

**The IP High Court Grand Panel will hear a Product-by-Process Claim
Infringement Suit (Asamura Circular No. 11-08)**

Masahiro Asamura
Attorney at Law & Patent Attorney
ASAMURA LAW OFFICES;
ASAMURA PATENT OFFICE, p.c.

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The IP High Court Grand Panel will hear an appeal against the Tokyo District court decision on a product-by-process claim infringement suit.

The IP High Court announced on July 26, 2011 that its Grand Panel consisting of 5 judges¹ would be hearing the appeal against the Tokyo District Court's decision [H19(Wa)35324] delivered on March 31, 2010, regarding the infringement claim of the product-by-process claim directed at "pravastatin sodium". The case will be the sixth grand panel case since the establishment of the IP High Court in 2005.

In short, the Tokyo District Court's decision states that in principle the scope of the product-by-process claim only covers a product produced by the process recited in the claim. It states that only under special circumstances the product-by-process claim covers an identical product produced by a different process from the process recited in the claim.

¹ Code of Civil Procedure, Article 310^{bis}.

Summary of the Tokyo District Court Decision [H19(Wa)35324]

- The patentee of Japanese patent 3,737,801 (" '801 patent", hereinafter) sought for an injunction relief before the Tokyo District Court.
- Claim 1 of '801 patent reads:
 - "1. Pravastatin sodium containing less than 0.5% pravastatin lactone and less than 0.2% epiprava, prepared by a process comprising of the steps:
 - 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."
- The defendant admitted that the accused product met the requirement of "Pravastatin sodium containing less than 0.5% pravastatin lactone and less than 0.2% epiprava" in claim 1, but asserted that the accused product was produced by a different process from the process recited in claim 1.
- In the decision, the court regards the claim as a product-by-process claim and sets the criteria that
 - "... when the production process is recited in the claim directed to the product invention, in principle the production process recited in the claim should not be disregarded. The technical scope of such a claim should be construed to be limited to the product that is produced by the recited production process. Only under special

circumstances, for example, when it is difficult to specify the product by its configuration and thus the applicant has no choice but to specify the product by its production process, the scope of the claim should be construed to cover the identical product but produced by a different process from the process recited in the claim."

- The court found that "Regarding the product, "pravastatin sodium containing less than 0.5% pravastatin lactone and less than 0.2% epiprava", in claim 1, there is no need to specify the product by its production process."
- The court, based on this principle, examined whether the defendant's production process met steps (a-e in claim 1 and found that it did not comprise step (a). It then rejected the plaintiff's infringement claim.

Note

- In the examination of the product-by-process claim at the JPO, the novelty and inventive step of the product *per se* is examined².
- In the precedents, the courts tend not to limit the scope of the product-by-process claim. The Tokyo High Court's decision [H13 (Gyo-Ke)84] denied the construction of JPO's trial decision limiting the scope of the product-by-process claim. The Tokyo High Court's decision [H14(Ne)1089] stated that the scope of the product-by-process covers the identical product

² Examination Guideline for Patent and Utility Model, Part II, Chapter 2, 1.5.2(3)

regardless of its production process in the infringement case. There has been, however, no precedent that found the product-by-process claim was infringed by the product actually produced by a different process from the recited process.

- On a different note, in another infringement suit decision based on the same '801 patent but with different defendant Tokyo District Court's decision [H20(Wa)16895] was delivered on July 28, 2011. In the decision, the court acknowledged the defendant's invalidity defense. In this suit, there was no dispute between the parties that the product-by-process was construed to cover the product *per se*, regardless of the recited process. The court then found that the product *per se* of '801 patent lacking inventive step. This case is independent of the above Grand Panel case.