JAPAN

# Right of prior use for pharmaceutical patents denied

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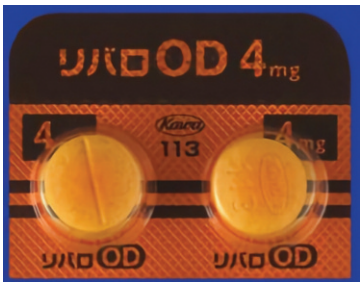
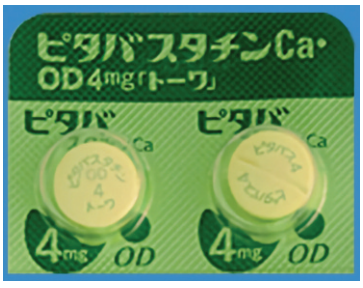
After the expiration of the product patent of therapeutic agent for hypercholesterolemia "LIVALO" (pitavastatin Ca), many generic drugs entered the market. Nissan Chemical and Kowa filed infringement lawsuits against generic drug manufacturers, based on a patent for a crystal form and a trade mark right, respectively, however both were unsuccessful. This case is about an infringement lawsuit filed thereafter based on a formulation patent, which was successful.




## Summary of the case

The plaintiff Kowa owns a patent for an invention titled "Medicine". The defendant Towa Pharmaceutical manufactures, sells and offers to sell pharmaceutical products called "PITAVASTATIN CALCIUM OD TABLETS 4 mg "TOWA" ("defendant's product"). Kowa sought an injunction against the defendant's manufacturing, selling and offering for sale of the defendant's products. Towa, admitting that the defendant's products fall within the technical scope of the patented invention, argued that it holds a right of prior use.

## Judgement of September 29 2017, Tokyo District Court

The Tokyo District Court (Presiding Judge Shimasue) denied the establishment of the right of prior use and granted Kowa's claim, holding as follows.

### 1) Establishment of the right of prior use

The defendant argued that, as the evidence supporting the establishment of the right of prior use, the clinical trial was conducted by the filing date of the patent (August 8, 2012), which is necessary for a marketing application for "PITAVASTATIN CALCIUM OD TABLETS 2mg "TOWA"" by manufacturing sample drugs of 2 mg tablets and for the defendant's product by manufacturing sample drugs of 4 mg tablets.

However, it is difficult to recognise that the invention which has the same content as the patented invention had been made inside the defendant's office without knowing the content of the patented invention by the filing date. Even apart from the above, it cannot be recognised that the contents of 2 mg products and the defendant's products (4 mg products) were clearly determined by the filing date so as to satisfy element E of the claim. Thus, regarding the business utilising the patented invention, since it is not recognised that the defendant had an intention to immediately implement the business, and such an intention had been expressed in a manner and to an extent which is objectively recognisable, the right of prior use is not established.

### 2) Whether the invention which has the same content as the patented invention had been made inside the defendant's office

On the premise that 2 mg products and the defendant's products (4 mg products) fall within the technical scope of the patented invention, the defendant argued as follows: the sample drugs of 2 mg tablets were manufactured by the same prescription and the same process as the actual products of 2 mg tablets, and the sample drugs of 4 mg tablets were manufactured by the same prescription and the same process as the defendant's tablets (actual products of 4 mg tablets), thus each of the sample drugs of 2 mg tablets and the sample drugs of 4 mg tablets satisfy element E of the claim.

However, it is difficult to recognise that the actual products and the sample drugs were manufactured by the same process from the evidence the defendant submitted. The issue here is whether "the water content" of "tablet" constituting "pharmaceutical product packaged in PTP package" was controlled so as to fall within the range of 1.5 to 2.9 mass % . However, as water is not an active ingredient or positive additive, and it is not dealt as impurities, information is insufficient even considering all of the defendant's evidence to specify the identity of the process from the perspective of what value the water content of the tablet takes in a state the tablet is packaged in PTP package after the tablet was manufactured.

The defendant argued that water content of the sample drugs of 2 mg tablets and the sample drugs of 4 mg tablets fall within the numerical range of element E of the claim, and submitted experimental report.

However, the values of water content of the sample drugs of 2 mg tablets and the sample drugs of 4 mg tablets presented on the experimental report were measured more than four years after the date when these tablets were allegedly manufactured. According to the defendant and the experimental report, after manufactured, these tablets were packaged in PTP packages and aluminum pillow packages, then stored in that state in a specimen storage warehouse of the central research institute of the defendant at the temperature of 20°C and at a humidity without artificial control, and one tablet of specimen was taken out from the PTP package, crushed in a mortar, then water content was measured by Karl Fischer Method. However, there is no evidence which directly supports that the water content of the tablet can be sustained even after four years under above condition.

### 3) Whether the contents of 2 mg products and 4 mg products (defendant's products) were clearly

**determined**

Even if the water contents of the sample drugs of 2 mg tablets and the sample drugs of 4 mg tablets fall within the numerical range of the element E of the claim at the time of its manufacturing, it cannot be immediately recognized that the contents of 2 mg products and 4 mg products (defendant's products) were clearly determined.

Even if the ingredient and the process themselves are similar, the water content of the tablets which are packaged in PTP packages may differ depending on the condition whether each value of water content of granule A and granule B is near an upper limit or a lower limit in a management range, and how the granules and the tablets mixed and tableted are stored until they are packaged in PTP packages. Thus, even if the sample drug of specific lot number satisfies element E of the claim, it is not clear what water content the tablets of other lot number have, and whether element E is satisfied.

## Practical tips

Prior use is difficult to prove. It is extremely difficult to predict in advance for what inventions with parameters other companies will obtain patents. Moreover, if there is a possibility that the property concerning parameters of the patent (in this case, the water content) alters with the lapse of time, measure the sample existed at the filing date after the patentee alleged infringement may be too late.

It seems that the alleged infringers arguing the right of prior use have no choice but to take the following actions: at the time when the sample drugs were completed, obtain measurement data regarding parameters which are often to be targets of patents of parameters in pharmaceutical products, and check frequently the state of the related patents and in case the related patents are the patents including parameters, immediately measure the sample drugs to obtain the data. In both cases, according to this judgment, it will be necessary to measure all of the samples.

On the other hand, it will be effective for a patentee to use patents with parameters which easily alter with the lapse of time in order to avoid the right of prior use.