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PreCision Dermatology, Inc.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PRECISION DERMATOLOGY, INC.,	)	
	)	
Plaintiff,	)	
	)	Civil Action No.:
v.	)	
	)	
LUPIN LIMITED,	)	
	)	
Defendant.	)	
	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff PreCision Dermatology, Inc. ("Precision") for its Complaint against Defendant Lupin Limited ("Lupin"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35 of the United States Code.

THE PARTIES

2. PreCision is a corporation organized and existing under the laws of Delaware having its principal place of business at 400 Highland Corporate Drive, Cumberland, Rhode Island 02864.

3. On information and belief, Lupin is a corporation organized and existing under the laws of India, and having a principle place of business at B/4, Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mubai 400 051, India.

JURISDICTION AND VENUE

4. This action arises under the Patent Laws of the United States and Food and Drug Laws of the United States, Titles 35 and 21 of the United States Code. Jurisdiction is based on 28 U.S.C. §§ 1331 and 1338.

5. On information and belief, this Court has personal jurisdiction over Lupin.

6. Lupin has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to PreCision in the State of New Jersey, and throughout the United States.

7. On information and belief, Lupin regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial

revenue from services or things used or consumed in New Jersey, demonstrating that Lupin has continuous and systematic contacts with New Jersey.

8. On information and belief, Lupin is in the business of among other things, manufacturing, marketing, importing, preparing, and selling generic pharmaceutical products that it distributes in the State of New Jersey and throughout the United States.

9. On information and belief, Lupin has purposefully conducted business in the state of New Jersey, continues to conduct business in New Jersey, and New Jersey is a likely destination of Lupin's products or the products of its affiliates or agents.

10. This Court also has personal jurisdiction over Lupin by virtue of the fact that Lupin has previously submitted to the jurisdiction of this Court and availed itself of this Court by consenting to this Court's jurisdiction and asserting counterclaims in civil actions initiated in this jurisdiction. *See, e.g.*, *AstraZeneca Pharm. LP et al. v. Lupin Ltd. et al.*, No. 12-cv-6888 (D.N.J.), *Janssen Prods. L.P. v. Lupin Ltd. et al.*, No. 10-cv-05954 (D.N.J.), and *Elan Pharma Int'l Ltd. v. Lupin Ltd. & Lupin Pharms., Inc.*, No. 09-1008 (D.N.J.).

11. In the alternative, this Court has jurisdiction over Lupin because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) PreCision's claims arise under federal law; (b) Lupin is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting Abbreviated New Drug Application ("ANDA") No. 210209 to the Food and Drug Administration ("FDA") and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin satisfies due process.

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

BACKGROUND

13. PreCision is the holder of approved New Drug Application ("NDA") No. 022076 for LOCOID® Lotion (hydrocortisone butyrate, 0.1%).

14. The FDA approved NDA No. 022076 for LOCOID® Lotion on May 18, 2007 for the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

15. United States Patent No. 7,981,877 ("the '877 patent"), entitled "Stabilized Steroid Composition and Method for Its Preparation," was duly and legally issued to Triax Pharmaceuticals, LLC on July 19, 2011. A true and correct copy of the '877 patent is attached hereto as Exhibit A.

16. The '877 patent is listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("FDA Orange Book") for LOCOID® Lotion.

17. The '877 patent claims, *inter alia*, stabilized 17-hydrocortisone butyrate containing compositions and methods of manufacturing them.

18. On April 24, 2012, Triax Pharmaceuticals, LLC assigned all rights, title, and interest to the '877 patent to PreCision.

CLAIM FOR RELIEF – PATENT INFRINGEMENT

19. By a letter dated June 6, 2017 (the "Lupin Notice Letter"), Lupin advised PreCision that it had submitted ANDA No. 210209 to the FDA seeking approval to manufacture, use, or sell Hydrocortisone Butyrate Lotion, 0.1% ("Lupin's Generic Product") prior to the expiration of the '877 patent.

20. On information and belief, Lupin submitted ANDA No. 210209 to the FDA under § 505(j) of the Federal Food, Drug and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, and sale of Lupin's Generic Product as a generic version of LOCOID® Lotion.

21. On information and belief, ANDA No. 210209 seeks FDA approval of Lupin's Generic Product for the indication of the topical treatment of mild to moderate atopic dermatitis in patients 3 months of age and older.

22. The Lupin Notice Letter also advised PreCision that ANDA No. 210209 included certifications under 21 U.S.C. § 355(j)(2)(B)(iv)(II) that, in Lupin's opinion, the claims of the '877 patent are invalid, unenforceable and/or not infringed.

23. There is an actual, real, immediate, and justiciable controversy between PreCision and Lupin regarding the infringement, validity, and enforceability of the '877 patent.

COUNT I

Infringement Of The '877 Patent

24. PreCision incorporates each of the preceding paragraphs 1 to 23 as if fully set forth herein.

25. By submitting ANDA No. 210209 to the FDA to obtain approval under the Food, Drug, and Cosmetic Act to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's Generic Product throughout the United States, including New Jersey, prior to expiration of the '877 patent, Lupin committed an act of infringement of the '877 patent under 35 U.S.C. § 271(e)(2)(A).

26. Lupin's manufacture, use, sale, offer for sale, or importation into the United States of Lupin's Generic Product prior to the expiration of the '877 patent, including any

applicable exclusivities or extensions, will infringe one or more claims of the '877 patent under 35 U.S.C. §§ 271(a), (b) and/or (c).

27. PreCision will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. PreCision has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, PreCision respectfully requests the following relief:

A. A judgment that Lupin has infringed one or more claims of United States Patent No. 7,981,877 by submitting ANDA No. 210209 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of Lupin's Generic Product before the expiration of the '877 patent under 35 U.S.C. § 271(e)(2)(A);

B. A judgment that Lupin's commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Lupin's Generic Product will infringe one or more claims of the '877 under 35 U.S.C. §§ 271(a), (b), and/or (c);

C. A judgment that the '877 patent remains valid and enforceable;

D. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283 restraining and enjoining Lupin, its officers, agents, servants, and employees, and those persons in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale in, and/or importation into the United States of Lupin's Generic Product prior to the expiration date of the '877 patent, inclusive of any exclusivities or extensions;

E. An order under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 210209 under Section 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall be a date that is not earlier than the expiration date of the '877

patent, inclusive of any exclusivities or extensions;

F. A declaration that this case is "exceptional" under 35 U.S.C. § 285 and an award of attorneys' fees;

G. Costs and expenses in this action; and

H. Such other and further relief as the Court may deem just and proper.

Dated: July 20, 2017

/s/ Charles H. Chevalier

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