Doctrine of equivalents in Japan: criteria of special conditions and estoppel

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- DKSH Japan KK, Iwaki Seiyaku Co Ltd, Takata Pharmaceutical Co Ltd, and POLA-Pharma, versus Chugai Pharmaceutical Co Ltd and The Trustees of Columbia University in the City of New York, decision by the Intellectual Property High Court of Japan (Heisei 27 [ne] 10014) dated 25 March 2016 [1].
- DKSH Japan KK, Iwaki Seiyaku Co Ltd, Takata Pharmaceutical Co Ltd, and POLA-Pharma, versus Chugai Pharmaceutical Co Ltd Grand Panel decision by the Intellectual Property High Court of Japan (Heisei 27 [gyo-ke] 10014) dated 25 March 2016 [2].

The Grand Panel of the Intellectual Property High Court of Japan (IPCH-J) accepted the argument made by Chugai (the patentee), a subsidiary of F Hoffmann-La Roche AG, that the four generic drug makers including DKSH Japan K.K. infringed their patent (Japanese patent no. 3310301) directed to a vitamin D derivative by applying the Doctrine of Equivalence (DoE). The pharmaceutical product in suit is a maxacalcitol formulation, and a patent covering the active ingredient has already expired in 2010, but the subject patent in suit still in force that covers a manufacture process thereof. The claims of the patent in suit recite the use of *cis*-type vitamin D structure as a starting material and an intermediate thereof, whereas the four generic drug makers have used the

corresponding *trans*-type structure, and have argued that their act does not fall within the scope of the patented claims. However, Chugai argued that the difference in *cis*- and *trans*-structure is inessential to the invention and, thus, the manufacture process used by the four generic makers infringes the patent in suit by means of the DoE. The IPCH-J held that whether or not the DoE is applicable should be decided based on whether the accused product satisfies the patent elements, which constitutes the essential part of the invention, and if so the DoE shall be applied, and that even if there is any difference in the other parts, in other words, inessential parts, this does not negate the satisfaction of the claim elements. Furthermore, the IPCH-J analyzed the patent and stated that the patented invention contributed to the art by providing a novel manufacture route, particularly in terms of introducing side chains of maxacalcitol at the 20-alcohol position by a single step and, thus, the difference in isomerism, in other words, *trans*- or *cis*-structure, is not relevant to the essential part of the claims. In addition to inessential part, the first criteria of the five stipulated in the Japanese Supreme Court's precedent, the IPCH-J further gave judgments favorable to the patentee regarding the other criteria of the DoE including possibility of interchangeability, ease of interchangeability, nonprior art and special circumstances and estoppel. With respect to estoppel, the Court further

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analyzed in detail and held that even if there were other embodiments different from but obvious from the literal interpretation of the claims, which is substantially the same as the claims, and the applicant could have arrived at that embodiments, that circumstances alone are not sufficient to recognize that there was a special circumstance and estoppel to negate the fulfillment of the DoE. Furthermore, in order to negate the fulfillment, it would be required to show the circumstances where the applicant/patentee has recognized the alternative embodiments that are outside the scope of the claims in an objective and external manner, for example, the applicant has described the particular alternative embodiments in the patent specification or in the published academic journal published around the time of filing of the patent, etc. In the subject case, the defendants (four generic drug makers) fail to show that the patent specification or any other published articles describe such an alternative, in other words, the *trans*-type structure. The IPHC-J also held that the patent remains valid in the decision issued on the same date. The decision regarding the infringement was issued by the Grand Panel of IPCH-J, which is similar to en banc system in USA, where all the four departments are involved and the judgment are deemed to be the position of the entire IPHC-J.

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No writing assistance was utilized in the production of this manuscript.

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