Doctrine of equivalents: Grand Panel / Supreme Court decision- new rulings for the first and fifth requirements of the doctrine of equivalents, for the first time in the pharmaceutical field

1. Points of this decision

Infringement of a patent under the doctrine of equivalents was recognized for the first time in the pharmaceutical field (The Maxacalcitol Case, judgment of of the IP High Court Grand Panel March 25, 2016, 2015 (Ne) 10014, original judgment Tokyo District Court 2013 (Wa) 4040), Supreme Court (Supreme Court Second Petty Bench March 24, 2017, 2016 (Ju) 1242).

The court found that, in regard to the first requirement of the doctrine of equivalents (the difference should be non-essential part), the scope of equivalents can be either widened or narrowed in accordance with the degree of contribution of the patented invention compared with prior art, and also that the scope in which equivalent infringement is established becomes narrower when description of problems are insufficient, taking prior art that are not mentioned in the specification into consideration. With respect to the fifth requirement of the doctrine of equivalents, the court negated the situation, as "special circumstances" that constitute reasons to negate equivalent infringement, in which equivalent allegation is not allowed only because a feature which could have been easily conceived at the time of the filing was not written in the claims (the Supreme Court made a decision only on the fifth requirement, approving the Grand Panel judgment in general).

Since the description of problems affects the scope of equivalents, this decision will likely have influence on the future practice of equivalent infringement not only in the pharmaceutical field but also in every technical field.

2. Outline of the case

The patentee who holds the patent for an invention titled "intermediates for the synthesis of vitamin D and steroid derivatives and method for manufacturing thereof" (hereinafter, the "Patent") alleged that the method of manufacturing (the "Defendants' Method") of the maxacalcitol end products, etc. (the "Defendants' Products") sold by the defendants who sells maxacalcitol raw substance and its

end products, etc., which are used to remedy keratosis, is equivalent to the Corrected Invention and that the Defendants' Products infringes on the Patent. Based on this allegation, the patentee filed this lawsuit against the defendants to seek an injunction against the import, sales, etc. of the Defendants' Products and disposal thereof.

The difference between the Corrected Invention and the Defendants' Method is that the Corrected Invention uses a cis-form vitamin D structure as a starting material for producing the objective substance, whereas the Defendants' Method uses its geometric isomer, i.e. a trans-form vitamin D structure. The Defendants' Method fulfills the rest of the constituent features of the Corrected Invention.

In relation to the doctrine of equivalents, the five requirements for applying the doctrine of equivalents are indicated in the judgment of the Supreme Court in 1998 ("ball spline bearing case"). In the present case, the parties disputed whether the Defendants' Products infringes under the doctrine of equivalents especially in relation to the first and the fifth requirements or not.

3. Summary of the judgment (excerpts)

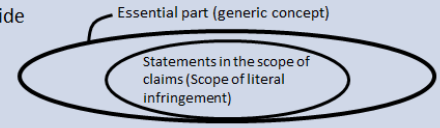
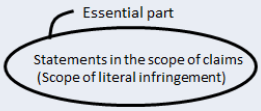
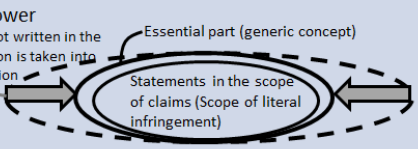
(1) The first requirement of the doctrine of equivalents (non-essential part)

The first requirement of the doctrine of equivalents in the Supreme Court judgment on the "ball spline bearing case" is that even if the structure stated in the scope of claims contains any part that is different from that of the product manufactured, or the like, by the other party or the method used thereby, said part should not be the essential part of the patented invention.

The court stated that "... the essential part of a patented invention means a characteristic part constituting a unique technical concept that did not exist in prior art, among the description of patented claims of the said patented invention", and that "the aforementioned essential part should be found by first understanding the problem to be solved and means for solving the problem of the patented invention ... and its effects ... based on the statements in the scope of claims and the specification and then determining the characteristic part that constitutes a unique technical concept that did not exist in prior art in the statements among the description of patented claims of the patented invention. That is, since the substantial value of a patented invention is defined in

accordance with the degree of contribution compared with prior art in the relevant technical field, the essential part of a patented invention should be found based on the wording of the claims and the specification, and particularly on comparison with prior art mentioned in the specification".

In addition to above, the court indicated a following three-pattern judgment technique.

Pattern	Typical Case	Judgment Technique	Scope of Infringement under the Doctrine of Equivalents
(i) A case in which the degree of contribution of the patented invention is considered to be large on comparison with prior art	Basic Patent	Part of the statements in the scope of claims is found as a generic concept.	◎ Wide 
(ii) A case in which the degree of contribution of the patented invention is considered to be not so large on comparison with prior art	Improvement Invention	The patented invention is found to have almost the same meaning as stated in the scope of claims	× Narrow 
(iii) A case in which the statement of the problem, which is described as one that prior art could not solve, in the specification is objectively insufficient in light of prior art as of the filing date	Foreign application in Japan	A characteristic part which constitutes a unique technical concept of the patented invention that is not seen in prior art is recognized, taking even prior art that is not stated in the specification into consideration.	△Narrower  Essential part is closer to the statements in the scope of claims compared to the cases where it is found only based on the statements in the scope of claims (case (i) above), and the scope of equivalents is narrower.

(2) The fifth requirement of the doctrine of equivalents (special circumstances)

The court stated that "the technology which the patentee had once acknowledged not to belong to the technical scope of the patent claim, or in relation to which he/she had behaved as if he/she had objectively acknowledged so, e.g. by intentionally excluding the technology from the scope of patent claim in the prosecution of a patent application, the patentee is not entitled to claim otherwise afterwards, since this is against the doctrine of estoppel, and thus, if there are such special circumstances, the infringement under the doctrine of equivalents should be negated exceptionally (according to the judgment of the ball spline bearing case mentioned above)" and that the matter shown below in (A) alone does not constitute the reason to negate the infringement under the doctrine of equivalents since there are no special circumstances, whereas in the

case of (B) shown below, the infringement under the doctrine of equivalents should be negated as special circumstances exist.

<table>
<tr><th>Non-special circumstances (Fulfilling the 5th requirement)</th><th colspan="2">Special circumstances (Unfulfilling the 5th requirement → Equivalent infringement denied)</th></tr>
<tr><td rowspan="2">(A) There is another structure that is outside the scope of claims, which a person ordinarily skilled in the art can easily conceive of as of the filing date as one that is substantially identical with the structure stated in the scope of claims and the applicant could thus have also easily conceived of said another structure as of the filing date.</td><td rowspan="2">(B) Even in the case of (A), when the applicant is found to have objectively and externally recognized another structure that is outside the scope of claims as a substitute for a different part in the structure stated in the scope of claims as of the filing date</td><td>(B)(a) The applicant can be considered to have stated the invention based on said another structure in the specification.</td></tr>
<tr><td>(B)(b) The applicant stated the invention based on another structure that is outside the scope of claims in a paper or the like which he/she published as of the filing date.</td></tr>
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Although the above-mentioned special circumstances were approved in general in the Supreme Court (Supreme Court Second Petty Bench March 24, 2017, 2016 (Ju) 1242), the Supreme Court did not mention about the above example (B)(b).

4. Practical guidelines

Taking the pharmaceutical field for instance, a manufacturer of a new medical drug when filing an application should not only have broad claims but also state the claims so that it is possible to be clearly understood what is the technical concept of the prior art, problems to be solved, and means to solve the problems described in its specification, for it is essential not to be judged that the problems are insufficient when compared objectively with prior art as of the filing date. This is because, if they are judged insufficient, the above-mentioned pattern (iii) would be applied and prior art not mentioned in the specification would be taken into consideration so the scope in which the equivalents can be established might become narrower. As for an invention that can be seen as a pioneer patent that has a greater degree of contribution compared to prior art, it is preferable to state this point clearly, aiming for a broader scope of the infringement under the doctrine of equivalents as shown in the pattern (i) above.

On the other hand, manufactures selling latecomer generic medicines should

not merely check that the medicine does not literally infringe the earlier patent, but also, especially in relation to an invention that can be seen as a pioneer patent where an insignificant substitution may lead to constitute the infringement under the doctrine of equivalents, it may be necessary to consider narrowing the scope in which the infringement under the doctrine of equivalents is applied by researching prior art which are not written in the specification, or, in some cases, it may be necessary to research papers and the like that the patentee presented at the time of filling and to consider the possibility that the fifth requirement of the doctrine of equivalents is unfulfilled.

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