IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUN PHARMACEUTICAL INDUSTRIES, INC. and MICAL PHARMACEUTICALS LLC-H SERIES, Plaintiffs, v. PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LIMITED and PERRIGO NEW YORK, INC., Defendants.	C.A. No. 1:18-cv-00703-CFC

ANSWER AND SEPARATE DEFENSES OF DEFENDANTS PERRIGO COMPANY, PERRIGO ISRAEL PHARMACEUTICALS LIMITED, AND PERRIGO NEW YORK, INC. TO PLAINTIFFS' COMPLAINT AND COUNTERCLAIMS OF PERRIGO ISRAEL PHARMACEUTICALS LIMITED

Defendants Perrigo Company ("Perrigo Co."), Perrigo Israel Pharmaceuticals Limited ("Perrigo Israel") and Perrigo New York, Inc. ("Perrigo NY") (collectively, "Perrigo"), by and through the undersigned attorneys, hereby answer the Complaint of Sun Pharmaceutical Industries, Inc. ("Sun") and MiCal Pharmaceuticals LLC-H Series ("MiCal") (collectively, "Plaintiffs") as follows:

NATURE OF THE ACTION

COMPLAINT:

1. This is an action under 35 U.S.C. § 271(e)(2) for infringement of United States Patent No. 8,962,028 (the "'028 Patent") (attached as **Exhibit A**), and for declaratory judgment of infringement under 28 U.S.C. § 2201-02 and 35 U.S.C. § 271(a), (b), and (c) relating to Plaintiffs' commercially successful product, Ultravate® (halobetasol propionate) Lotion, 0.05%. This action arises from Defendants' filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to market a generic version of Ultravate® (halobetasol propionate) Lotion, 0.05% prior to the expiration of the '028 Patent.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement of U.S. Patent No. 8,962,028 ("the '028 patent") under 35 U.S.C. § 271(e)(2), and for declaratory judgment of alleged infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c), but Perrigo denies that Plaintiffs are entitled to any relief. Answering further, Perrigo admits that Perrigo Israel submitted Abbreviated New Drug Application ("ANDA") No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification") to the '028 patent; and that Perrigo Israel seeks approval from the U.S. Food and Drug Administration ("FDA") to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo further admits that the reference listed drug ("RLD") identified in Perrigo Israel's ANDA No. 211464 is Ultravate® (halobetasol propionate) lotion, 0.05%. Perrigo denies the remaining allegations contained in this paragraph, including Plaintiffs' assertion that Ultravate® lotion is commercially successful and any suggestion that the '028 patent is valid or enforceable.

THE PARTIES

COMPLAINT:

2. Sun Pharmaceutical Industries, Inc. is a company organized and existing under the laws of the State of Michigan, with a principal place of business at 2 Independence Way, Princeton, New Jersey 08540.

ANSWER: On information and belief, Perrigo admits that Sun is a company organized and existing under the laws of the State of Michigan with a place of business at 2 Independence Way, Princeton, New Jersey. Perrigo lacks knowledge or information sufficient to

form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies same.

COMPLAINT:

3. MiCal Pharmaceuticals LLC-H Series, a Series of MiCal Pharmaceuticals LLC, a Multi-Division Limited Liability Company ("MiCal"), is a company organized and existing under the laws of the State of Delaware, with a principal place of business at 9025 Balboa Avenue, Suite 110, San Diego, CA 92123.

ANSWER: On information and belief, Perrigo admits that MiCal is a company organized and existing under the laws of the State of Delaware with a place of business at 9025 Balboa Avenue, San Diego, CA 92123. Perrigo lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in this paragraph, and therefore denies same.

COMPLAINT:

4. On information and belief, Defendant Perrigo Company is a corporation operating and existing under the laws of Michigan, having a principal place of business at 515 Eastern Avenue, Allegan, Michigan 49010.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Company is a Michigan corporation with a place of business at 515 Eastern Avenue, Allegan, Michigan 49010. Perrigo further states that Perrigo Co. does not contest personal jurisdiction in the District of Delaware for purposes of this action. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

5. On information and belief, Defendant Perrigo Israel Pharmaceuticals Limited ("Perrigo Israel") is a corporation operating and existing under the laws of Israel, having a principal place of business at 29 Lehi Street, Bnei Brak 51200, Israel.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel is an Israeli

corporation with a place of business at 1 Rakefet St., Shoham, Israel, P.O. Box 944, Shoham 6085001. Perrigo further states that Perrigo Israel does not contest personal jurisdiction in the District of Delaware for purposes of this action. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

6. On information and belief, Defendant Perrigo Israel is a wholly owned subsidiary of Perrigo Company.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel and Perrigo Co. are, directly or indirectly, subsidiaries of Perrigo Company plc. Perrigo denies the remaining allegations of this paragraph.

COMPLAINT:

7. On information and belief, Defendant Perrigo New York, Inc. is a corporation operating and existing under the laws of Delaware, having a principal place of business at 1700 Bathgate Avenue, Bronx, NY 10457.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo New York, Inc. is a Delaware corporation with a place of business at 1700 Bathgate Avenue, Bronx, NY 10457. Perrigo further states that Perrigo NY does not contest personal jurisdiction in the District of Delaware for purposes of this action. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

8. On information and belief, Defendant Perrigo New York, Inc. is a wholly owned subsidiary of Perrigo Company.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo New York, Inc.

operates directly or indirectly as a subsidiary of Perrigo Company. Perrigo denies the remaining allegations of this paragraph.

COMPLAINT:

9. On information and belief, Perrigo Israel and Perrigo New York, Inc. manufacture, sell, market, and distribute generic pharmaceutical products throughout the United States, including in this district, in conjunction with or under the direction of Perrigo Company. On information and belief, Perrigo Israel has designated Perrigo Company as its US agent for its ANDA submission.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph, including that Perrigo Israel designated Perrigo Co. as its U.S. agent for ANDA No. 211464.

COMPLAINT:

10. On information and belief, Perrigo developed its generic halobetasol propionate lotion, 0.05%, and prepared ANDA No. 211464 for submission. On information and belief, upon receiving approval of its ANDA No. 211464, Perrigo will manufacture, sell, offer to sell, and/or import Perrigo's generic halobetasol propionate lotion, 0.05% in the United States, including in this district.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j);

that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph.

JURISDICTION AND VENUE

COMPLAINT:

11. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*. and the Declaratory Judgement Act. Based on the facts alleged herein, this Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202, and has personal jurisdiction over Perrigo Company, Perrigo Israel, and Perrigo New York, Inc.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo also states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claims against Perrigo Co. and Perrigo NY.

COMPLAINT:

12. Perrigo Israel has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to manufacture, use, sell, and offer for sale its proposed generic halobetasol propionate lotion, 0.05% in Delaware. On information and belief, Perrigo Company directed Perrigo Israel to participate and collaborate in the research and development of the proposed generic halobetasol propionate lotion, 0.05% and in the preparation and filing of ANDA No. 211464.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

13. On information and belief, Perrigo sought FDA approval because it intends to commit acts of patent infringement under 35 U.S.C. § 271(a), (b), and (c) through its manufacture, use, sell, and offer for sale of its generic halobetasol propionate lotion, 0.05% in Delaware.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph, including any suggestions or implication that the product that is the subject of Perrigo Israel's ANDA No. 211464 ("Perrigo Israel's ANDA Product") infringes any claim of the '028 patent,

either literally or under the doctrine of equivalents, directly or indirectly, or that such patent is valid or enforceable.

COMPLAINT:

14. An actual and justiciable controversy exists between the parties under the patent laws of the United States, Title 35 of the United States Code.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph, including that subject matter jurisdiction exists with respect to Plaintiffs' infringement claims against Perrigo Co. and Perrigo NY.

COMPLAINT:

15. This Court has personal jurisdiction over Perrigo. Perrigo avails itself of the benefits and protections of the laws of the State of Delaware. For example, Perrigo New York, Inc. is incorporated in the State of Delaware and is a manufacturer and wholesale distributor of pharmaceuticals.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo New York, Inc. is a Delaware corporation with a place of business at 1700 Bathgate Avenue, Bronx, NY 10457. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

16. This Court also has personal jurisdiction over Perrigo by virtue of its systematic and continuous contacts with the State of Delaware. On information and belief, Perrigo

Company, Perrigo Israel, Perrigo New York, Inc. and their affiliates manufacture generic pharmaceuticals and sell, offer for sale, and distribute generic pharmaceuticals throughout the State of Delaware.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

17. On information and belief, Perrigo has at all relevant times maintained continuous and systematic contacts with the State of Delaware, including but not limited to, its aforementioned business of preparing generic pharmaceuticals that Perrigo distributes throughout the United States.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

18. On information and belief, Perrigo's generic halobetasol propionate lotion, 0.05% will be marketed and distributed in Delaware by Perrigo, prescribed by physicians practicing in this state, and dispensed by pharmacies located in this state, all of which would have a substantial effect on commerce.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

19. Perrigo has previously availed themselves of the jurisdiction of this Court by filing suit in this district, consenting to jurisdiction in this district, and/or asserting counterclaims in at least the following civil actions initiated in this district: *Leo Pharma A/S et al. v. Perrigo Uk Finco L.P. et al*., 1:18-cv-401; *Perrigo Company v. International Vitamin Corp. et al*., 1:17-cv-1778; *Leo Pharma A/S et al. v. Perrigo Uk Finco L.P. et al*., 1:17-cv-1753; *Meda Pharmaceuticals Inc.et al. v. Perrigo Uk Finco L.P. et al*., 1:16-cv-794; *Galderma Laboratories, L.P. et al. v. Perrigo Uk Finco L.P. et al*, 1:16-cv-732; *Leo Pharma A/S et al. v. Perrigo Uk Finco L.P. et al.*, 1:16-cv-430; *Senju Pharmaceutical Co. Ltd. et al. v. Paddock Laboratories LLC et al.*, 1:15-cv-87; *Horizon Pharma Ireland Ltd. et al. v. Paddock Laboratories LLC et al.*, 1:15-cv-43; *Endo Pharmaceuticals Solutions Inc. et al. v. Custopharm Inc. et al.*, 1:14-cv-1422; *Unimed Pharmaceuticals LLC et al. v. Perrigo Company et al*., 1:14-cv-1003; *Taro Pharmaceuticals USA Inc. et al. v. Perrigo Israel Pharmaceuticals Ltd*., 1:14-cv-989; *Unimed Pharmaceuticals LLC et al. v. Perrigo Company et al.*, 1:14-cv-985; *Teva Branded Pharmaceutical Prods. R&D Inc. et al. v. Perrigo Pharmaceuticals Co. et al*., 1:13-cv-1441*; Unimed Pharmaceuticals LLC et al. v. Perrigo Company et al*., 1:13-cv-236; *Teva Branded Pharmaceutical Prods. R&D Inc. et al. v. Perrigo Pharmaceuticals Co. et al*., 1:12-cv-1101; *Cumberland Pharmaceuticals Inc. v. Paddock Laboratories LLC et al*., 1:12-cv-619; *Cadence Pharmaceuticals Inc. et al. v. Exela Pharma Sciences LLC et al*., 1:11-cv-733; *KV Pharmaceutical Co. et al. v. Perrigo Israel Pharmaceuticals et al*., 1:10-cv-641; *Stiefel*

Laboratories Inc. et al. v. Perrigo Israel Pharmaceuticals Ltd. et al., 1:10-cv-592; *Schering-Plough Healthcare Prods., Inc v. Perrigo Company*, 1:09-cv-906; *Stiefel Research Australia Pty Ltd v. Perrigo Company et al.*, 1:09-cv-758; *Stiefel Laboratories Inc. et al. v. Cobrek Pharmaceuticals Inc. et al.*, 1:09-cv-167.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that: Perrigo Company was a named defendant in complaints filed in Civil Action Nos. 09-167, 09-758, 09-906, 10-592, 10-641, 11-733, 12-619, 12-1101, 13-236, 13-1441, 14-985, 14-1003, 14-1422, 15-43, 15-87, 16-430, 16-732, 16-794, 17-1753, and 18-401 in this Judicial District; that Perrigo Israel was a named defendant in complaints filed in Civil Action Nos. 09-758, 10-592, 10-641, 13-236, 14-985, 14-989, and 14-1003 in this Judicial District; that Perrigo Company was a named plaintiff in a complaint filed in Civil Action No. 17-1778 in this Judicial District; that Perrigo Company filed counterclaims in Civil Action Nos. 09-167, 10-641, 11-733, and 13-1441 in this Judicial District; and that Perrigo Israel filed counterclaims in Civil Action Nos. 09-758, 10-592, 13-236, and 14-989 in this Judicial District. Answering further, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

20. Upon information and belief, Perrigo's business model for its generic drugs is in large part predicated upon participating in a significant amount of litigation under the framework of the Hatch-Waxman Act. Upon information and belief, the largest number of Hatch-Waxman cases have historically been filed each year in this district.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j);

that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Answering further, Perrigo states that the District of Delaware has a far more congested docket than the Western District of Michigan. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

21. Upon information and belief, Perrigo, as a frequent ANDA filer, appears in front of this Court with regularity for the purpose of getting its generic drugs on the market, and when that litigation concludes favorably for Perrigo, those generic drugs are distributed to and used by Delaware residents through a distribution network that has been established for that purpose.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

22. Upon information and belief, Perrigo is part of a corporate family that includes at least fifteen Delaware entities, including Defendant Perrigo New York, Inc., which reside in Delaware for patent venue purposes. Upon information and belief, the Perrigo corporate family as a whole relies on Delaware for its successful business operations.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction or venue in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo New York, Inc. is a Delaware corporation with a place of business at 1700 Bathgate Avenue, Bronx, NY 10457. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

23. Upon information and belief, Perrigo Company works in concert with its subsidiaries Perrigo Israel and Perrigo New York, Inc. to sell, market, and distribute its generic drugs in the United States, including in this district.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations in this paragraph.

COMPLAINT:

24. Venue is proper in this district under 28 U.S.C. § 1400(b) because Perrigo "committed an act of infringement" in this district and has a "regular place and established place of business" in this district. Perrigo submitted an ANDA leading to FDA approval of its generic halobetasol propionate lotion, 0.05% and, having received approval, will manufacture, sell, offer to sell, and/or import its generic halobetasol propionate lotion, 0.05% throughout the United States, including in this district. Perrigo also has a "regular and established place of business" in this district because of its pattern of litigation behavior, which largely takes place in

this district and is directed to obtaining approval for the manufacture of and distribution of drugs to Delaware residents through established channels in this district.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that Perrigo does not contest venue for purposes of this action. Answering further, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph.

BACKGROUND

The FDA Marketing Approval Process

COMPLAINT:

25. The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments, sets forth the rules that the FDA follows when considering the approval of applications for both brand-name and generic drugs.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that the Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA"), sets forth a statutory framework that FDA follows for the approval of both brand-name and generic drugs. Perrigo is without sufficient

knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

COMPLAINT:

26. Under the Hatch-Waxman Amendments, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by the FDA. *See* 21 U.S.C. § 355.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that, under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

27. An NDA must include, among other things, the patent number of any patent that claims the drug or a method of using such drug, for which the applicant submitted the NDA and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1) and (c)(2); 21 C.F.R. §§ 314.53(b) and (c)(2).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that an NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). Answering further, the decision to submit patent information to FDA rests solely with the NDA holder. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

28. Upon approval of the NDA, the FDA publishes patent information for the approved drug in its publication, Approved Drug Products with Therapeutic Equivalence Evaluation ("Orange Book"). *See* 21 U.S.C. § 355(j)(7)(A)(iii).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that upon approval of the NDA, FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii). Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

29. A pharmaceutical company may seek to market a generic version of the innovator's brand drug by submitting an Abbreviated New Drug Application ("ANDA") under 21 U.S.C. § 355(j). The generic company may then rely on the studies the innovator includes in its NDA.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo states that, under Hatch-Waxman, a generic manufacturer may submit an ANDA to FDA, and the generic manufacturer must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j). Perrigo denies the remaining allegations contained in this paragraph.

Sun's Ultravate® Product

COMPLAINT:

30. On November 6, 2015, the FDA approved Sun's NDA for Ultravate® (halobetasol propionate) Lotion, NDA No. 208183. Sun began marketing Ultravate® shortly after that approval.

ANSWER: Perrigo admits that, according to the online records of the FDA, FDA approved NDA No. 208183 for Ultravate® (halobetasol propionate) lotion, 0.05%, on or

about November 6, 2015. Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

COMPLAINT:

31. Ultravate® is a corticosteroid indicated for the treatment of plaque psoriasis in patients 18 years of age or older. Psoriasis is a systemic inflammatory disease of immune dysfunction that affects an estimated 2%-3% of the U.S. population.

ANSWER: Perrigo admits that, according to the approved label, available on the online records of FDA, Ultravate® (halobetasol propionate) lotion, 0.05% "is indicated for the topical treatment of plaque psoriasis in patients eighteen (18) years of age and older." Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

Plaintiffs' Patent Covering Ultravate®

COMPLAINT:

32. The United States Patent & Trademark Office ("PTO") legally issued the '028 Patent, titled "Topical Steroid Composition And Method" on February 24, 2015. MiCal owns the '028 Patent, which lists Keith Johnson and Karl Popp as its inventors. The invention provides a storage stable topical lotion which includes a halobetasol material comprising halobetasol or its pharmaceutically acceptable salts, esters, and solvates; and a pharmaceutically acceptable carrier which includes one or more fatty alcohols and/or one or more alkoxylated fatty alcohols, one or more polyol humectants, and diisopropyl adipate. The invention also provides processes for preparing such topical lotion composition and methods for treating corticosteroid responsive dermatosis, including plaque psoriasis with such topical lotion composition.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the face of the patent, the U.S. Patent & Trademark Office ("USPTO") issued the '028 patent on February 24, 2015. Answering further, Perrigo admits that, according to the face of the '028 patent, the '028 patent lists Keith A. Johnson and Karl F. Popp as "Inventors," and that the face of the '028 patent includes the following abstract:

> Storage stable, topical lotion compositions for treating corticosteroid-responsive dermatoses are provided by the present invention which include a halobetasol material comprising halobetasol or its pharmaceutically acceptable salts, esters, and solvates; and a pharmaceutically acceptable carrier which includes: (a) one or more fatty alcohols and/or one or more alkoxylated fatty alcohols, (b) one or more polyol humectants, and (c) diisopropyl adipate. Storage stable, topical lotion compositions for treating corticosteroid-responsive dermatoses are provided by the present invention which include 0.05% halobetasol propionate; and a pharmaceutically acceptable carrier which includes: (a) one or more fatty alcohols and/or one or more alkoxylated fatty alcohols, (b) one or more polyol humectants, and (c) diisopropyl adipate.

Perrigo denies the remaining allegations of this paragraph, including that the '028 patent was legally issued, as well as any suggestion or implication that the '028 patent claims are valid or enforceable or that one or more claims of the '028 patent cover Ultravate® (halobetasol propionate) lotion, 0.05%.

COUNT I

(Infringement of the '028 Patent Under 35 U.S.C. § 271(e)(2)(A) by Perrigo's Proposed Generic Halobetasol Propionate Lotion, 0.05%)

COMPLAINT:

33. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

COMPLAINT:

34. Perrigo submitted ANDA No. 211464 to the FDA under section 505(j) of the US Federal Food, Drug, and Cosmetic Act ("FDCA") to obtain approval to engage in the manufacture, use or sale throughout the United States, of Perrigo's proposed generic halobetasol propionate lotion, 0.05% prior to the expiration of the '028 Patent. By submitting ANDA No. 211464, Perrigo has committed an act of infringement of the '028 Patent under 35 U.S.C. § 271(e)(2)(A).

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel submitted

ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph, including that Perrigo Israel's Halobetasol Propionate Lotion, 0.05% ANDA Product infringes any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

COMPLAINT:

35. The commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo's proposed generic halobetasol propionate lotion, 0.05% prior to the expiration of the '028 Patent will constitute an act of infringement of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

36. On information and belief, Perrigo became aware of the '028 Patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Perrigo admits that Perrigo Israel and Perrigo Co. became aware of the '028 patent at least as early as the date Perrigo Israel submitted its ANDA No. 211464. Perrigo further admits that Perrigo NY became aware of the '028 patent at least as early as the date Plaintiffs' Complaint was served. Perrigo denies the remaining allegations contained in this paragraph, including that Perrigo Israel's Halobetasol Propionate Lotion, 0.05% ANDA Product infringes any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

COMPLAINT:

37. On information and belief, Perrigo knows or is willfully blind to the fact that its commercial manufacture, use, offer for sale, sale, and/or importation of their proposed generic

halobetasol propionate lotion, 0.05% will actively induce and contribute to the actual infringement of the ’028 Patent.

ANSWER: Denied.

COMPLAINT:

38. On information and belief, Perrigo knows or is willfully blind to the fact that Perrigo’s proposed generic halobetasol propionate lotion, 0.05% will be especially made for or especially adapted for use in infringement of the ’028 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use, and that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic halobetasol propionate lotion, 0.05% will actively contribute to the actual infringement of the ’028 Patent.

ANSWER: Denied.

COUNT II

(Declaratory Judgement of Infringement of the ’028 Patent Under 35 U.S.C. § 271(a) by Perrigo’s Generic Halobetasol Propionate Lotion, 0.05%)

COMPLAINT:

39. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

COMPLAINT:

40. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs’ Complaint is for alleged patent infringement of the ‘028 patent under 35 U.S.C. § 271(e)(2), and for declaratory judgment of alleged infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c), but Perrigo denies that Plaintiffs are entitled to any relief. Perrigo admits that this Court has

subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

41. An actual case or controversy between Plaintiffs and Perrigo exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

42. Perrigo has made, and will continue to make, substantial preparation in the United States to manufacture, sell, offer to sell and/or import its generic halobetasol propionate lotion, 0.05%.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

43. Perrigo's recent actions indicate that it does not intend to change its course of conduct.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo Israel submitted ANDA No. 211464, pursuant to 21 U.S.C. § 355(j); that Perrigo Israel's ANDA contains a paragraph IV certification to the '028 patent; and that Perrigo Israel seeks approval from the FDA to engage in the commercial manufacture, use, sale, or importation of Halobetasol Propionate Lotion, 0.05%, before the expiration of the '028 patent. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

44. Any manufacture, use, offer for sale, sale and/or importation of Perrigo's generic Halobetasol Propionate Lotion, 0.05% prior to the expiration of the '028 Patent will constitute direct infringement of at least claim 1 of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

45. Plaintiffs are entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the generic halobetasol propionate lotion, 0.05% by Perrigo prior to the expiration of the '028 Patent will constitute direct infringement of said patent.

ANSWER: Denied.

COMPLAINT:

46. On information and belief, despite having actual notice of the '028 patent, Perrigo continues to willfully, wantonly, and deliberately prepare to infringe the '028 Patent in disregard of Plaintiffs' rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

ANSWER: Denied.

COUNT III

(Declaratory Judgment of Infringement of the '028 Patent Under 35 U.S.C. § 271(b) and (c) by Perrigo)

COMPLAINT:

47. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

ANSWER: Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

COMPLAINT:

48. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement of the '028 patent under 35 U.S.C. § 271(e)(2), and for declaratory judgment of alleged infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. § 271(a), (b), and (c), but Perrigo denies that Plaintiffs are entitled to any relief. Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

49. An actual case or controversy between Plaintiffs and Perrigo exists such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution.

ANSWER: This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Perrigo admits that this Court has subject matter

jurisdiction over Plaintiffs' infringement claims against Perrigo Israel. Perrigo denies the remaining allegations contained in this paragraph.

COMPLAINT:

50. Perrigo has actual knowledge of the '028 Patent.

ANSWER: Perrigo admits that Perrigo Israel and Perrigo Co. became aware of the '028 patent at least as early as the date Perrigo Israel submitted its ANDA No. 211464. Perrigo further admits that Perrigo NY became aware of the '028 patent at least as early as the date Plaintiffs' Complaint was served. Perrigo denies the remaining allegations contained in this paragraph, including that Perrigo Israel's Halobetasol Propionate Lotion, 0.05% ANDA Product infringes any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

COMPLAINT:

51. On information and belief, Perrigo became aware of the '028 Patent no later than the date on which that patent was listed in the Orange Book.

ANSWER: Perrigo admits that Perrigo Israel and Perrigo Co. became aware of the '028 patent at least as early as the date Perrigo Israel submitted its ANDA No. 211464. Perrigo further admits that Perrigo NY became aware of the '028 patent at least as early as the date Plaintiffs' Complaint was served. Perrigo denies the remaining allegations contained in this paragraph, including that Perrigo Israel's Halobetasol Propionate Lotion, 0.05% ANDA Product infringes any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

COMPLAINT:

52. On information and belief, Perrigo has acted with full knowledge of the '028 Patent and without a reasonable basis for believing that Perrigo would not be liable for actively inducing or contributing to the infringement of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

53. The commercial manufacture, use, sale, offer for sale, and/or importation of Perrigo's generic halobetasol propionate lotion, 0.05% will induce the actual infringement of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

54. On information and belief, Perrigo knows or is willfully blind to the fact that their commercial manufacture, use, sale, offer for sale, and/or importation of its generic halobetasol propionate lotion, 0.05% will actively induce the actual infringement of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

55. On information and belief, Perrigo will encourage another's infringement of the '028 Patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of their generic halobetasol propionate lotion, 0.05%, which is covered by the claims of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

56. Perrigo's acts of infringement will be done with knowledge of the '028 Patent and with the intent to encourage infringement.

ANSWER: Denied.

COMPLAINT:

57. The foregoing actions by Perrigo will constitute active inducement of infringement of the '028 Patent.

ANSWER: Denied.

COMPLAINT:

58. On information and belief, Perrigo knows or is willfully blind to the fact that Perrigo's proposed halobetasol propionate lotion, 0.05% will be especially made or

especially adapted for use in an infringement of the ’028 Patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

ANSWER: Denied.

COMPLAINT:

59. The commercial manufacture, use, sale, offer for sale, and/or importation of Perrigo’s halobetasol propionate lotion, 0.05% will contribute to the actual infringement of the ’028 Patent.

ANSWER: Denied.

COMPLAINT:

60. On information and belief, Perrigo knows or is willfully blind to the fact that Perrigo’s offer for sale, sale and/or importation of its generic halobetasol propionate lotion, 0.05% will contribute to the actual infringement of the ’028 Patent.

ANSWER: Denied.

COMPLAINT:

61. The foregoing actions by Perrigo will constitute contributory infringement of the ’028 Patent.

ANSWER: Denied.

COMPLAINT:

62. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and/or importation of Perrigo’s generic halobetasol propionate lotion, 0.05% by Perrigo will induce and/or contribute to infringement of the ’028 Patent.

ANSWER: Denied.

COMPLAINT:

63. The commercial manufacture, use, offer for sale, sale and/or importation of Perrigo’s generic halobetasol propionate lotion, 0.05%, which will actively induce and/or contribute to infringement of the ’028 Patent, in violation of Plaintiffs’ patent rights, will cause harm to Plaintiffs for which damages are inadequate.

ANSWER: Denied.

COMPLAINT:

64. Unless Perrigo is enjoined from actively inducing and contributing to the infringement of the ’028 Patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

ANSWER: Denied.

COMPLAINT:

65. On information and belief, despite having actual notice of the ’028 Patent, Perrigo will willfully, wantonly, and deliberately prepare to actively induce and/or contribute to infringement of the ’028 Patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

ANSWER: Denied.

* * *

RESPONSE TO REQUESTED RELIEF

Perrigo denies that Plaintiffs are entitled to any relief as set forth in Paragraphs (a)-(f) of the Complaint, or to any relief whatsoever, and further requests that Plaintiffs’ Complaint be dismissed with prejudice and that Perrigo be awarded its attorney fees and costs incurred in defending this suit under 35 U.S.C. § 285, at least because Plaintiffs lacked a good faith basis for bringing the instant infringement action.

SEPARATE DEFENSES

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted (and, for purposes of clarity, those allegations not specifically admitted are denied), and without undertaking any of the burdens imposed by law on Plaintiffs, Perrigo asserts the following defenses to the Complaint:

First Defense

The claims of the ‘028 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. § 101 *et seq.*

Second Defense

The manufacture, use, sale, offer for sale, or importation of Halobetasol Propionate Lotion, 0.05%, that is the subject of Perrigo Israel's ANDA, has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '028 patent.

Third Defense

Plaintiffs are barred by prosecution history estoppel from presenting an interpretation of the claims of the '028 patent necessary to find infringement.

Fourth Defense

This Court lacks subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo Company.

Fifth Defense

This Court lacks subject matter jurisdiction over Plaintiffs' infringement claims against Perrigo New York, Inc.

Sixth Defense

The Complaint fails to state a claim upon which relief can be granted.

Seventh Defense

The '028 patent is unenforceable, at the very least, due to patent misuse for at least the reasons detailed in Perrigo Israel's counterclaim, which is incorporated herein. Among other things, Plaintiffs filed and are prosecuting this objectively baseless patent infringement lawsuit, which seeks to enforce a patent that is neither valid nor infringed. No reasonable litigant could realistically expect success on the merits of this sham lawsuit, which Plaintiffs have filed

solely for the improper purpose of interfering with Perrigo Israel's ability to market its competing product.

Eighth Defense

Any additional defenses or counterclaims that discovery may reveal, as Plaintiffs have not begun producing discovery to Perrigo, and Perrigo has not yet had the opportunity to pursue relevant third-party discovery.

PERRIGO ISRAEL PHARMACEUTICALS LIMITED'S COUNTERCLAIMS

Perrigo Israel Pharmaceuticals Limited ("Perrigo Israel"), for its Counterclaims against Sun Pharmaceutical Industries, Inc. ("Sun") and MiCal Pharmaceuticals LLC-H Series ("MiCal") (collectively, "Plaintiffs/Counterclaim-Defendants"), alleges as follows:

The Parties

1. Perrigo Israel is an Israeli corporation with a place of business at 1 Rakefet St., Shoham, Israel, P.O. Box 944, Shoham 6085001.

2. On information and belief, and according to its Complaint, Sun is a company organized and existing under the laws of the State of Michigan with a place of business at 2 Independence Way, Princeton, New Jersey. (Complaint at ¶ 2).

3. On information and belief, and according to its Complaint, MiCal is a company organized and existing under the laws of the State of Delaware with a place of business at 9025 Balboa Avenue, San Diego, CA 92123. (Complaint at ¶ 3).

Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare

Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants because they have purposefully availed themselves of the rights and privileges of this forum by suing Perrigo Israel in this District, and, on information and belief, because Plaintiffs/Counterclaim-Defendants conduct substantial business in, and have regular systematic contact with, this District.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

Background

A. FDA Approval of New Brand-Name Drugs.

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth a statutory framework that FDA follows for the approval of both brand-name and generic drugs.

9. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

10. An NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was

submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). The decision to submit patent information to FDA rests solely with the NDA holder.

11. Upon approval of the NDA, FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

B. Generic Competition – Abbreviated New Drug Applications.

12. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

13. To receive approval of its ANDA, an applicant must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

14. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant generally must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

15. When seeking FDA approval to market prior to patent expiration, an ANDA applicant generally submits a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

17. With respect to a patent the information for which was submitted to FDA prior to ANDA filing, patentees and NDA holders have a significant financial incentive to bring an infringement suit against an ANDA applicant regardless of the merit – or lack thereof – of that infringement suit.

C. Ultravate® (Halobetasol Propionate) Lotion, 0.05%, And The Patent-In-Suit.

18. On or about February 24, 2015, according to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), U.S. Patent No. 8,962,028 ("the '028 patent"), entitled "TOPICAL STEROID COMPOSITION AND METHOD," issued, on its face, to purported named inventors Keith A. Johnson and Karl F. Popp, and was assigned, on its face, to "MiCal Pharmaceuticals LLC—H Series, a Series of MiCal Pharmaceuticals LLC, a Multi-Division Limited Liability Company." What purports to be a true and correct copy of the '028 patent is attached to Plaintiffs/Counterclaim-Defendants' Complaint as Exhibit A.

19. According to the online records of the USPTO, "MiCal Pharmaceuticals LLC—H Series, a Series of MiCal Pharmaceuticals LLC, a Multi-Division Limited Liability Company" is the current assignee of the '028 patent. Plaintiffs/Counterclaim-Defendants assert that "MiCal owns the '028 Patent, which lists Keith Johnson and Karl Popp as its inventors." (Complaint at ¶ 32).

20. According to the online records of FDA, and as Plaintiffs/Counterclaim-Defendants assert, Sun is the holder of New Drug Application No. 208183 for Ultravate® (halobetasol propionate) lotion, 0.05%. (Complaint at ¶ 30).

21. On information and belief, the ‘028 patent was submitted to FDA for listing in the Orange Book.

22. By virtue of Sun’s submission, FDA listed the ‘028 patent in the Orange Book in connection with the approved NDA No. 208183 for Ultravate® (halobetasol propionate) lotion, 0.05%.

23. On or about May 9, 2018, Plaintiffs/Counterclaim-Defendants purport to have brought suit against Perrigo Israel, asserting “direct infringement of at least claim 1” of the ‘028 patent, but not otherwise identifying the asserted claims of the ‘028 patent.

D. Perrigo Israel’s Halobetasol Propionate Lotion, 0.05% ANDA.

24. Perrigo Israel filed an ANDA with FDA seeking approval for Halobetasol Propionate Lotion, 0.05%. Perrigo Israel is the sole ANDA holder for this ANDA.

25. FDA assigned Perrigo Israel’s ANDA No. 211464.

26. Perrigo Israel’s ANDA references NDA No. 208183 for Ultravate® (halobetasol propionate) lotion, 0.05%.

27. Because Perrigo Israel’s ANDA seeks FDA approval to market its generic Halobetasol Propionate Lotion, 0.05% product before expiration of the Orange Book-listed ‘028 patent, Perrigo Israel’s ANDA included a paragraph IV certification to the ‘028 patent.

28. The Halobetasol Propionate Lotion, 0.05% product described in Perrigo Israel’s ANDA does not infringe any claim of the ‘028 patent (either literally or under the doctrine of equivalents, directly or indirectly), even if such claims were valid or enforceable.

29. On March 26, 2018, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Perrigo Israel provided, *inter alia*, Sun and MiCal with notice that Perrigo Israel submitted an ANDA containing a paragraph IV certification to the ‘028 patent (“Perrigo Israel’s

Notice Letter"). Perrigo Israel's Notice Letter included a detailed statement setting forth factual and legal bases as to why the '028 patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo Israel's ANDA No. 211464 ("Perrigo Israel's ANDA Product"), and *inter alia*, expressly reserved the right to raise additional defenses (including, but not limited to, unenforceability due to patent misuse) in the event that suit was filed on the '028 patent.

30. Sun received a copy of Perrigo Israel's Notice Letter on March 27, 2018.

31. MiCal received a copy Perrigo Israel's Notice Letter on March 27, 2018.

E. Plaintiffs' Baseless Infringement Suit Against Perrigo, Brought For The Improper Purpose Of Delaying Approval Of Perrigo Israel's Non-Infringing Halobetasol Propionate Lotion, 0.05% ANDA Product.

32. Perrigo Israel's Notice Letter includes an Offer of Confidential Access ("OCA") setting forth the confidentiality terms pursuant to which it would voluntarily produce a copy of its ANDA to counsel representing Plaintiffs/Counterclaim-Defendants before the filing of an infringement suit.

33. Perrigo Israel's Notice Letter contains the name, address, phone number, and email address of the outside counsel to whom Sun and MiCal should direct inquiries regarding obtaining access to Perrigo Israel's ANDA under the OCA.

34. Prior to bringing suit against Perrigo Israel for alleged infringement of the '028 patent, Sun did not make a good faith request for information to confirm that, as Perrigo Israel's March 26, 2018 Notice Letter explains in detail, Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent.

35. Prior to bringing suit against Perrigo Israel for alleged infringement of the '028 patent, MiCal did not make a good faith request for information to confirm that, as Perrigo

Israel's March 26, 2018 Notice Letter explains in detail, Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent.

36. Neither MiCal nor any attorney purporting to represent MiCal ever contacted Perrigo Israel's outside counsel prior to MiCal filing the instant action against Perrigo Israel for alleged infringement.

37. Counsel for Sun contacted Perrigo Israel's outside counsel in response to Perrigo Israel's Notice Letter.

38. Counsel for Sun refused to accept access to Perrigo Israel's confidential ANDA on terms that would ensure adequate protection for that highly confidential, proprietary business information.

39. Sun's counsel's pre-suit conduct demonstrates that they had no legitimate interest in obtaining access to Perrigo Israel's ANDA, and instead affirmatively acted to prevent obtaining such access.

40. Prior to bringing suit, counsel for Sun did not respond to Perrigo Israel's counsel's April 26, 2018 and/or April 30, 2018 correspondence seeking to reach agreement on OCA terms.

41. Prior to bringing suit against Perrigo Israel for alleged infringement of the '028 patent, the only information MiCal had about Perrigo Israel's ANDA Product was found in Perrigo Israel's Notice Letter.

42. Prior to bringing suit against Perrigo Israel for alleged infringement of the '028 patent, the only information Sun had about Perrigo Israel's ANDA Product was found in Perrigo Israel's Notice Letter.

43. Perrigo Israel's Notice Letter sets forth at least one factual basis as to why Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

44. Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

45. Perrigo Israel's Notice Letter sets forth at least one factual basis as to why the claims of the '028 patent are invalid.

46. The claims of the '028 patent are invalid.

47. Sun and MiCal filed the instant action on May 9, 2018.

48. Sun lacked a good faith basis to bring suit against Perrigo Israel for alleged infringement of the '028 patent.

49. Sun lacked a good faith basis to bring suit against Perrigo Company ("Perrigo Co.") for alleged infringement of the '028 patent.

50. Sun lacked a good faith basis to bring suit against Perrigo New York, Inc. ("Perrigo NY") for alleged infringement of the '028 patent.

51. Sun's suit against Perrigo Israel, Perrigo Co. and Perrigo NY (collectively, "Perrigo") on the '028 patent is objectively baseless; it is sham litigation brought for the improper purpose of, *inter alia*, obtaining a 30-month stay of FDA's approval of Perrigo Israel's ANDA Product and interfering with Perrigo Israel's ability to market its competing product.

52. MiCal lacked a good faith basis to bring suit against Perrigo Israel for alleged infringement of the '028 patent.

53. MiCal lacked a good faith basis to bring suit against Perrigo Co. for alleged infringement of the '028 patent.

54. MiCal lacked a good faith basis to bring suit against Perrigo NY for alleged infringement of the '028 patent.

55. MiCal's suit against Perrigo on the '028 patent is objectively baseless; it is sham litigation brought for the improper purpose of, *inter alia*, obtaining a 30-month stay of FDA's approval of Perrigo Israel's ANDA Product and interfering with Perrigo Israel's ability to market its competing product.

56. The '028 patent is unenforceable due, at the very least, to patent misuse for at least the reasons detailed herein.

F. Sun And MiCal Have No Reasonable Expectation Of Success On The Merits Of Any Infringement Claim Relating To The '028 Patent.

57. Sun is aware, *inter alia*, that Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly, as a result of, *inter alia*, the facts set forth in Perrigo Israel's Notice Letter.

58. MiCal is aware, *inter alia*, that Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly, as a result of, *inter alia*, the facts set forth in Perrigo Israel's Notice Letter.

59. Sun is aware, *inter alia*, that the '028 patent is invalid as a result of, *inter alia*, the facts set forth in Perrigo Israel's Notice Letter.

60. MiCal is aware, *inter alia*, that the '028 patent is invalid as a result of, *inter alia*, the facts set forth in Perrigo Israel's Notice Letter.

61. By purporting to bring this lawsuit within 45 days of receiving Perrigo Israel's Notice Letter, Sun and MiCal claim to have triggered a 30-month stay of FDA approval of Perrigo Israel's ANDA, thereby improperly delaying the sale of the product described in that ANDA.

62. Sun and MiCal are attempting to enforce the '028 patent in bad faith and for the improper purpose of, *inter alia*, keeping Perrigo Israel's ANDA product off the competitive marketplace for at least 30 months.

63. Sun's and MiCal's actions in, *inter alia*, maintaining the '028 patent in the Orange Book and asserting the '028 patent against Perrigo Israel (despite knowing that patent, *inter alia*, to be invalid and not infringed) have, according to Sun and MiCal, resulted in a 30-month stay of the approval of Perrigo Israel's ANDA. By their acts of misuse, Sun and MiCal have impermissibly broadened the scope of the '028 patent with anti-competitive effect.

64. Sun and MiCal have no realistic expectation of success on the merits in bringing the present lawsuit, as at least the '028 patent is not infringed and is invalid.

65. Sun's and MiCal's lawsuit is objectively baseless because, at the very least, based upon the information in Perrigo Israel's Notice Letter, Sun and MiCal knew or should have known that the '028 patent is not infringed and is invalid.

66. Sun's and MiCal's lawsuit against Perrigo on the '028 patent is objectively baseless; it is sham litigation brought for the improper purpose of, *inter alia*, obtaining a 30-month stay of FDA's approval of Perrigo Israel's ANDA Product and interfering with Perrigo Israel's ability to market its competing product.

COUNT I
(Declaration Of Non-Infringement Of The '028 Patent)

67. Perrigo Israel realleges and incorporates by reference the allegations of Paragraphs 1-66.

68. A present, genuine, and justiciable controversy exists between Sun and MiCal and Perrigo Israel regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale,

sale, or importation of the Halobetasol Propionate Lotion, 0.05% product described in Perrigo Israel's ANDA would infringe any valid or enforceable claim of the '028 patent.

69. The manufacture, use, offer for sale, sale, or importation of the Halobetasol Propionate Lotion, 0.05% product described in Perrigo Israel's ANDA would not infringe any valid or enforceable claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

70. For at least the reasons set forth in Perrigo Israel's detailed March 26, 2018 Notice Letter, Perrigo Israel's ANDA Product does not infringe any claim of the '028 patent, either literally or under the doctrine of equivalents, directly or indirectly.

71. Perrigo Israel is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo Israel's ANDA would not infringe any valid or enforceable claim of the '028 patent.

COUNT II
(Declaration Of Invalidity Of The '028 Patent)

72. Perrigo Israel realleges and incorporates by reference the allegations of Paragraphs 1-71.

73. A present, genuine, and justiciable controversy exists between Sun and MiCal and Perrigo Israel regarding, *inter alia*, the invalidity of the '028 patent.

74. The claims of the '028 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the ‘028 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the ‘028 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the ‘028 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the ‘028 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the ‘028 patent and would have had a reasonable expectation of success in doing so.

d. The ‘028 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the ‘028 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the ‘028 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole

was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '028 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, includes, *but is expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo Israel's March 26, 2018 Notice Letter. Such references and products include, but are not limited to: U.S. Patent Nos. 4,052,513, 4,370,322, and 4,738,842; U.S. Patent Application Publication No. 2012/0129824; Jacques Decroix, *et al.*, "Clobetasol Propionate Lotion in the Treatment of Moderate to Severe Plaque-Type Psoriasis," CUTIS, vol. 4, pgs. 201-06 (September 2004); and PHYSICIANS' DESK REFERENCE (*e.g.*, Medical Economics Co., 55th ed. 2001) (as well as prior art products identified therein).

75. Perrigo Israel is entitled to a declaration that the claims of the '028 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

COUNT III
(Declaration Of Unenforceability Of The '028 Patent: Patent Misuse)

76. Perrigo Israel realleges and incorporates by reference the allegations of Paragraphs 1-75.

77. A present, genuine, and justiciable controversy exists between Sun and MiCal and Perrigo Israel regarding, *inter alia*, the unenforceability of the '028 patent.

78. Sun's and MiCal's acts of misuse include bringing this lawsuit in bad faith with the knowledge, *inter alia*, that the '028 patent is not infringed by Perrigo Israel's ANDA Product and is invalid in order to stay Perrigo Israel's entry into the market.

79. Sun's and MiCal's intention was to use this lawsuit against Perrigo Israel (and the resultant 30-month stay of approval), rather than the outcome of the lawsuit, to forestall, frustrate and prevent competition in the relevant market.

80. By its acts of misuse, Sun and MiCal have used the '028 patent to restrain competition, even though the '028 patent is, *inter alia*, not infringed by Perrigo Israel's ANDA Product and is invalid, for an additional 30 months.

81. By its acts of misuse, Sun and MiCal have impermissibly broadened the scope of the '028 patent with anti-competitive effect.

82. Sun's and MiCal's acts of misuse were done in bad faith and with the knowledge that the '028 patent is not infringed by Perrigo Israel's ANDA Product and is invalid.

83. The '028 patent is unenforceable as a result of Sun's and MiCal's patent misuse.

84. Perrigo Israel is entitled to a declaration that the '028 patent is unenforceable.

REQUEST FOR RELIEF

WHEREFORE, Perrigo respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim-Defendants Sun and MiCal as follows:

(a) Declaring that the manufacture, sale, offer for sale, use or importation of the Halobetasol Propionate Lotion, 0.05% product described in Perrigo Israel's ANDA No. 211464 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '028 patent;

(b) Declaring that the claims of the '028 patent are invalid;

(c) Declaring that the '028 patent is unenforceable due to patent misuse;

(d) Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Perrigo;

(e) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Perrigo attorneys' fees, costs, and expenses in this action; and

(f) Awarding Perrigo any further and additional relief as the Court deems just and proper.

Dated: October 8, 2018

PHILLIPS, GOLDMAN, MCLAUGHLIN & HALL, P.A.

By: */s/ John C. Phillips, Jr.*

John C. Phillips, Jr. (No. 110)
Megan C. Haney (No. 5016)
1200 North Broom Street
Wilmington, DE 19806
(302) 655-4200
jcp@pgmhlaw.com
mch@pgmhlaw.com

Attorneys for Defendants Perrigo Company, Perrigo Israel Pharmaceuticals Limited, and Perrigo New York, Inc.

Christine J. Siwik
William A. Rakoczy
Alice L. Riechers
Gregory A. Duff
RAKOCZY MOLINO MAZZOCHI SIWIK LLP
6 West Hubbard Street, Suite 500
Chicago, IL 60654
(312) 222.6304 (telephone)
(312) 222.6324 (facsimile)