

To whom it may concern:

June 2, 2014
Nissan Chemical Industries, Ltd.

Bringing patent infringement actions in the United States concerning drug applications of generic drugs of "LIVALO®," a therapeutic agent for hypercholesterolemia.

Nissan Chemical Industries, Ltd. (Head office: Chiyoda-ku, Tokyo; President and Representative Director: Kojiro Kinoshita, hereinafter "Nissan Chemical") recently filed complaints with the United States District Court for the Southern District of New York, and other certain District Courts with co-plaintiffs, Kowa Company, Ltd. (Head office: Naka-ku, Nagoya-shi; President and Representative Director: Yoshihiro Miwa, hereinafter "Kowa") and Kowa Pharmaceuticals America, Inc. (Head Office, Montgomery, Alabama, President & CEO : Ben Stakely, hereinafter "KPA"). The complaints were filed against the companies below, which had submitted an Abbreviated New Drug application (ANDA) with the Food and Drug Administration, seeking permission to market a generic version of "LIVALO®," the therapeutic agent for hypercholesterolemia (non-proprietary name; pitavastatin calcium).

Aurobindo Pharma Ltd.¹⁾, Mylan Inc.²⁾, Amneal Pharmaceuticals, LLC,
Orient Pharma Co., Ltd., and Zydus Pharmaceuticals (USA), Inc.³⁾

The complaints were for the reason of infringement of certain U. S. patents.

■About "LIVALO®"

"LIVALO®" is a pharmaceutical whose API is invented and manufactured by Nissan Chemical, and licensed to Kowa. Kowa is exclusively expanding its business globally (developing, manufacturing formulations, selling, and doing business with other companies, etc). In the United States, KPA is selling the pharmaceutical under the brand names, "LIVALO® Tablet 1mg; LIVALO® Tablet 2mg; and LIVALO® Tablet 4mg." LIVALO® is a HMG-CoA reductase inhibitor. It is indicated for patients with primary hyperlipidemia or mixed dyslipidemia 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 high-density lipoprotein cholesterol (HDL-C).⁴⁾ LIVALO® is prescribed to many patients having dyslipidemia in Japan and also overseas.

Notes:

¹⁾ Aurobindo Pharma Ltd. and Aurobindo Pharma USA Inc.

²⁾ Mylan Inc. and Mylan Pharmaceuticals, Inc.

³⁾ Zydus Pharmaceuticals (USA), Inc. and Cadila Healthcare, Ltd. (dba Zydus Cadila)

⁴⁾ See package insert for full product and prescribing information, available at:
http://www.kowapharma.com/documents/LIVALO_PI_CURRENT.pdf

Contact information for inquiries on the above
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