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Chugai Wins the First Instance of the Patent Infringement Lawsuit for Oxarol® Ointment

December 25, 2014 (Tokyo) - Chugai Pharmaceutical Co., Ltd. (Head Office: Chuo-ku, Tokyo; Chairman & CEO: Osamu Nagayama) (hereafter “Chugai”) announced that on December 24, 2014, the Tokyo District Court (Civil affairs No. 29, Chief Judge Kazuhide Shimasue) has granted Chugai an overall victory for the first instance demanding the suspension of patent infringement of the manufacturing process patent owned by Chugai (Patent No. 3310301, hereafter “the Patent”) related to Oxarol® Ointment 25 µg/g, a treatment drug for keratosis including psoriasis vulgaris (hereafter “Oxarol® Ointment”).

Chugai filed a patent infringement lawsuit with the Tokyo District Court on February 19, 2013 against Iwaki Seiyaku Co., Ltd., Takata Seiyaku Co., Ltd., and Pola Pharma Inc., the distributors of the generic version of Oxarol® Ointment, as well as DKSH Japan Co., Ltd., the importer of the active pharmaceutical ingredient (API) of the generic drugs (hereafter “four companies”), alleging to suspend the infringement of the Patent.

In accordance with this judgment, a provisional disposition order will be issued towards four companies to suspend the import of API and the distribution of products.

Meanwhile, Cerbios-Pharma SA (hereafter “Cerbios-Pharma”), the manufacturer of API of the generic drug, and the four companies have respectively filed a request for patent invalidation with the Japan Patent Office. Details of the filings are described below.

- Outline of the requests for patent invalidation
 - i. May 2, 2013: First filing of a request for patent invalidation by Cerbios-Pharma
 - July 25, 2014: Trial decision declaring the Patent to be valid
 - November 28, 2014: Filing of a lawsuit with the Intellectual Property High Court by Cerbios-Pharma to revoke the first decision declaring the Patent to be valid
 - ii. December 10, 2013: Filing of a request for patent invalidation by four companies
 - iii. October 30, 2014: Second filing of a request for patent invalidation by Cerbios-Pharma

Impact resulting from these requests and lawsuits on Chugai’s business performance is minimal.

[Reference]

About Oxarol[®] Ointment

Oxarol[®] Ointment is an agent for the treatment of keratosis, using the active vitamin D₃ derivative, maxacalcitol, as an active ingredient which Chugai has discovered. It is indicated for the treatment of four diseases, namely, psoriasis vulgaris, ichthyosis, palmoplantar keratosis, and palmoplantar pustulosis.