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The Supreme Court Rendered Favorable Judgment on Patent-Infringement Lawsuit Regarding OXAROL[®] Ointment

March 24, 2017 (Tokyo) -- Chugai Pharmaceutical Co., Ltd. announced its final victory in a lawsuit in which Chugai sought injunction against generic drug manufacturers based on infringement of the process patent (Patent No. 3310301; hereinafter referred to as "Patent") on "OXAROL[®] Ointment 25 µg/g" (hereinafter referred to as OXAROL Ointment), a Chugai's drug for treatment of keratosis including psoriasis vulgaris. On March 24, the Supreme Court rendered a judgment dismissing the appeal by the generic companies, thereby Chugai's victory in this lawsuit has become final.

<Background>

- As of February 19, 2013, Chugai filed a lawsuit with Tokyo District Court against Iwaki & Co., Ltd., Takata Seiyaku Co., Ltd., and Pola Pharma Inc., distributors of generics of OXAROL Ointment, and also against DKSH Japan K.K., importer of the active ingredient of these generic products (hereinafter collectively referred to as "4 companies") seeking injunction based on infringement of the Patent.
- As of December 24, 2014, Tokyo District Court rendered a decision that was fully in favor of Chugai's claim, and as of February 25, 2015, issued a preliminary injunction to the 4 companies.
- The 4 companies appealed the decision of Tokyo District Court to the Intellectual Property High Court as of January 6, 2015. The Intellectual Property High Court heard this case by the Grand Panel and as of March 25, 2016 the Grand Panel affirmed the District Court decision and dismissed the appeal by the generic companies.
- As of April 7, 2016, the 4 companies filed a petition with the Supreme Court to take an appeal from the judgment of Intellectual Property High Court.

The Supreme Court made a decision to take the appeal petitioned by the generic companies and rendered the judgment to dismiss the appeal from the decision of Intellectual Property High Court. Thereby, Chugai's victory in the lawsuit seeking injunction of the generic products has become final. Chugai is now seeking recovery of damages caused by the infringement of Patent against 3 generic companies in a lawsuit at Tokyo District Court.

Meanwhile, the lawsuit above is expected to be negligible on the business performance of Chugai.

About Acceptance of Appeal by the Supreme Court

It is rather rare for the Supreme Court to accept an appeal from petitions. However, since this case involves an important legal issue relating to the doctrine of equivalents on the Patent Act, the Supreme Court accepted the appeal and expressed the expertise on the legal issue through the court ruling. For the conclusion of the case, the Supreme Court affirmed the judgment by the Intellectual Property High Court, and dismissed the appeal of the generic companies.

About OXAROL[®] Ointment

OXAROL Ointment is a drug with the active ingredient, "maxacalcitol," an active vitamin D₃ derivative created by Chugai for treatment of keratosis, and has been approved for 4 indications, which are psoriasis vulgaris, ichthyosis group, palmoplantar keratosis, and palmoplantar pustulosis.