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UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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

Plaintiffs,

v.

Mylan, Inc. and
Mylan Pharmaceuticals, Inc.,

Defendants.

14 CV 2647

Civil Action No. _____

COMPLAINT

Plaintiffs, Kowa Company, Ltd. ("KCL"), Kowa Pharmaceuticals America, Inc. ("KPA")(collectively, "Kowa"), and Nissan Chemical Industries, Ltd. ("NCI") by their undersigned counsel, for their Complaint against defendants Mylan Pharmaceuticals, Inc. ("MPI") and Mylan, Inc. ("Mylan, Inc.") (collectively, "Mylan"), 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), 271(b), 271(c), 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 the defendants in New York is proper under N.Y. C.P.L.R. §§ 301 and 302(a) and because defendants are doing business in this jurisdiction.

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, MPI is incorporated in West Virginia having a place of business in Morgantown, West Virginia, and is a wholly owned subsidiary of Mylan, Inc. Upon information and belief, Abbreviated New Drug Application ("ANDA") No. 20-6070 was filed under the name of MPI.

6. Upon information and belief, Mylan, Inc. is a Pennsylvania corporation having its corporate headquarters in Canonsburg, Pennsylvania. Upon information and belief, Mylan, Inc. has actual control over the activities of MPI including MPI's filing of ANDA No. 20-6070.

7. Upon information and belief, Mylan is currently transacting business in the Southern District of New York, 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 into this Judicial District.

8. Upon information and belief, Mylan derives substantial revenue from interstate and/or international commerce, including substantial revenue from goods used or consumed or services rendered in the State of New York and the Southern District of New York. Both Mylan, Inc. and MPI are registered with the N.Y. State Department of State, Division of Corporations, to do business as foreign corporations in New York. Upon information and belief, Mylan also has a place of business at 405 Lexington Avenue, New York, NY 10754. Additionally, Mylan, Inc. common stock is listed on the NASDAQ, and Mylan, Inc. has contractual dealings with at least the American Stock Transfer & Trust Company located at 59 Maiden Lane, Plaza Level, New York, NY 10038. By filing its ANDA, Mylan has committed, and unless enjoined, will continue to commit a tortious act without the state of New York, that Mylan expects or should reasonably expect to have consequences in the State of New York 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 Patents in Suit

13. United States Patent No. 5,856,336 ("the '336 patent"), entitled "Quinoline Type Mevalonolactones," a true and correct copy of which is appended hereto as **Exhibit A**, was duly issued on January 5, 1999 to inventors Yoshihiro Fujikawa, Mikio Suzuki, Hiroshi Iwasaki, Mitsuaki Sakashita, and Masaki Kitahara, and assigned to plaintiff NCI. The '336 patent claims, inter alia, the pitavastatin drug product, and a method for reducing hyperlipidemia, hyperlipoproteinemia or atherosclerosis, which comprises administering an effective amount of the pitavastatin drug product.

14. Plaintiff NCI has been and still is the owner through assignment of the '336 patent, which expires on December 25, 2020 pursuant to a patent-term extension. KCL is NCI's licensee for the '336 patent and KPA holds a license from KCL for the '336 patent.

15. United States Patent No. 6,465,477 ("the '477 patent"), entitled "Stable Pharmaceutical Composition," a true and correct copy of which is appended hereto as **Exhibit B**, was duly issued on October 15, 2002 to inventors Toyojiro Muramatsu, Katsumi Mashita, Yasuo Shinoda, Hironori Sassa, Hiroyuki Kawashima, Yoshio Tanizawa, and Hideatsu Takeuchi, and

jointly assigned to plaintiffs KCL and NCI. The '477 patent claims, inter alia, pharmaceutical compositions containing pitavastatin salts.

16. Plaintiffs KCL and NCI have been and still are the owners through assignment of the '477 patent, which expires on December 20, 2016. KPA holds a license from KCL for the '477 patent.

17. 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 C**, 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.

18. 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.

19. 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.

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

21. Plaintiffs Kowa and NCI will be substantially and irreparably harmed by infringement of any of the '336, '477, or '993 patents (the "Livalo® patents"). There is no adequate remedy at law.

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