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ATTORNEYS FOR PLAINTIFFS
GALDERMA LABORATORIES, L.P.,
GALDERMA S.A., AND
GALDERMA HOLDING S.A.

IN THE UNITED STATES DISTRICT COURT
FOR THE 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. _____**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs GALDERMA LABORATORIES, L.P., GALDERMA S.A., and GALDERMA HOLDING, S.A., (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. 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.

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.

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.

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 '587 Patent

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

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

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.

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

C. The '118 Patent

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

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

D. The '425 Patent

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

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

E. The '939 Patent

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

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

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%.

G. Zydus' Infringement

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

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%.

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.

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.

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.

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.

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