

To whom it may concern:

January 16, 2014
Kowa Company Ltd.
Nissan Chemical Industries, Ltd.

Bringing patent/trademark infringement actions concerning generic drugs of "LIVALO," a therapeutic agent for hypercholesterolemia (the second report)

As the generic drug marketing authorization holders started manufacturing and selling generic drugs of "LIVALO," the therapeutic agent for hypercholesterolemia (non-proprietary name; pitavastatin calcium), manufactured and sold by Kowa Company Ltd. (Head office: Naka-ku, Nagoya-shi; President and Representative Director: Yoshihiro Miwa, hereinafter "Kowa") after their respective NHI price listings on December 13, 2013, Kowa and Nissan Chemical Industries, Ltd. (Head office: Chiyoda-ku, Tokyo; President and Representative Director: Kojiro Kinoshita, hereinafter "Nissan Chemical") intend to bring legal actions against the generic drug marketing authorization holders under Kowa's or Nissan Chemical's intellectual property rights concerning "LIVALO" (hereinafter "Intellectual Property Rights") after having investigated their infringement upon the Intellectual Property Rights.

This time, Kowa filed complaints dated January 15, 2014 against generic drug marketing authorization holders which are likely to infringe a certain trademark right owned by Kowa, with Tokyo District Court seeking injunctive relief to cease and desist from infringing upon such trademark right, and Nissan Chemical filed complaints of the same date against Sagami Chemical Industry Co., Ltd., Nichi-Iko Pharmaceutical Co., Ltd., and Kotobuki Pharmaceutical Co., Ltd., with the same court seeking injunctive relief to cease and desist from infringing upon the patent rights relating to a certain crystal form of the API of "LIVALO" owned by Nissan Chemical (hereinafter "Patent Rights").

As announced earlier, Nissan Chemical had already filed complaints dated December 25, 2013 against the following entities which are generic drug marketing authorization holders of "LIVALO," with Tokyo District Court seeking injunctive relief to cease and desist from infringing upon the Patent Rights: 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. The present action is therefore the second legal action.

Kowa and Nissan Chemical will in the future bring similar actions against any other

entities as soon as their infringement upon the Intellectual Property Rights 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.

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