

## JAPAN

## Supreme Court affirms DOE for Maxacalcitol's manufacturing process patent

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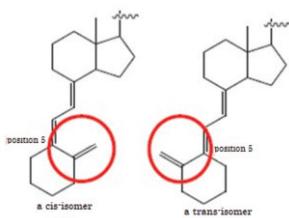
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After its product patent had expired, the brand name pharmaceutical company sued generic drug manufacturers based on a manufacturing process patent. On March 24 2017, the Supreme Court affirmed infringement under the doctrine of equivalents (DOE) for the medicinal compound's manufacturing process patent.

### Summary of the case

The appellee in the final appeal, Chugai Pharmaceutical, jointly owns a patent for a manufacturing process of compounds including maxacalcitol. Chugai manufactures and sells Oxarol ointment, a therapeutic agent of keratosis, whose active ingredient is maxacalcitol. Chugai had owned a product patent regarding maxacalcitol. This patent expired on December 26 2010 after the patent term was extended.

The appellant in the final appeal, Iwaki Seiyaku etc, sold generic Oxarol ointments and the other appellant, DKSH Japan, had imported the active ingredients of the generic product from Cerbios Pharma and sold it. Chugai sought an injunction against the appellants' importation and assignment claiming that their manufacturing process of maxacalcitol preparations and their active pharmaceutical ingredient was equivalent to the patented process. The appellants' process did not literally satisfy the claim elements because the structure of a starting material and an intermediate of the patented process is cis-isomer whereas the appellants' process was trans-isomer. The main issue was DOE.



### Judgment of Tokyo District Court

On December 24 2014, the Tokyo District Court (Presiding Judge Shimasue) affirmed satisfaction of five requirements of the ball spline case (judgment of February 24 1998, Supreme Court) and held that the appellants' process is equivalent to the Chugai invention. In February 2015, the Court granted a preliminary injunction.

### Judgment of Grand Panel of the IP High Court

On March 25 2016, the Grand Panel of the IP High Court (Presiding Judge Shitara) affirmed infringement under the DOE: even if there is another structure that is outside the claims, and the applicant could have easily conceived of this other structure as of the filing date, this fact alone cannot serve as a reason that "special circumstances" in the fifth requirement of DOE, estoppel, exists.

However, if the applicant is objectively and externally regarded as having recognised another structure that is outside the claims as a replacement for a different part in the structure stated in the claims as of the filing date (for example, where the applicant can be considered to have stated the invention based on this other structure in the description or where the applicant stated the invention based on another structure that is outside the claims in a paper, etc which he/she published as of the filing date), "special circumstances" in the fifth requirement of DOE exist.

### Supreme Court judgment

Even if there is a structure that is different to the opponent's product and is outside the claims, and the applicant could have easily conceived of the structure of the opponent's product as of the filing date,

this fact alone cannot serve as a reason that there are special circumstances that the opponent's product was intentionally excluded from the claim during the prosecution.

However, even in such a case, if the applicant is objectively and externally regarded as expressing that he/she intentionally did not state the structure of the opponent's product in the claims, recognising the structure of the opponent's product could be a replacement for the structure stated in the claims, for example when the applicant stated in the description etc that a structure in the claims that is different from the opponent's product could be replaced to the structure of the opponent's product as of the filing date, the applicant can be regarded as admitting that the opponent's product does not fall under the technical scope of the patented invention. This is because third parties who were disclosed the description will understand that the opponent's product was excluded from the claim. In addition, it is reasonable to recognise that "special circumstances" exist in such a case because this interpretation meets the purpose of the Patent Act: through promoting the protection and the utilisation of inventions, encourage inventions and thereby contribute to the development of industry, and adjust the interests of the applicant and third parties appropriately.

Therefore, even if there is a structure that is different from the opponent's product and is outside the claims, and the applicant could have easily conceived of the structure of the opponent's product as of the filing date, if the applicant is objectively and externally regarded as expressing that he/she intentionally did not state the structure of the opponent's product in the claims, recognising the structure of the opponent's product could be a replacement for the structure stated in the claims, "special circumstances" exist that the opponent's product was intentionally excluded from the claim during the prosecution.

Here, the special circumstances do not exist.

### Practical tips

Prior judgements have been split as to

whether DOE is applicable to equivalent materials and arts that already existed at the time of the filing of patent applications. This judgment denied that equivalent materials and arts easily conceived at the time of the filing of patent applications alone result in estoppel. It has ended a long debate.

While the IP High Court clearly listed the examples where the applicant states technical factors in the description or papers as the case where the applicant is objectively and externally regarded as having recognised another structure that is outside the claims as a replacement for a different part in the structure stated in the claims as of the filing date, the Supreme Court avoided referring to such a concrete example. In addition, the Supreme Court held as follows and used the term "intentionally": "If the applicant is objectively and externally regarded as expressing that he/she intentionally did not state the structure of the opponent's product in the claims, recognising the structure of the opponent's product could be a replacement for the structure stated in the claims." This means that the Supreme Court is more cautious in affirming the fifth requirement of DOE than the IP High Court.

The Supreme Court judgment was rendered just one year after the IP High Court judgment which is extremely quick. It could be evaluated that the Supreme Court emphasised the rapidity in the patent lawsuit, a business lawsuit.