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As reported in our previous Asamura Circular No. 11-08 (http://www.asamura.jp/judgments/infringement_suit.pdf), the Product-by-Process patent infringement case has been in the hands of the Grand Panel of the IP High Court. The subject patent is Japanese Patent 3,737,801, entitled as “PRAVASTATIN SODIUM SUBSTANTIALLY FREE OF PRAVASTATIN LACTONE AND EPI-PRAVASTATIN, AND COMPOSITIONS CONTAINING SAME” and was found not infringed in the district court decision.

On January 27, 2012, the Grand Panel delivered the decision that affirmed the district court decision and rejected the patentee’s appeal. The court made public a summary of the decision on the same date.

According to the summary, the court established the rule that the Product-by-Process Claim in principle covers only the product that is produced by the process recited in the claim, and only under exceptional circumstances, it may cover the identical product but produced by different production processes. The decision also teaches how validity of the Product-by-Process Claims should be determined.

As a quick report, the following is the translation of the summary posted on the IP High Court’s website:

1. Technical Scope of Each Claim

(1) Determination of the Technical Scope of a Patented Invention in the Patent Infringement Litigation

a) Article 70 of the Patent Act [Technical Scope of Patented Invention] stipulates that upon determining the technical scope of the patented invention in the infringement litigation,

“The technical scope of a patented invention shall be determined based upon the statements in the scope of claims attached to the application.” (Paragraph 1) and

“In the case of the preceding paragraph, the meaning of each term used in the scope of claims shall be interpreted in consideration of the statements in the description and drawings attached to the application.” (Paragraph 2).

Therefore, when determining the technical scope of a patented invention that forms a premise for an injunction claim or a damage claim for patent infringement, the wording in the ‘claim’ has to be the criteria. The wording in the claim is to be construed to define the technical scope of the patented invention specifically. If such criteria are denied and specific ‘wording’ stated as the scope of claims are construed to have no meanings to limit the technical scope of the invention, the third persons’ confidence who acted in accordance with the recitation of the ‘claim’ published in the Patent Gazette would be undermined and the legal stability would be jeopardized as a result.

For this reason, in the case where a claim of “product invention” recites a process for producing the product, in principle, the technical scope of such an invention has to be construed and determined to be limited to the product produced by the process and it is not admitted that the scope is construed and determined to encompass processes other than the recited process.

Although it is desirable that the claim of “product invention” is described and specified by its structure or properties, when there are reasons that make it impossible or difficult to directly specify the invention by its structure or properties at the time of the filing of the subject application, the applicant is admitted to specify the product by its production process in compliance with Article 36 VI (ii) of the Patent Act [Clarity requirement], in view of Article 1 of the Patent Act [Purpose of the Patent Act].

When such reasons are present, even if a specific production process is recited in a product claim, its technical scope would not be limited to the recited production process but be construed and determined to cover the ‘product’ in general.

- b) When a production process is recited in a claim for a product invention, such claim may be broadly called a “Product-by-Process Claim”. In view of the position in section (a) above, the above Product-by-Process Claim include:

“the case where since there are reasons that make it impossible or difficult to directly specify the product by its structure or properties at the time of the filing of the subject application, the production process is recited (in this instance, such a case is called “**True Product-by-Process Claim**” for the sake of convenience), and

“the case where the production process is additionally recited in a product claim, but there are no reasons that make it impossible or difficult for the applicant to directly specify the product by its structure or properties at the time of the filing of the subject application (in this instance, such a case is called “**Pseudo Product-by-Process Claim**” for the sake of convenience)”.

For further consideration, these two different cases will be distinguished.

According to section (a) above, for the “**True Product-by-Process Claim**”, the technical scope of the invention is construed “not to be limited to the recited production process, but to cover products that are identical to the product produced by the recited process”. On the other hand, for the “**Pseudo Product-by-Process Claim**”, the technical scope of the invention is construed to be limited to “products that are produced by the production process recited in the claim”.

Further, from the viewpoint of distribution of burden of proof in the patent infringement litigation, when a production process is recited in a product claim, the recitation is in principle construed as it is. Therefore, a party who asserts that the claim is a “**True Product-by-Process Claim**” should have a burden to prove that “it is impossible or difficult to directly specify the product by its structure or properties at the time of

the filing of the subject application”. If such a party fails to prove it, the subject claim would be treated as a “**Pseudo Product-by-Process Claim**” and be construed and determined to have the meaning as recited in the claim.

(2) For claim 1 of the subject patent, since there is no “reason that makes it impossible or difficult to directly specify the product by its structure or properties at the time of the filing of the subject application”, it has to be regarded as a “**Pseudo Product-by-Process Claim**” as above and thus limited to the product that meets the production process elements.

(3) The defendant’s production process does not meet step a) of the production process in claim 1.

For the above reasons, it is found that the defendant’s product does not fall under the technical scope of claim 1.

2. Whether the Subject Patent is Recognized as One that Should be Invalidated by a Trial for Patent Invalidation

As found in Section 1 above, the defendant’s product does not fall under the technical scope of claim 1. However, the court will voluntarily decide on whether the defendant’s defense that the subject patent is ‘the one that should be invalidated by a trial for patent invalidation’ should be granted.

(1) Finding of the Substance of Invention

Article 104^{tris} of the Patent Act stipulates, “Where, in litigation concerning the infringement of a patent right or an exclusive license, the said patent is recognized as one that should be invalidated by a trial for patent invalidation, the rights of the patentee or exclusive licensee may not be exercised against the adverse party.”. Upon determining whether the defense of Article 104^{tris} should be granted or not, the substance of the invention should be found by the court, in the same manner as the Japan Patent Office (a Trial Examiner Panel) finds the specific content of a claim.

In the case of a Product-by-Process Claim where a ‘production process’ is recited in a ‘product claim’, in order to find the substance of an invention,

(i) When there are reasons that make it impossible or difficult to directly specify the constitution of the subject product by its structure or properties and not by its production process at the time of the filing of the subject application, the substance of the invention should not be limited to the production process but should cover ‘the product’ in general (**True Product-by-Process Claim**), but

(ii) When there are no such reasons, the substance of the invention should be found to be limited to the product that is produced by the recited production process (**Pseudo Product-by-Process Claim**).

From the above standpoint, for the present patent, since no reasons were found that make it impossible or difficult to directly specify the constitution of the subject product by its structure or properties and not by its production process. It is thus understood that the substance of the invention is to be found as the product

produced by the recited production process in a trial for patent invalidation. The same should apply to the decision on the Article 104^{tris} defense.

(2) The invention of claim 1 is found to have been readily thought of from the invention of the defendant's Exhibit 30, Exhibit 1 Prior Art, and the common technical knowledge and is found not in compliance with Article 29 (2) [Inventive Step]. The subject patent therefore is found to be "one that should be invalidated by a trial for patent invalidation".

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