UNITED STATES DISTRICT COURT
DISTRICT OF MARYLAND

Kowa Company, Ltd.
6-29, Nishiki 3-chome
Naka-ku, Nagoya, Aichi
Japan 460-8625,

Kowa Pharmaceuticals America, Inc.
530 Industrial Park Blvd.
Montgomery, AL 36117, and

Nissan Chemical Industries, Ltd.
4-14, 3-chome, Nihonbashi-Honcho
Chuo-ku, Tokyo
Japan 013-8433,

Plaintiffs,

v.

Lupin Limited
B/4 Laxmi Towers,
Bandra Kurla Complex,
Bandra (East), Mumbai, Maharashtra 400 051
India, and

Lupin Pharmaceuticals, Inc.
111 South Calvert Street, 21st Floor
Baltimore, MD 21202
Baltimore City County,

Defendants.

Civil Action No. _____

COMPLAINT

Plaintiffs, Kowa Company, Ltd. ("KCL"), Kowa Pharmaceuticals America, Inc. ("KPA") (collectively, "Kowa"), and Nissan Chemical Industries, Ltd. ("NCI") (Kowa and NCI, collectively, "Plaintiffs"), by their undersigned counsel, for their Complaint against defendants Lupin Limited and Lupin Pharmaceuticals, Inc. ("Lupin" or "Defendants"), allege as follows:

Jurisdiction and Venue

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code and arising under 35 U.S.C. §§ 271(e)(2), and 281-283. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper under 28 U.S.C. §§ 1391(b)-(c) and 1400(b). Personal jurisdiction over Defendants in Maryland is proper under Md. Code Ann., Cts. & Jud. Proc. § 6-103, because of Lupin's presence in Maryland, because Defendants are doing business in this jurisdiction, and/or under Fed. R. Civ. P. 4(k)(2).

Parties

2. KCL is a Japanese corporation having its corporate headquarters and principal place of business in Aichi, Japan. KPA is a wholly owned U.S. subsidiary of KCL. KPA has its corporate headquarters and principal place of business in Montgomery, Alabama and is organized under the laws of Delaware.

3. NCI is a Japanese corporation having its corporate headquarters and principal place of business in Tokyo, Japan.

4. KCL and NCI are engaged in the business of research, developing, manufacturing, and marketing of a broad spectrum of innovative pharmaceutical products, including Livalo®.

5. Upon information and belief, Lupin Limited is a company organized and existing under the laws of India, having its principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (East), Mumbai, Maharashtra 400 051, India.

6. Upon information and belief, Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202.

7. Upon information and belief, Lupin sells generic drugs throughout the United States, including at least in Maryland. Upon information and belief, Lupin Pharmaceuticals, Inc. is responsible for sales and marketing of Lupin Limited's products in the United States.

8. Upon information and belief, Lupin is currently transacting business in the District of Maryland, at least by making and shipping into this Judicial District, or by using, offering to sell or selling or by causing others to use, offer to sell or sell, pharmaceutical products. Upon information and belief, Lupin Limited makes and, through its wholly owned subsidiary, Lupin Pharmaceuticals, Inc., distributes drug products throughout the United States, including at least in the State of Maryland. Upon information and belief, Lupin Pharmaceuticals, Inc. maintains its principal place of business within the State of Maryland and this Judicial District. Upon information and belief, Lupin Pharmaceuticals, Inc. is registered with the Maryland Department of Assessments and Taxation to do business as a foreign corporation in Maryland. Upon information and belief, Lupin derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of Maryland and the District of Maryland. By filing its ANDA, Lupin has committed, and unless enjoined, will continue to commit a tortious act without the State of Maryland, which Lupin expects or should reasonably expect to have consequences in the State of Maryland, including in this Judicial District.

The New Drug Application

9. KPA sells drug products containing pitavastatin calcium (the "pitavastatin drug product") under the trade name Livalo® in the United States pursuant to the United States Food and Drug Administration's approval of a New Drug Application ("NDA") held by KCL (NDA No. 22-363).

10. Livalo® is approved for use as an adjunctive therapy to diet to reduce elevated total cholesterol, low-density lipoprotein cholesterol, apolipoprotein B, triglycerides, and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia.

11. The approval letter for Livalo®, with approved labeling, was issued by the FDA on August 3, 2009.

12. Certain amendments to the approved labeling for Livalo® have subsequently been approved.

The Patent in Suit

13. United States Patent No. 8,557,993 ("the '993 patent"), entitled "Crystalline Forms of Pitavastatin Calcium," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on October 15, 2013 to inventors Paul Adriaan Van Der Schaaf, Fritz Blatter, Martin Szelagiewicz, and Kai-Uwe Schoening, and ultimately was assigned to plaintiff NCI. The '993 patent claims, inter alia, crystalline polymorphs or the amorphous form of pitavastatin or processes for preparing the same.

14. Plaintiff NCI has been and still is the owner through assignment of the '993 patent, which expires on February 2, 2024. KCL is NCI's licensee for the '993 patent and KPA holds a license from KCL for the '993 patent.

15. In accordance with its license, KPA sells the pitavastatin drug product under the trade name Livalo® in the United States. Sales of Livalo® are made pursuant to approval by the FDA of NDA No. 22-363.

16. Plaintiff KCL manufactures the Livalo® drug products as sold by KPA.

17. Plaintiffs Kowa and NCI will be substantially and irreparably harmed by infringement of the '993 patent. There is no adequate remedy at law.

COUNT I

INFRINGEMENT OF THE '993 PATENT UNDER 35 U.S.C. § 271(e)(2)(A)

18. Plaintiffs repeat and incorporate herein by reference the allegations contained in each of the foregoing paragraphs.

19. Upon information and belief, Lupin filed an Abbreviated New Drug Application ("ANDA") with the Food and Drug Administration ("FDA") under 21 U.S.C. § 355(j) (ANDA No. 20-6029) seeking approval to market 1 mg, 2 mg, and 4 mg tablets comprising pitavastatin calcium.

20. By this ANDA filing, Lupin has indicated that it intends to engage, and that there is substantial likelihood that it will engage, in the commercial manufacture, importation, use, offer for sale, and/or sale, or inducement thereof, of Plaintiffs' patented pitavastatin drug product immediately or imminently upon receiving FDA approval to do so. Also by its ANDA filing, Lupin has indicated that its pitavastatin drug product is bioequivalent to Plaintiffs' pitavastatin drug product.

21. By its ANDA filing, Lupin seeks to obtain approval to commercially manufacture, use, import, offer for sale, and/or sell, alleged generic equivalents of Plaintiffs' Livalo® pitavastatin drug product prior to the expiration date of the '993 patent.

22. By a letter dated April 8, 2015 (the "Notice Letter"), Lupin informed Kowa and NCI that Lupin had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(I). On or about April 9, 2015, KPA received the Notice Letter. On or about April 10, 2015, KCL and NCI received the Notice Letter.

23. The Notice Letter, purporting to be Lupin's Notice of Certification under 21 U.S.C.§ 355(j)(2)(B)(ii), indicates that Lupin intends to manufacture, use, sell, or offer for sale, its proposed pitavastatin drug product prior to the expiration of the '993 patent.

24. The Notice Letter asserts that in Lupin's opinion, "[n]o valid claim of the . . . '993 patent will be infringed by the manufacture, use or sale of the proposed drug products for which the ANDA has been submitted" by Lupin.

25. Lupin's filing of ANDA No. 20-6029 for the purpose of obtaining FDA approval to engage in the commercial manufacture, use, importation, offer for sale and/or sale, or the inducement thereof, of its proposed pitavastatin drug product before the expiration of the '993 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

26. Lupin's manufacture, use, importation, offer for sale, sale, and/or importation of its proposed pitavastatin drug product will directly infringe or induce infringement of at least one claim of the '993 patent under 35 U.S.C. § 271(e)(2)(A).

27. Unless Lupin is enjoined from infringing the '993 patent, Plaintiffs will suffer substantial and irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that making, using, selling, offering to sell and/or importing Lupin's pitavastatin drug product for which it seeks FDA approval or any drug product containing pitavastatin will infringe at least one claim of the '993 patent;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. and an order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval for Lupin to commercially make, use, sell, offer to sell or import

its pitavastatin drug product or any drug product containing pitavastatin be no earlier than the date following the expiration date of the '993 patent;

(c) a permanent injunction restraining and enjoining against any infringement by Defendants, their officers, agents, attorneys, employees, successors or assigns, or those acting in privity or concert with them, of the '993 patent, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Lupin's pitavastatin drug product or any drug product containing pitavastatin, and/or any inducement of the same;

(d) attorneys' fees in this action under 35 U.S.C. § 285; and

(e) such further and other relief in favor of Plaintiffs and against Defendants as this Court may deem just and proper.

Dated: May 22, 2015

Kowa Company, Ltd.,
Kowa Pharmaceuticals America, Inc., and
Nissan Chemical Industries, Ltd.

By their attorneys,

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