

JAPAN

PITAVA trade mark infringement denied

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PITAVA

Source : Trade mark No. 4942833



Defendant's products

Source : Exhibit attached to November 28 2014 Tokyo District Court judgment

On September 22 2005, the Ministry of Health, Labour and Welfare (MHLW) notified that the drug name for the generic drug newly sought approval shall be generic name to prevent medical accident caused by drug mix-up. Facing a strong demand from medical practitioners, on December 27 2011, the Japan Generic Medicines Association requested members to also change the drug name from brand name to generic name for the generic drug already approved before the above MHLW's notice. Under such circumstances, whether the trade mark owner can register the portion of the generic name and exclude others' use became an issue.

Summary of the cases

Nissan Chemical creates and manufactures the active pharmaceutical ingredients of therapeutic agent for hypercholesterolemia pitavastatin calcium. Kowa performs their global marketing. Kowa has the trade mark right specifying the designated goods as drug and the registered trade mark as PITAVA.

Nissan Chemical has the patent right for pitavastatin calcium salt and its preservation method.

Many pharmaceutical companies manufacture and sell generic drugs including pitavastatin calcium as active ingredient. The PTP sheet packaging and the tablet itself had PITAVA on them. Kowa sued Meiji Seika, Sawai, Nipro, Kobayashi Kako, Towa, Kyowa, and Teva seeking an injunction on the ground of trade mark infringement. Nissan Chemical sued Daito and Mochida on the ground of patent infringement.

Among the brand name pharmaceutical company's Life Cycle Management (LCM) strategy using patent right and trade mark right, this case is about the one using trade mark right.

Judgments of Tokyo District Court

The Tokyo District Court dismissed all seven trade mark infringement lawsuits filed by Kowa: (1) judgment of August 28 2014, (2) judgment of October 30 2014, (3) judgment of October 30 2014, (4) judgment of November 28 2014, (5) judgment of November 28 2014, (6) judgment of April 27 2015, and (7) judgment of April 27 2015. These judgments came to the same conclusion with different reasoning as follows.

Judgment (1) (Presiding Judge Takano) and judgments (4) and (5) (Presiding Judge Shoji)

These courts stated that the mark PITAVA attached to the defendant's products was described as the abbreviated name on the surface of the tablet in order to call attention to pitavastatin calcium included in the products as active ingredient for the purpose of preventing medical accidents such as dispensing error and an accidental ingestion by patients caused by similarity of drug name. The courts further stated that medical practitioners such as doctors and pharmacists and patients as principal traders or consumers recognise PITAVA as such description. Therefore, these courts held that the mark attached to the defendant's products is not deemed to be used in per-

forming a function capable of distinguishing its goods and services from those of others and does not correspond to the "use" of the trade mark.

Judgments (6) and (7) (Presiding Judge Shimasue)

These courts stated that the portion of defendant's product name regarding the active ingredient, the dosage form, and the contained amount of the active ingredient is attached in order to show the nature of the generic drug according to the notices of MHLW and Japan Generic Medicines Association, and consumers recognise the portion as such. Therefore, the court held that the portion does not have a function capable of distinguishing its goods and services from those of others and correspond to the "use" of the trade mark.

In addition, these courts stated that it was assumed that the trade mark registration was done with an unfair purpose to prevent the third party other than Kowa's licensee from entering the generic drug market after the patent term expired, and that allowing Kowa to monopolize this trade mark's usage will unjustifiably restrict the method to avoid the drug mix-up and the public interest will be lost. Therefore, the court held that this trade mark right should be invalidated.

Furthermore, these courts made an additional remark that the method for the brand name pharmaceutical companies to prevent generic drug manufactures from entering the market should be the exercise of the patent right, and it is not allowed from the public interest point of view to assert trade mark infringement against the PITAVA mark which was attached to avoid drug mix-up.

Judgments (2) and (3) (Presiding Judge Hasegawa)

These courts recognised the similarity between the trade mark and defendant products' mark PITAVA. The courts further stated that attaching the trade mark to the designated goods not including pitavastatin calcium causes confusion among medical practitioners that the goods include pitavastatin calcium, thus the trade mark corresponds to the one to

mislead as to the quality of the goods and should be invalid. In judgment (2), the court held that the trade mark should be rescinded by trial for rescission of trade mark registration due to the unused trade mark, and thus seeking injunction will be deemed as an abuse of right.

Judgments of IP High Court

The IP High Courts dismissed the appeal on the ground that the use of appellee's mark (defendant's mark) does not have a function distinguishing its goods and services from those of others; judgment of June 8 2015 (Presiding Judge Tsuruoka), second instance of judgment (3), judgment of July 16 2015 (Presiding Judge Tomita), second instance of judgment (1), judgment of July 23 2015 (Presiding Judge Shimizu), second instance of judgment (5), and judgment of August 27 2015 (Presiding Judge Tomita), second instance of judgment (2) and judgment of September 9 2015 (Presiding Judge Shitara), second instance of judgment (4).

It is remarkable that in the judgment of July 16 2015 and the judgment of August 27 2015 the IP High Court held that the Article 26 (1) (vi) provided by 2014 Trade Mark Act amendment shall be applied in this case and the appellee's mark (defendant's mark) corresponds to "the trade mark which is not used in the method by which consumers are able to recognize the goods as those pertaining to business of a particular person".

Practical tips

Non-infringement of the PITAVA trade mark right may be concluded with various reasons and the judges' opinions regarding which reason is most persuasive seem to be divided. However, in all of the judgments the non-infringement conclusion is firm. It seems it is because the judges weigh the public interest to avoid medical accident. When intellectual property and medical safety intertwine, medical safety governs.

Therefore, according to the above judgments, the risk for generic drug manufacturers to be deemed as infringing a trade mark right using the portion of generic name is quite low. For the brand name

pharmaceutical companies, the primary method to prevent generic drug manufacturers from entering the market is the exercise of the patent right, as Presiding Judge Shimasue pointed out. In addition, the registration of the design or the trade mark regarding PTP packaging or packaging design should be considered.