

To whom it may concern

January 8, 2019
Kowa Company, Ltd.,
Nissan Chemical Corporation

News of victory of patent infringement litigation at high court in the United States
regarding Livalo, blood cholesterol lowering drug

Kowa Company Ltd.(Head office: Naka-ku, Nagoya-shi; President and Representative Director: Yoshihiro Miwa, hereinafter “Kowa”), Kowa Pharmaceuticals America, Inc.(Head Office: Montgomery, Alabama, CEO & President: Ben Stakely, hereinafter “KPA”) and Nissan Chemical Corporation (Head office: Chuo-ku, Tokyo; President and Representative Director: Kojiro Kinoshita, hereinafter “Nissan Chemical”) announce that in December of 2018, United States Court of Appeals for the Federal Circuit (hereinafter, “CAFC”) issued a judgement affirming the district court decision, which agreed arguments by plaintiff-appellee (Kowa, KPA and Nissan Chemical) that Amneal Pharmaceuticals LLC, a generic drug maker, would be infringing the valid patent covering the blood cholesterol lowering drug (hereinafter, the “patent for crystals,” expiring February 2, 2024), Livalo (non-proprietary name: pitavastatin calcium, hereinafter “Livalo”), and rejected Amneal’s argument.

Starting in April 2014, Kowa, KPA and Nissan Chemical filed a law suit in U.S. District Court for the Southern District of New York against Amneal, Apotex Inc. and Apotex Corp (hereinafter collectively, “Apotex”) and 7 other companies, when these companies filed ANDA for pitavastatin calcium (1mg, 2mg and 4 mg tablet) to the Food and Drug Administration (FDA). Kowa, KPA and Nissan Chemical won the case in October 2017, however, Amneal and Apotex disagreed with the district court decision and appealed to the CAFC.

Kowa, KPA and Nissan Chemical successfully entered settlement agreements with the 7 other companies than Amneal and Apotex before the district court decision, and settled with Apotex after its filing the appeal. However, Kowa, KPA and Nissan Chemical did not reach an agreement with Amneal and consequently the judgement came out. In the appeal, Amneal pursued only an issue of validity of the patent for crystals.

About Livalo

Livalo is a drug whose active pharmaceutical ingredient is created and manufactured by Nissan Chemical and its global evolution (development, drug manufacturing, sales and

business alliances) is carried out by Kowa. In the United States, KPA markets under tradename Livalo Tablet 1mg, Livalo Tablet 2mg, Livalo Tablet 4mg. Livalo is a HMG-CoA reductase inhibitor. Livalo is indicated as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase HDL-C in adult patients with primary hyperlipidemia or mixed dyslipidemia*. Livalo is prescribed to many patients with dyslipidemia in Japan and overseas.

*For product and prescription information, please see package insert (available at the website)

(http://www.kowapharma.com/documents/LIVALO_PI_CURRENT.pdf)

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