UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

Kowa Company, Ltd., Kowa Pharmaceuticals America, Inc., and Nissan Chemical Industries, Ltd., Plaintiffs, v. Zydus Pharmaceuticals (USA) Inc., and Cadila Healthcare Ltd. (dba Zydus Cadila), 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 Zydus Pharmaceuticals (USA) Inc. ("Zydus USA") and Cadila Healthcare Ltd. (dba Zydus Cadila) ("Zydus Cadila") (collectively, "Zydus"), 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 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, Zydus USA is incorporated in Delaware having a place of business in Pennington, New Jersey, and is a wholly owned subsidiary of Zydus Cadila.

6. Upon information and belief, Zydus Cadila is a corporation organized and existing under the laws of India having its principal place of business in Gujarat, India. Upon information and belief, Zydus filed 505(b)(2) NDA No. 20-8379 (the "505(b)(2) Application").

7. Upon information and belief, Zydus USA sells generic drugs, manufactured and supplied by Zydus Cadila, throughout the United States, including in at least New York.

8. Upon information and belief, Zydus USA 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.

9. Upon information and belief, Zydus 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. Further, Zydus USA and Zydus Cadila have availed themselves of the courts in the state of New York by filing suit in New York. By filing the 505(b)(2) Application, Zydus has committed, and unless enjoined, will continue to commit a tortious act without the state of New York, that Zydus expects or should reasonably expect to have consequences in the State of New York including in this Judicial District.

The New Drug Application

10. KPA sells drug products containing pitavastatin (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).

11. 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.

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

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

The Patent in Suit

14. 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 A,** 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.

15. 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.

16. 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.

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

18. Plaintiffs Kowa and NCI will be substantially and irreparably harmed by infringement of the '477 patent (the "Livalo® patent"). There is no adequate remedy at law.

COUNT I
INFRINGEMENT OF THE '477 PATENT UNDER 35 U.S.C. § 271(E)(2)(A)

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

20. Upon information and belief, defendant Zydus filed the 505(b)(2) New Drug Application with the Food and Drug Administration ("FDA") under 21 U.S.C. § 355(b) (NDA No. 20-8379) seeking approval to market 1 mg, 2 mg, and 4 mg tablets comprising pitavastatin.

21. By this 505(b)(2) Application filing, Zydus 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 505(b)(2) Application filing, Zydus has indicated that its drug product is bioequivalent to Plaintiffs' pitavastatin drug product.

22. By its 505(b)(2) Application filing, Zydus 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 '477 patent.

23. By a letter dated July 28, 2015 (the "Notice Letter"), Zydus informed Kowa and NCI that Zydus had filed a certification to the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(iv). On or about July 28, 2015, KPA received the Notice Letter. On or about July 30, 2015, NCI received the Notice Letter. On or about July 31, 2015, KCL received the Notice Letter.

24. Zydus's Notice Letter, purporting to be Zydus's Notice of Certification under 21 U.S.C. § 355(b)(3)(B), indicates that Zydus intends to manufacture, use, sell, or offer for sale, its proposed pitavastatin drug product prior to the expiration of the '477 patent.

25. The Notice Letter asserts that in Zydus's opinion, "no valid claim of [the '477 patent] . . . will be infringed by the manufacture, use, or sale of the Zydus [505(b)(2)] NDA Product."

26. Zydus's filing of 505(b)(2) NDA No. 20-8379 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 '477 patent is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

27. Zydus'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 '477 patent under 35 U.S.C. § 271(e)(2)(A).

28. Unless Zydus is enjoined from infringing the '477 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 Zydus's pitavastatin drug product for which it seeks FDA approval or any drug product containing pitavastatin will infringe at least one claim of the Livalo® patent;

(b) a declaratory judgment pursuant to 28 U.S.C. § 2201 et seq. that the making, using, offering for sale, selling and/or importing of Zydus's pitavastatin drug product or any drug product containing pitavastatin, will induce the infringement at least one claim of the Livalo® patent;

(c) 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 Zydus 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 Livalo® patent (as extended, if applicable);

(d) 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 Livalo® patent, through the commercial manufacture, use, sale, offer for sale or importation into the United States of Zydus's pitavastatin drug product or any drug product containing pitavastatin, and/or any inducement of or contribution to the same;

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

(f) Such further and other relief in favor of Plaintiffs and against defendants as this Court may deem just and proper.

Dated: New York, New York
September 10, 2015

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

By their attorneys,

s/Jennifer L. Dereka

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