

## Sonderhoff & Einsel News Update: IP Newsletter (February 2017)

### **Decision by the IP High Court regarding average molecular weight and the clarity of claims requirement**

Date of Decision: January 18, 2017

Docket No.: 2016 (Gyo-Ke) 10005

Court in charge: Intellectual Property High Court (First Division)

1. Overview
2. Summary of the High Court's decision
3. Our comment

## Decision by the IP High Court regarding average molecular weight and the clarity of claims requirement

### 1. Overview

The plaintiff, X, filed an invalidation trial against a patent held by defendant ROHTO Pharmaceutical Co. Ltd. which claimed a violation of the clarity of claims requirement based on the lack of clarity of the "average molecular weight" in the claims. The JPO, however, made a decision to maintain the patent.

The plaintiff was not satisfied with the decision by the JPO and appealed to the Intellectual Property High Court, which led to the JPO's decision being denied.

The subject matter of the present patent was a "refreshing composition for ophthalmology" containing chondroitin sulfate or a salt thereof which has a specific average molecular weight. The defendant filed a patent application in 2005, and the establishment of the patent right was registered in 2013.

### 2. Summary of the High Court's decision

"Average molecular weight" can mean different types of molecular weight such as "weight average molecular weight", "viscosity average molecular weight", "number average molecular weight", etc., and the definitions and the measuring methods are not the same. Thus, the values obtained by each measurement can vary depending on the measuring methods even if the material measured is the same.

According to the Board of Appeals decision by the JPO, the "average molecular weight" in the claims and the detailed explanation of the invention was to be understood as "weight average molecular weight" based on the explanation in the specification and common technical knowledge at the time of filing. However, in the specification, there is a description "sodium chondroitin sulfate (average molecular weight: approx. 7,000 etc.) distributed by Maruha Nichiro Corporation can be used." The value which Maruha Nichiro gave as a reply to an inquiry was, however, viscosity average molecular weight of approximately 6,000 to 10,000. Thus, the "average molecular weight" in the above description should be understood to refer to "viscosity average molecular weight". Also, since the specification does not disclose the conditions for the experiments, it cannot be determined clearly and unambiguously whether the "average molecular weight" of the present patent was "weight average molecular weight" or "viscosity average molecular weight". Furthermore, according to a document which was available at the time of filing, the weight average molecular weight of the same product of Maruha Nichiro is acknowledged to be 20,000 to 25,000 or so, which clearly contradicts the value of 7,000 disclosed in the detailed description of the invention.

Accordingly, it is unclear whether "average molecular weight" in the claims means "weight average molecular weight" or "viscosity average molecular weight", and the numerical range of the

molecular weight cannot be determined. Therefore, the decision by the JPO's Board of Appeal that denied the violation of Art. 36(6)(ii) (i.e., the clarity of the claims), despite such an unclear description in the claims which would be disadvantageous to third parties, was wrong.

### 3. Our comment

There are often cases where claimed parameters such as molecular weight, particle diameter, surface area or the like are found to be unclear. This is quite natural when the definitions, measuring methods, conditions for measurement, etc., are not clearly disclosed in the specification. In another ruling by the IP High Court concerning a patent right infringement lawsuit (2008 (Ne) 10013), the request for an injunction by the patentee was rejected, because the clarity of claims requirement was determined not to be met due to the conditions for the measurement of "mean particle size" being unclear. As a result, the patent invalidity defense was admitted. Therefore, definitions, measuring methods, etc., of parameters need to be described in the specification in such a manner that those parameters can be determined clearly and unambiguously even if they are obvious to applicants.

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