

JAPAN

Supreme Court gives new ruling on product-by-process claims

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The Supreme Court has given a new and unique ruling on the interpretation of product-by-process (PBP) claims.

Teva Pharmaceutical Industries Ltd owns a patent with a PBP claim for “Pravastatin sodium substantially free of pravastatin lactone and epi-pravastatin, and compositions containing the same”. Teva asserted that the medicinal products manufactured and sold by Kyowa Hakko Kirin Co, Ltd infringed its patent right and sought an injunction on the manufacturing and selling such products and the disposal of such products in stock.

In a judgment of March 31 2010, the Tokyo District Court held that, unless there were special circumstances, the technical scope of PBP claims should be limited to the products manufactured by the process of manufacture stated in the claim. The Tokyo District Court concluded that here there were no special circumstances and dismissed Teva’s claims because Kyowa’s medicinal products did not use the process of manufacture claimed in Teva’s patent.

In a judgment of January 27 2012, the Grand Panel of the IP High Court stated that PBP claims fell into two types: claims in which a product was specified by means of a process to manufacture the product because there were circumstances where it was impossible or difficult to directly specify the product by means of the structure or feature of the product at the time of filing an application (“circumstances to be impossible or difficult”), and claims in which a process to manufacture the product was stated in addition to a product although there were no circumstances to be impossible or difficult. We will call the former “genuine PBP claims” and the latter “quasi PBP claims”.

The IP High Court held that in principle PBP claims will be interpreted as the quasi PBP claims being limited to products manufactured through the manufacturing process stated in the claims (the “manufacturing process limitation theory”) in the determination of both the technical scope of the invention and the gist of the invention. However as far as there were circumstances to be impossible or difficult it will be interpreted as the genuine PBP claims not being limited to products manufactured through the manufacturing process stated in the claims but also covering any products that are identical to the products manufactured through said process (the “product identity theory”).

The IP High Court concluded that here there were no circumstances to be impossible or difficult and dismissed Teva’s claims because Kyowa’s medicinal products did not use the process of manufacture claimed in Teva’s patent and the patented invention lacked inventive step.

In a judgment of August 9 2012 in which Teva filed a suit against Tori Co, Ltd based on the above-mentioned patent infringement, the IP High Court held the same as the judgment of January 27 2012 for the determination of the gist of the invention.

Supreme Court

In its judgment of June 5 2015, the Supreme Court reversed the two IP High Court judgments and remanded the cases to the IP High Court. Of the nine Grand Panel judgments in the IP High Court since it was established in 2005, this was the first to be reversed by the Supreme Court.

First, the Supreme Court held that for an invention of a product, even if a process to manufacture the product is stated in the claims, the technical scope of the invention and the gist of the invention should be determined and recognised as covering products that are identical in structure and feature to the products manufactured through the process described in a patent. The Supreme Court adopted the product identity theory.

Second, on the premise that the claims should be described clearly (Patent Act

Article 36 (6) (ii)), the Supreme Court stated that if a process to manufacture the product is stated in the claims for an invention of a product it is usually unclear which kinds of structure or feature of the product would be expressed by the process to manufacture the product. Whether the determination of the technical scope of the invention and the gist of the invention would be interpreted as being limited to the products manufactured through the manufacturing process stated in the claims is also unclear. Therefore it is inappropriate, as readers of the claims cannot understand the contents of the invention clearly and it makes it harder to foresee the scope of the patentee’s monopoly right.

Further, the Supreme Court stated that in light of it being technically impossible to analyse the structure or feature of the product at the time of filing an application, depending on the specific contents or characteristics of the product, or in light of it being necessary to file an application immediately due to the nature of a patent application, it might be impractical to require an applicant to specify the product if it involved excessive time and money. It is not appropriate to never allow an applicant to state the process to manufacture the product in the claims.

Therefore, the Supreme Court held that if a process to manufacture the product is stated in the claims for an invention of a product, the description of the claims might satisfy the clarity requirement only when there were circumstances where it was impossible or entirely impractical to directly specify the product by means of the structure or feature of the product at the time of filing an application.

Thus, the Supreme Court reversed the two IP High Court judgments and remanded the cases to the IP High Court to further review as to whether the description of the claims satisfies the clarity requirement.

This judgment was unanimous. Justice Chiba filed a concurring opinion and Justice Yamamoto filed the opinion.

Practical tips

On July 6, the JPO announced that they will proceed the examination and trial in

accordance with the Supreme Court judgment. This new practice will apply not only to the future examination and trial but also to the current one as well. The JPO started to revise its examination guidelines and manual entirely which includes the one for PBP claims. The JPO will start the new practice based on the revised examination guidelines and manual from early October.

According to the Supreme Court's interpretation, it looks like a patentee with PBP claims may enjoy advantages as the product identity theory was adopted in the determination of the technical scope of the invention. However as the same theory was adopted in the determination of the gist of the invention, the PBP claims easily overlap with the cited prior art documents and the possibility of invalidation will be higher.

According to Justice Chiba, the reason the majority opinion adopted the product identity theory in the determination of both the gist of the invention and the technical scope of the invention was that the invalidity defence was allowed to be asserted in the infringement lawsuit due to the 2004 Patent Act amendment and both determinations came to be examined through an identical legal procedure, the interpretation and treatment of PBP claims in both stages should be dealt with uniformly. Therefore, Japanese practice will differ from that in the US where the product identity theory is adopted for the determination of the gist of the invention and the manufacturing process limitation theory is adopted for the determination of the technical scope of the invention. Foreign companies should pay special attention to the application and enforcement in Japan.

The majority opinion held that PBP claims will be exceptionally allowed when there were circumstances where it was impossible or entirely impractical to directly specify the product ("impossible" or "entirely impractical"). According to Justice Chiba, "impossible" means that it is impossible for a person skilled in the art primarily from the technical point of view to directly specify the product by means of analysing the structure or feature of the product at the time of filing an application, and "entirely impractical" means that it is entirely impractical for a person skilled in the art to directly iden-

tify the product not because of the technical difficulty but because of the waste of time and money and that it is too cruel for an applicant to be required to directly identify the product when facing the rapid progress of the technology and drastic competition in the global patent application. The meaning of "entirely impractical" in particular is not clear, and should be clarified by the future judgments.

Patents with PBP claims had been granted relatively easily in the past. However from now on they will be rejected if an applicant fails to prove "impossible" or "entirely impractical". Justice Yamamoto expressed his anxiety that most of the patents with PBP claims may be rejected due to violation of the clarity requirement. Justice Chiba stated that if applicants wanted to avoid this situation, they should also file an application as to the invention of a process for producing a product. This Supreme Court judgment could be deemed as a death sentence to PBP claims.

From now on, an invalidation or defence against patents with PBP claims, which were granted relatively easily in the past, may occur frequently. Justice Chiba stated that invalidation is inevitable if the patentee fails to prove "impossible" or "entirely impractical" at the time of filing an application. Should the patentee wish to avoid this situation they should utilise correction of the claims. On the other hand, Justice Yamamoto stated that as applicants could not recognise the "impossible" or "entirely impractical" criterion at the time the patent was granted, such circumstance should be carefully considered in the relevant lawsuits.

Which opinion the courts and JPO will adopt in future invalidity actions or defences against patents with PBP claims should be watched closely.