IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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| GALDERMA LABORATORIES, L.P. and NESTLÉ SKIN HEALTH S.A., | ) | |
| Plaintiffs, | ) | |
| v. | ) | C.A. No. _____ |
| PERRIGO UK FINCO L.P. and PERRIGO CO., | ) | |
| Defendants. | ) | |

**COMPLAINT**

Plaintiffs Galderma Laboratories, L.P. ("Galderma") and Nestlé Skin Health S.A. ("NSH") (collectively, "Plaintiffs"), for their Complaint against Defendants Perrigo UK FINCO L.P. ("Perrigo UK"), and Perrigo Co. (together with Perrigo UK, "Perrigo" or "Defendants"), hereby allege as follows:

**PARTIES**

1. Plaintiff Galderma is a privately held partnership registered in the State of Texas, having a principal place of business at 14501 North Freeway, Fort Worth, Texas 76177.

2. Plaintiff NSH is a "société anonyme" organized and existing under the laws of Switzerland, having a principal place of business at Avenue Gratta Paille 2, 1018 Lausanne, Switzerland.

3. Upon information and belief, Defendant Perrigo UK is a limited partnership organized and existing under the laws of the United Kingdom, having a principal place of business at Braunton, Devon, EX33 2DL, United Kingdom.

4. Upon information and belief, Defendant Perrigo Co. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

## NATURE OF THE ACTION

5. This is a civil action for infringement of United States Patent Nos. 7,439,241 ("the '241 patent"); 8,426,410 ("the '410 patent"); 8,859,551 ("the '551 patent"); 8,410,102 ("the '102 patent"); 8,513,247 ("the '247 patent"); and 8,513,249 ("the '249 patent") (collectively, "the patents-in-suit"). (Exhibits A-F.) 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.

## JURISDICTION AND VENUE

6. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

8. This Court has personal jurisdiction over Defendants Perrigo UK and Perrigo Co. by virtue of the fact that, *inter alia*, Defendants have committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Plaintiffs, including in the State of Delaware. Defendants state that they intend to engage in the commercial manufacture, use, sale and/or offer for sale under ANDA No. 209158 ("Perrigo's ANDA") for "Brimonidine Topical Gel, 0.33%" ("Perrigo ANDA Product") before the expiration of the patents-in-suit, throughout the United States, including in the State of Delaware.

9. Upon information and belief, Perrigo UK is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including in the

State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Perrigo Co.

10. Upon information and belief, Perrigo Co. is in the business of, *inter alia*, developing, manufacturing, obtaining regulatory approval, marketing, selling, and distributing generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware, through its own actions, and through the actions of its agents and affiliates, including, at least, Perrigo UK.

11. Upon information and belief, Perrigo UK and Perrigo Co. are affiliates of each other, and are both subsidiaries of Perrigo Company plc.

12. Upon information and belief, Perrigo UK and Perrigo Co. each act as an agent of the other and work together to, *inter alia*, develop, manufacture, obtain regulatory approval, market, sell, and distribute generic copies of branded pharmaceutical products throughout the United States, including in the State of Delaware.

13. Upon information and belief, Perrigo UK and Perrigo Co. have participated and collaborated in the preparation, filing and seeking FDA approval of ANDA No. 209158 for the Perrigo ANDA Product; continue to participate and collaborate in seeking FDA approval of ANDA No. 209158; and intend to participate and collaborate in the commercial manufacture, marketing, offer for sale, and sale of the Perrigo ANDA Product throughout the United States, including in the State of Delaware.

14. Defendants' infringing activities with respect to their filing of ANDA No. 209158 and intent to commercialize the Perrigo ANDA Product have led and/or will lead to foreseeable harm and injury to Plaintiffs.

15. This Court also has personal jurisdiction over Perrigo UK and Perrigo Co. by virtue of the fact that, upon information and belief, *inter alia*, Perrigo UK and Perrigo Co. have availed themselves of the rights and benefits of Delaware law, and have engaged in systematic and continuous contacts with the State of Delaware.

16. This Court also has personal jurisdiction over Defendants Perrigo UK and Perrigo Co. because they have previously submitted to the jurisdiction of this Court and have affirmatively availed themselves of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction. *See Stiefel Research Australia Pty Ltd. v. Perrigo Co. et al.*, C.A. No. 09-758-GMS (D. Del.); *Stiefel Labs Inc. et al. v. Perrigo Israel Pharms., Ltd. et al.*, C.A. No. 10-592-GMS (D. Del.); *Unimed Pharms. LLC et al. v. Perrigo Co. et al.*, 13-236-RGA (D. Del.); *Taro Pharms. U.S.A., Inc. et al. v. Perrigo UK FINCO Ltd. P'ship*, 15-859-RGA (D. Del.); and *LEO Pharma A/S et al. v. Perrigo UK FINCO Ltd P'ship et al.*, 16-430 –SLR (D. Del.).

**THE PATENTS-IN-SUIT**

17. On October 21, 2008, the '241 patent, titled "Compounds, Formulations, and Methods for Treating or Preventing Rosacea," was duly and legally issued. A copy of the '241 patent is attached as Exhibit A.

18. NSH is the owner of the '241 patent.

19. On April 23, 2013, the '410 patent, titled "Compounds, Formulations, and Methods for Treating or Preventing Inflammatory Skin Disorders," was duly and legally issued. A copy of the '410 patent is attached as Exhibit B.

20. NSH is the owner of the '410 patent.

21. On October 14, 2014, the ’551 patent, titled “Compounds, Formulations, and Methods for Treating or Preventing Inflammatory Skin Disorders,” was duly and legally issued. A copy of the ’551 patent is attached as Exhibit C.

22. NSH is the owner of the ’551 patent.

23. On April 2, 2013, the ’102 patent, titled “Methods and Compositions for Treating or Preventing Erythema,” was duly and legally issued. A copy of the ’102 patent is attached as Exhibit D.

24. NSH is the owner of the ’102 patent.

25. On August 20, 2013, the ’247 patent, titled “Methods and Compositions for Safe and Effective Treatment of Erythema,” was duly and legally issued. A copy of the ’247 patent is attached as Exhibit E.

26. NSH is the owner of the ’247 patent.

27. On August 20, 2013, the ’249 patent, titled “Methods and Compositions for Safe and Effective Treatment of Erythema,” was duly and legally issued. A copy of the ’249 patent is attached as Exhibit F.

28. NSH is the owner of the ’249 patent.

29. NSH acquired ownership of the ’241 patent, the ’410 patent, the ’551 patent, the ’102 patent, the ’247 patent, and the ’249 patent from Galderma by agreement on May 4, 2015.

**ACTS GIVING RISE TO THIS ACTION**

30. Galderma holds New Drug Application (“NDA”) No. 204708 for a topical gel containing 0.33% of the active ingredient brimonidine. Galderma markets and sells this gel in the United States under the brand name “Mirvaso® Gel.”

31. Pursuant to 21 U.S.C. § 355(b)(1), the ’241 patent, the ’410 patent, the ’551 patent, the ’102 patent, the ’247 patent, and the ’249 patent are listed in the FDA’s publication

titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (also known as the "Orange Book") as covering Mirvaso® Gel and its method of use.

32. Upon information and belief, Defendants submitted ANDA No. 209158 to the FDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)). Upon information and belief, Perrigo's ANDA seeks FDA approval to engage in the commercial manufacture, use, sale, or offer for sale the Perrigo ANDA Product prior to the expiration of the '241 patent, the '410 patent, the '551 patent, the '102 patent, the '247 patent, and the '249 patent.

33. Upon information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act, Perrigo certified in ANDA No. 209158, *inter alia*, that the claims of the '241 patent, the '410 patent, the '551 patent, the '102 patent, the '247 patent, and the '249 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of the Perrigo ANDA Product.

34. Plaintiffs received written notification of Perrigo's ANDA and its accompanying § 505(j)(2)(A)(vii)(IV) certification by a letter ("Notice Letter"), dated July 6, 2016 and sent via Federal Express and certified mail.

35. This action was commenced by Plaintiffs within 45 days of the date of the receipt of Perrigo's Notice Letter.

36. Perrigo's Notice Letter included an accompanying Offer of Confidential Access ("OCA") to certain Perrigo confidential information regarding the Perrigo ANDA Product. Plaintiffs subsequently negotiated with Perrigo, over the course of weeks, in an effort to agree on reasonable terms for Perrigo's OCA. The parties were not able to reach an agreement with respect to the revisions to the terms of Perrigo's OCA that Plaintiffs proposed.

37. To date, Defendants have not provided Plaintiffs with a copy of any portions of their ANDA or any information regarding the Perrigo ANDA Product, beyond the information that was set forth in Perrigo's Notice Letter.

38. The limited information relating to the Perrigo ANDA Product that was provided in Perrigo's Notice Letter does not demonstrate that the Perrigo ANDA Product, which Perrigo is asking the FDA to approve for sale in the U.S., will not fall within the scope of issued claims of the '241 patent, the '410 patent, the '551 patent, the '102 patent, the '247 patent, and the '249 patent.

**PERRIGO'S INFRINGEMENT OF THE PATENTS-IN-SUIT**

39. Plaintiffs re-allege paragraphs 1-38 as if fully set forth herein.

40. Perrigo's submission of ANDA No. 209158 to the FDA, including its § 505(j)(2)(A)(vii)(IV) certification, constitutes infringement of the '241 patent, the '410 patent, the '551 patent, the '102 patent, the '247 patent, and the '249 patent under 35 U.S.C. § 271(e)(2)(A).

41. Moreover, if Perrigo manufactures, uses, sells, offers for sale, or imports into the United States any of the Perrigo ANDA Product, or induces or contributes to any such conduct, prior to the expiration of the '241 patent, the '410 patent, the '551 patent, the '102 patent, the '247 patent, and the '249 patent, including any applicable patent term exclusivities or extensions, Perrigo would infringe one or more claims of those patents-in-suit under 35 U.S.C. § 271(a), (b), and/or (c), either literally or under the doctrine of equivalents.

42. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Perrigo's ANDA No. 209158 be a date that is not earlier than the latest expiration of the patents-in-suit, including any patent term exclusivities or extensions to which Plaintiffs are or become entitled.

43. Plaintiffs will be irreparably harmed by Perrigo's infringing activities, unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

44. Upon information and belief, Perrigo was aware of the existence of the patents-in-suit, and was also aware that the filing of Perrigo's ANDA No. 209158 and accompanying § 505(j)(2)(A)(vii)(IV) certification with respect to the patents-in-suit constituted an act of infringement.

**PRAYER FOR RELIEF**

WHEREFORE, Plaintiffs respectfully request that the Court grant the follow relief:

A. An Order adjudging and decreeing that Perrigo has infringed the '241 patent, the the '410 patent, the '551 patent, '102 patent, the '247 patent, and the '249 patent;

B. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 209158 under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest expiration of the patents-in-suit, including any applicable patent term exclusivities or extensions to which Plaintiffs are or become entitled;

C. An Order permanently enjoining Perrigo, its officers, agents, servants, and employees, and those acting in privity or concert with any of them, from commercially manufacturing, using, offering to sell, selling, marketing, distributing or importing into the United States the Perrigo ANDA Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '241 patent, the '410 patent, the '551 patent, the '102 patent, the '247 patent, or the '249 patent prior to their expiration, including any patent term exclusivities or extensions to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief to the extent Perrigo commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the '241 patent,

the ’410 patent, the ’551 patent, the ’102 patent, the ’247 patent, or the ’249 patent prior to their expiration, including any patent term exclusivities or extensions to which Plaintiffs are or become entitled;

E. That this case be declared an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded costs, including reasonable attorneys’ fees; and

F. That Plaintiffs be awarded such other and further relief as this Court deems just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

*/s/ Maryellen Noreika*

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