IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SEBELA PHARMACEUTICALS INC., and PERRIGO NEW YORK, INC. Plaintiffs, v. TRUPHARMA, LLC, Defendants.	C.A. No. _____ **JURY TRIAL DEMANDED**

COMPLAINT

Plaintiffs Sebela Pharmaceuticals Inc. and Perrigo New York, Inc. for their Complaint against Defendant TruPharma, LLC hereby state and allege as follows:

PARTIES

1. Plaintiff Sebela is a corporation organized under the laws of the State of Delaware with a principal place of business in Roswell, Georgia.

2. Plaintiff Perrigo is organized under the laws of the state of Delaware with a principal place of business in Allegan, Michigan.

3. Upon information and belief, Defendant TruPharma is a limited liability company organized under the laws of Delaware with an address of 4100 West Kennedy Boulevard, Suite 220, Tampa, FL, 33609.

4. Upon information and belief, TruPharma is a privately owned pharmaceutical company, whose products are advertised and marketed through all major distribution channels in the United States.

5. Upon information and belief, Doe TruPharma is other persons or entities involved in the false and misleading activities alleged herein.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the claims asserted herein pursuant to 28 U.S.C. §§ 1331, 1332, and 1338, and 15 U.S.C. §§ 1116 and 1121, as this case arises under the Lanham Act. This Court also has supplemental jurisdiction over Plaintiffs' state and common law claims pursuant to 28 U.S.C. § 1367.

7. At all times relevant to this lawsuit, TruPharma, and one or more of its agents, have been engaged in the business of advertising, promoting, marketing, distributing, and/or selling, within the State of Delaware and in interstate commerce throughout the United States, the products which are the subject of this Complaint, namely, a hydrocortisone acetate 2.5% and pramoxine hydrochloride 1% cream that is marketed under NDC Code 52817-0817-01 (hereinafter, "TruPharma's Unauthorized HCA/Pram Product").

8. TruPharma is subject to personal jurisdiction in Delaware because, upon information and belief, Defendant TruPharma is incorporated in Delaware; TruPharma transacts business and/or advertise or contract to supply services or things in this State; TruPharma has caused tortious injury in Delaware by an act or omission committed in Delaware; TruPharma has caused tortious injury in Delaware by an act or omission outside Delaware; TruPharma has caused tortious injury to a corporation organized under the laws of Delaware.

9. Venue is proper in this judicial District pursuant to 28 U.S.C. § 1391(b) because TruPharma is incorporated in Delaware and subject to personal jurisdiction in this District.

STATEMENT OF FACTS

A. Sebela's Products

10. Sebela is in the business of marketing, promoting, distributing, and selling authorized prescription pharmaceutical products in the gastroenterology and dermatology fields, including certain hydrocortisone acetate and pramoxine hydrochloride products formerly owned by Ferndale Laboratories, Inc. (later reorganized as Ferndale Pharma Group, Inc.) ("Ferndale").

11. From at least the 1970s, Ferndale developed, manufactured, and marketed a line of prescription products containing varying dosages of hydrocortisone acetate and pramoxine hydrochloride in cream, lotion, or ointment form (collectively, the "HCA/Pram Products"), which are currently marketed under the trademarks and trade names "PRAMOSONE" ("PRAMOSONE") and "ANALPRAM HC" ("ANALPRAM").

12. The PRAMOSONE and ANALPRAM prescription products have been continuously on the market for over 30 years and are topical corticosteroids with anti-inflammatory, antipruritic, and vasoconstrictive qualities and are available only by prescription.

13. In the 1970s, Ferndale submitted and received Food and Drug Administration ("FDA") approval of several ANDAs for a number of hydrocortisone acetate and pramoxine hydrochloride products, including the HCA/Pram Products.

14. On July 1, 1988, the FDA published in the Federal Register a Notice of Opportunity for a Hearing ("NOOH") regarding the regulatory status of fixed combination drug products that contain hydrocortisone acetate and pramoxine hydrochloride, which included Ferndale's HCA/Pram Products. (53 Fed. Reg. 25013 (July 1, 1988)).

15. Under the NOOH, the FDA required the ANDA holders to submit clinical evidence within 60 days of the NOOH showing that genuine and material issues of fact exist

about the effectiveness of the drug that require an administrative hearing for resolution.

16. In response to the 1988 FDA notice, Ferndale submitted a timely hearing request for the HCA/Pram Products. This request for hearing was affirmed by Ferndale Laboratories, Inc., on January 3, 2011. (77 Fed. Reg. 43337 (July 24, 2012)).

17. As recently as 2017, FDA confirmed that the HCA/Pram Products are subject to the NOOH proceedings.

18. In 2013, Sebela acquired the right to sell and promote the HCA/Pram Products in the United States. Sebela has marketed, promoted, and/or sold the HCA/Pram Products since that time, and has derived income and revenue therefrom. Ferndale continues to act as the manufacturer of these products.

19. In addition to product rights, Sebela acquired all of Ferndale's regulatory rights and history concerning the HCA/Pram Products, including historical correspondence between Ferndale and the FDA.

20. Having acquired these product rights in 2013, Sebela, either directly or as FDA agent for the ANDA owner, received and asserts the same exclusive legal rights to a hearing and other regulatory procedures under the Federal Food, Drug, and Cosmetic Act (FD&C Act), and which assertion has been affirmed by the FDA.

21. One of the HCA/Pram Products marketed by Sebela is hydrocortisone acetate 2.5% pramoxine hydrochloride 1% cream, which is marketed under the PRAMOSONE and ANALPRAM trademarks and trade names (hereinafter, "PRAMOSONE Cream").

22. PRAMOSONE Cream is a topical preparation containing hydrocortisone acetate 2.5% w/w and pramoxine hydrochloride 1% w/w in a hydrophilic cream base containing stearic acid, cetyl alcohol, Aquaphor®, isopropyl palmitate, polyoxyl 40 stearate, propylene glycol,

potassium sorbate, sorbic acid, triethanolamine lauryl sulfate, and purified water.

23. Sebela has expended significant resources in the marketing and selling its prescription products in compliance with existing laws and regulations and derives economic benefits, including revenue and profits, through sales of PRAMOSONE Cream.

24. Sebela enjoys a strong reputation and has developed substantial goodwill among suppliers, medical professionals, pharmacists, wholesalers, regulators, consumers and others in connection with PRAMOSONE Cream, which is manufactured in accordance with current good manufacturing practices ("cGMP").

25. Sebela maintains contractual relationships with pharmaceutical manufacturers, pharmaceutical drug databases, insurers, wholesalers, distributors, and/or suppliers in order to make and sell PRAMOSONE Cream. These contractual relationships result in economic benefits to Sebela, and will continue to do so in the future. These contractual relationships are standard for the industry.

B. Perrigo's Authorized Cream

26. Perrigo is in the business of marketing, promoting, distributing, and selling authorized prescription pharmaceutical products in the gastroenterology and dermatology fields, including certain hydrocortisone acetate and pramoxine hydrochloride products.

27. With Sebela's authorization, Perrigo markets a hydrocortisone acetate 2.5% pramoxine hydrochloride 1% cream ("Perrigo's authorized cream").

28. Perrigo enjoys a strong reputation and has developed substantial goodwill among suppliers, medical professionals, pharmacists, wholesalers, regulators, consumers and others in connection with Perrigo's authorized cream, which is manufactured in accordance with current good manufacturing practices ("cGMP").

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