

To whom it may concern:

December 26, 2013
Nissan Chemical Industries, Ltd.
Kowa Company Ltd.

Bringing patent infringement actions concerning generic drugs of "LIVALO," a therapeutic agent for hypercholesterolemia.

As the generic drug marketing authorization holders started this year manufacturing and selling generic drugs of the therapeutic agent for hypercholesterolemia, manufactured and sold by Kowa (as defined below), corresponding to "LIVALO Tablet 1mg, LIVALO Tablet 2mg, LIVALO Tablet 4mg/LIVALO OD Tablet 1mg, and LIVALO OD Tablet 2mg" (non-proprietary name; pitavastatin calcium, hereinafter "LIVALO"), after their respective NHI price listings on December 13, Nissan Chemical Industries, Ltd. (Head office: Chiyoda-ku, Tokyo; President and Representative Director: Kojiro Kinoshita, hereinafter "Nissan Chemical") and Kowa Company Ltd. (Head office: Naka-ku, Nagoya-shi; President and Representative Director: Yoshihiro Miwa, hereinafter "Kowa") intend to bring legal actions against the generic drug marketing authorization holders under Nissan Chemical's or Kowa's patent rights concerning LIVALO (hereinafter, the "Patents") after having investigated their infringement upon the Patents.

Nissan Chemical consequently filed complaints dated December 25, 2013 against the following entities with Tokyo District Court, seeking injunctive relief to cease and desist from infringing upon the Patents: Daito Pharmaceutical Co., Ltd., Mochida Pharmaceutical Co., Ltd., Kobayashi Kako Co., Ltd., Meiji Seika Pharma Co., Ltd., Towa Pharmaceutical Co., Ltd., Tsuruhara pharmaceutical Co., Ltd., and Kaken Pharmaceutical Co., Ltd.

These companies obtained the marketing approval of the generic drugs of LIVALO dated August 15, 2013, and then have started, or have announced to start the sales.

The above filing is due to their infringement of the Patents owned by Nissan Chemical relating to a certain crystal form of the API.

Nissan Chemical and Kowa will in the future bring similar actions against any other entities as soon as their infringement upon the Patents has been confirmed.

■ About LIVALO

LIVALO is a pharmaceutical whose API is invented and manufactured by Nissan Chemical, and Kowa is exclusively expanding its business globally (developing, manufacturing formulations, selling, and the business tie up with other companies, etc.). In Japan, Kowa is to manufacture and sell the products under the brand names, “LIVALO Tablet 1mg; LIVALO Tablet 2mg; LIVALO Tablet 4mg/LIVALO OD Tablet 1mg; and LIVALO OD Tablet 2mg,” and Kowa Pharmaceutical Co. Ltd., is selling them. This pharmaceutical is ranked as a strong statin as a HMG-CoA reductase inhibitor which exhibits strong LDL cholesterol lowering activity. Besides its superior improvement effect against dislipidaemia, LIVALO is known by various supporting information to have characteristics, such as safety in long term use, less emergence of drug interactions, and clinical benefit with diabetic complication, etc., and is prescribed to many patients having dislipidaemia in Japan and also overseas. The sales of LIVALO in Japan in the 2012 fiscal year were about 51 billion yen, and further growth of the sales is expected in the present fiscal year. In overseas countries, LIVALO has been approved in thirty-eight countries including those in Europe, and America. The scale of the sales including that of overseas is growing up so that we may bring approximately a hundred billion yen sales into perspective.

Contact information for inquiries on the above	
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