

**Pravastatin Sodium case**  
**Intellectual Property High Court**  
**Case No. 10043(Ne) of 2010**  
**27 January 2012**

**FACTS**

In this case, the appellant (the plaintiff of the first instance) who has the patent right demanded upon appellee (the accused of the first instance) for an injunction against manufacture and sale of products and the destruction of goods in stock of the accused under Article 100 of the Patent Act.

[Claim 1]

Pravastatin sodium prepared by a process comprising the steps of:

- a) forming an enriched organic solution of pravastatin,
- b) precipitating pravastatin as its ammonium salt,
- c) purifying the ammonium salt by recrystallization,
- d) transposing the ammonium salt to pravastatin sodium, and
- e) isolating pravastatin sodium,

wherein said pravastatin sodium contains less than 0.5% pravastatin lactone and less than 0.2% epiprava.

**ISSUE**

Scope of product-by-process claim

**HOLDING**

If a claim for a "product invention" recites a "process" for producing the product, the scope of such a product-by-process claim shall be determined as follows: (i) if there were circumstances at the time of filing the application that made it impossible or difficult to specify the constituents of the subject matter of the invention directly with the structure or property of the product and not with the process for producing the product, the scope of the invention should not be limited by the process recited in the claim and should be considered as covering the "product" *per se* (genuine product-by-process claim); (ii) if there was no such

circumstance as mentioned above, the scope of the invention should be limited by the process recited in the claim (pseudo product-by-process claim).

Moreover, in view of the burden of proof in a patent infringement case, when a claim for product invention recites a process, in principle, such a recitation shall be interpreted literally. Therefore, the party who asserts that his or her claim is a genuine product-by-process claim shall have the burden of proof to establish that at the time of filing the application it was impossible or difficult to specify the constituents of the subject matter of the invention directly with the structure or property of the product. If he or she fails to show such proof thoroughly, the claim should be considered as a pseudo product-by-process claim and the scope of the claim should be interpreted literally as recited in the claim.

The same applies when the scope of claim is determined in a patent invalidation trial.

With regard to the "pravastatin sodium which contains less than 0.5% pravastatin lactone and less than 0.2% epiprava" of Claim 1, it is considered that there was no circumstance that made it impossible or difficult to specify the product without relying on the process for producing the product. In the meantime, the appellant himself has admitted that it was not necessary to recite the process in order to specify the product. Consequently, the invention of Claim 1 should be considered as a pseudo product-by-process claim discussed above, and therefore, the scope of the claim is limited by the process feature.