA No. 215210 includes a Paragraph IV Certification with respect to the '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent. Zydus denies all other allegations of paragraph 22.

23. The Accused Product that is the subject of the ANDA will directly and indirectly infringe one or more claims of the '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent, either literally or under the doctrine of equivalents.

ANSWER: Denied.

24. On or about November 2, 2020, Zydus sent the Paragraph IV Certification to GLLP in Fort Worth, Texas as well as to 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 '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 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.

ANSWER: Zydus admits that it sent a letter dated November 2, 2020 to Galderma Laboratories, L.P. and Galderma S.A. notifying them that Zydus submitted ANDA No. 215210 under 21 U.S.C. § 355(j) to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and importation of ivermectin cream, 1%, and that ANDA No. 215210 includes a Paragraph IV Certification with respect to the '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent. Zydus denies all other allegations in paragraph 24.

25. Zydus was aware of the '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent when it filed the ANDA and/or sent the Paragraph IV Certification.

ANSWER: Zydus admits that ANDA No. 215210 includes Paragraph IV Certifications with respect to the '587 Patent, '117 Patent, '118 Patent, '425 Patent, and '939 Patent. Zydus denies all other allegations in paragraph 25.

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

ANSWER: The allegations in paragraph 26 state legal conclusions to which no answer is required. To the extent an answer is required, Zydus admits that the Complaint has a filing date of December 17, 2020. Zydus denies all other allegations in paragraph 26.

27. 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.

ANSWER: Zydus admits that it submitted ANDA No. 215210 under 21 U.S.C. § 355(j) to the FDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and importation of ivermectin cream, 1%, and that Zydus continues to seek approval of ANDA No. 215210. Zydus denies all other allegations in paragraph 27.

COUNT I:

INFRINGEMENT OF U.S. PATENT NO. 9,089,587

28. Plaintiffs incorporate paragraphs 1 through 27 above by reference as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-27, as if fully set forth herein.

29. The ’587 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

30. 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 ’587 Patent, Zydus has infringed at least claim 1 of the ’587 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

31. The Accused Product and/or its use as directed infringes one or more of the claims of the ’587 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 ’587 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the ’587 Patent.

ANSWER: Denied.

32. Zydus will induce infringement of one or more claims of the '587 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 '587 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 Soolantra® (Ivermectin) Cream 1%, including substantially identical dosage and administration information and drug product description.

ANSWER: Zydus denies the allegations in the first sentence of paragraph 32. The allegations in the second sentence of paragraph 32 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 32.

33. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '587 Patent. Because the proposed label for the Accused Product must mirror the approved label for Soolantra® (Ivermectin) Cream 1%, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of inflammatory lesions of rosacea in accordance with the methods claimed in the '587 Patent. The proposed label also will include reference to clinical studies showing that use of the Accused Product in accordance with the methods claimed in the '587 Patent will achieve certain clinical benefits and efficacy(ies), including with respect to reductions of inflammatory lesions and success in treating rosacea, as claimed in the '587 Patent. Zydus's sale and marketing of the Accused Product will therefore encourage use of the Accused Product for the treatment of rosacea as set forth in one or more claims of the '587 Patent.

ANSWER: The allegations in paragraph 33 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 33.

34. 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 '587 Patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

35. 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 Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

ANSWER: The allegations in paragraph 35 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the RLD and that ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 35.

36. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '587 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '587 Patent.

ANSWER: Denied.

37. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '587 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '587 Patent.

ANSWER: Denied.

38. 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.

ANSWER: Denied.

39. 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 '587 Patent, or from otherwise infringing or inducing the infringement of the '587 Patent.

ANSWER: Denied.

COUNT II:

INFRINGEMENT OF U.S. PATENT NO. 9,233,117

40. Plaintiffs incorporate paragraphs 1 through 39 above by reference as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-39, as if fully set forth herein.

41. The '117 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

42. 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 '117 Patent, Zydus has infringed at least claim 1 of the '117 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

43. The Accused Product and/or its use as directed infringes one or more of the claims of the '117 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 '117 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '117 Patent.

ANSWER: Denied.

44. Zydus will induce infringement of one or more claims of the '117 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 '117 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 Soolantra® (Ivermectin) Cream 1%, including substantially identical dosage and administration information and drug product description.

ANSWER: Zydus denies the allegations in the first sentence of paragraph 44. The allegations in the second sentence of paragraph 44 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 44.

45. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '117 Patent. Because the proposed label for the Accused Product must mirror the approved label for Soolantra® (Ivermectin) Cream 1%, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of inflammatory lesions of rosacea in accordance with the methods claimed in the '117 Patent. The proposed label also will include reference to clinical studies showing that use of the Accused Product in accordance with

the methods claimed in the '117 Patent will achieve certain clinical benefits and efficacy(ies), including with respect to reductions of inflammatory lesions and success in treating rosacea, as claimed in the '117 Patent. Zydus's sale and marketing of the Accused Product will therefore encourage use of the Accused Product for the treatment of rosacea as set forth in one or more claims of the '117 Patent.

ANSWER: The allegations in paragraph 45 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 45.

46. 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 '117 Patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

47. 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 Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

ANSWER: The allegations in paragraph 47 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the RLD and that ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 47.

48. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '117 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '117 Patent.

ANSWER: Denied.

49. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '117 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '117 Patent.

ANSWER: Denied.

50. 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.

ANSWER: Denied.

51. 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 '117 Patent, or from otherwise infringing or inducing the infringement of the '117 Patent.

ANSWER: Denied.

COUNT III:

INFRINGEMENT OF U.S. PATENT NO. 9,233,118

52. Plaintiffs incorporate paragraphs 1 through 51 above by reference as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-51, as if fully set forth herein.

53. The '118 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

54. 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 '118 Patent, Zydus has infringed at least claim 1 of the '118 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

55. The Accused Product and/or its use as directed infringes one or more of the claims of the '118 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 '118 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '118 Patent.

ANSWER: Denied.

56. Zydus will induce infringement of one or more claims of the '118 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 '118 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 Soolantra®

(Ivermectin) Cream 1%, including substantially identical dosage and administration information and drug product description.

ANSWER: Zydus denies the allegations in the first sentence of paragraph 56. The allegations in the second sentence of paragraph 56 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 56.

57. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '118 Patent. Because the proposed label for the Accused Product must mirror the approved label for Soolantra® (Ivermectin) Cream 1%, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of inflammatory lesions of rosacea in accordance with the methods claimed in the '118 Patent. The proposed label also will include reference to clinical studies showing that use of the Accused Product in accordance with the methods claimed in the '118 Patent will achieve certain clinical benefits and efficacy(ies), including with respect to reductions of inflammatory lesions and success in treating rosacea, as claimed in the '118 Patent. Zydus's sale and marketing of the Accused Product will therefore encourage use of the Accused Product for the treatment rosacea as set forth in one or more claims of the '118 Patent.

ANSWER: The allegations in paragraph 57 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 57.

58. 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 '118 Patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

59. 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 Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

ANSWER: The allegations in paragraph 59 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the RLD and that ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 59.

60. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '118 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '118 Patent.

ANSWER: Denied.

61. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '118 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '118 Patent.

ANSWER: Denied.

62. 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.

ANSWER: Denied.

63. 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 '118 Patent, or from otherwise infringing or inducing the infringement of the '118 Patent.

ANSWER: Denied.

COUNT IV:

INFRINGEMENT OF U.S. PATENT NO. 9,782,425

64. Plaintiffs incorporate paragraphs 1 through 63 above by reference as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-63, as if fully set forth herein.

65. The '425 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

66. 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 '425 Patent, Zydus has infringed at least claim 1 of the '425 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

67. The Accused Product and/or its use as directed infringes one or more of the claims of the '425 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 '425 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '425 Patent.

ANSWER: Denied.

68. Zydus will induce infringement of one or more claims of the '425 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 '425 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 Soolantra® (Ivermectin) Cream 1%, including substantially identical dosage and administration information and drug product description.

ANSWER: Zydus denies the allegations in the first sentence of paragraph 68. The allegations in the second sentence of paragraph 68 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 68.

69. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '425 Patent. Because the proposed label for the Accused Product must mirror the approved label for Soolantra® (Ivermectin) Cream 1%, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of inflammatory lesions of rosacea in accordance with the methods claimed in the '425 Patent. The proposed label also will include reference to clinical studies showing that use of the Accused Product in accordance with the methods claimed in the '425 Patent will achieve certain clinical benefits and efficacy(ies), including with respect to reductions of inflammatory lesions and success in treating rosacea, as claimed in the '425 Patent. Zydus's sale and marketing of the Accused Product will therefore encourage use of the Accused Product for the treatment of rosacea as set forth in one or more claims of the '425 Patent.

ANSWER: The allegations in paragraph 69 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 69.

70. Zydus intends that physicians will prescribe, and that 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 '425 Patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

71. 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 Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

ANSWER: The allegations in paragraph 71 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the RLD and that ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 71.

72. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '425 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '425 Patent.

ANSWER: Denied.

73. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '425 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '425 Patent.

ANSWER: Denied.

74. 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.

ANSWER: Denied.

75. 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 '425 Patent, or from otherwise infringing or inducing the infringement of the '425 Patent.

ANSWER: Denied.

COUNT V:

INFRINGEMENT OF U.S. PATENT NO. 10,206,939

76. Plaintiffs incorporate paragraphs 1 through 75 above by reference as if fully set forth herein.

ANSWER: Zydus repeats and re-alleges its answers to each of the preceding paragraphs 1-75 as if fully set forth herein.

77. The '939 Patent is valid, enforceable, and has not expired.

ANSWER: Denied.

78. 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 '939 Patent, Zydus has infringed at least claim 1 of the '939 Patent under 35 U.S.C. § 271(e)(2)(A), either literally or under the doctrine of equivalents.

ANSWER: Denied.

79. The Accused Product and/or its use as directed infringes one or more of the claims of the '939 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 '939 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '939 Patent.

ANSWER: Denied.

80. Zydus will induce infringement of one or more claims of the '939 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 '939 Patent, including 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 Soolantra® (Ivermectin) Cream 1%, including substantially identical dosage and administration information and drug product description.

ANSWER: Zydus denies the allegations in the first sentence of paragraph 80. The allegations in the second sentence of paragraph 80 state legal conclusions to which no answer is

required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 80.

81. Zydus seeks approval of at least one indication for the Accused Product that is claimed in the '939 Patent. Because the proposed label for the Accused Product must mirror the approved label for Soolantra® (Ivermectin) Cream 1%, if approved, the label for the Accused Product will state that the Accused Product is indicated for treatment of inflammatory lesions of rosacea in accordance with the methods claimed in the '939 Patent. The proposed label also will include reference to clinical studies showing that use of the Accused Product in accordance with the methods claimed in the '939 Patent will achieve certain clinical benefits and efficacy(ies), including with respect to reductions of inflammatory lesions and success in treating rosacea, as claimed in the '939 Patent. Zydus's sale and marketing of the Accused Product will therefore encourage use of the Accused Product for the treatment rosacea as set forth in one or more claims of the '939 Patent.

ANSWER: The allegations in paragraph 81 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that the labelling for the proposed product described in ANDA No. 215210 will comply with applicable law. Zydus denies all other allegations in paragraph 81.

82. Zydus intends that physicians will prescribe, and that 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 '939 Patent under 35 U.S.C. § 271(b).

ANSWER: Denied.

83. 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 Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(II)]; (2) has the same route of administration, dosage form, and strength as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iii)]; and (3) is bioequivalent and/or has the same therapeutic effect as Soolantra® (Ivermectin) Cream 1% [21 U.S.C. § 355(j)(2)(A)(iv)].

ANSWER: The allegations in paragraph 83 state legal conclusions to which no answer is required. To the extent that an answer is required, Zydus admits that ANDA No. 215210 identifies NDA No. 206255, Soolantra® (Ivermectin) Cream, 1% as the RLD and will comply with applicable law. Zydus denies all other allegations in paragraph 83.

84. As such, under 35 U.S.C. § 271(e)(2)(A), Zydus has infringed the '939 Patent by submitting the ANDA seeking permission to commercially manufacture, use, or sell the Accused Product prior to the expiration of the '939 Patent.

ANSWER: Denied.

85. As a result of Zydus' infringement, Plaintiffs are entitled to a declaration that the Accused Product infringes the '939 Patent if made, used as directed, sold, offered for sale, or imported during the term of the '939 Patent.

ANSWER: Denied.

86. 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.

ANSWER: Denied.

87. 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 '939 Patent, or from otherwise infringing or inducing the infringement of the '939 Patent.

ANSWER: Denied.

PRAYER FOR RELIEF

Zydus denies that Plaintiffs are entitled to the general or specific relief requested against Zydus, or to any relief whatsoever, and pray for judgment in favor of Zydus, dismissing this action with prejudice and awarding Zydus its reasonable attorneys' fees pursuant to 35 U.S.C. § 285, interest, and costs of this action, and such other or further relief as this Court may deem just and proper.

AFFIRMATIVE DEFENSES

Without prejudice to the denials set forth in its Answer and without admitting any allegations of the Complaint not otherwise admitted, Zydus avers and asserts the following Affirmative Defenses to Plaintiffs' Complaint.

FIRST AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,089,587)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of ivermectin cream, 1%, described in ANDA No. 215210 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '587 Patent.

SECOND AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,089,587)

Upon information and belief, the claims of the '587 Patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

THIRD AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,233,117)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of ivermectin cream, 1%, described in ANDA No. 215210 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '117 Patent.

FOURTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,233,117)

Upon information and belief, the claims of the '117 Patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

FIFTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,233,118)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United

States of ivermectin cream, 1%, described in ANDA No. 215210 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '118 Patent.

SIXTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,233,118)

Upon information and belief, the claims of the '118 Patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

SEVENTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 9,782,425)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of ivermectin cream, 1%, described in ANDA No. 215210 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '425 Patent.

EIGHTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 9,782,425)

Upon information and belief, the claims of the '425 Patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

NINTH AFFIRMATIVE DEFENSE
(Noninfringement of U.S. Patent No. 10,206,939)

Plaintiffs will not and cannot meet the burden of proof required to show that the commercial manufacture, use, sale, or offer to sell within, and/or importation into, the United States of ivermectin cream, 1%, described in ANDA No. 215210 will directly or indirectly infringe, either literally or under the doctrine of equivalents, any valid claim of the '939 Patent.

TENTH AFFIRMATIVE DEFENSE
(Invalidity of U.S. Patent No. 10,206,939)

Upon information and belief, the claims of the '939 Patent are invalid for failure to comply with one or more of the provisions of Title 35 of the United States Code, including, but not limited to, §§ 101, 102, 103, and/or 112, and/or for obviousness-type double patenting.

RESERVATION OF DEFENSES

Zydus hereby reserves any and all defenses that are available under the Federal Rules of Civil Procedure and the United States Patent Laws and any other defenses, at law or in equity, that may now exist or become available later as a result of discovery and further factual investigation during this investigation.

Dated: June 11, 2021

Respectfully submitted,

/s/ Theodora McCormick

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 AND 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, Defendant Zydus Pharmaceuticals (USA) Inc., by their undersigned counsel, certify that, to the best of its knowledge, information, and belief, the matter in controversy in this action is not related to actions in this district.

By: *s/ Theodora McCormick*
Theodora McCormick

DATED: June 11, 2021

CERTIFICATION OF SERVICE

The undersigned hereby certifies that a copy of the foregoing Defendnat Zydus Pharmaceuticals (USA), Inc.'s Answer and Affirmative Defenses to Plaintiffs' Complaint for Patent Infringement was served by ECF upon all counsel of record on June 11, 2021.

DATED: June 11, 2021

By: *s/ Theodora McCormick*
Theodora McCormick