### **Articles**

# The Intellectual Property High Court Grand Panel Decision on the Requirements for Infringement under the Doctrine of Equivalents

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Present Case: Case No. 2015 (Ne) 10014 Appeal of Case Seeking Injunction against Patent Infringement (Appealed from the Tokyo District Court (Case No. 2013 (Wa) 4040))

[Appellants/Defendants] DKSH Japan K.K., Pola Pharma Inc., Iwaki Seiyaku Co., Ltd. and Takata Seiyaku Co., Ltd.

[Appellee/Plaintiff] Chugai Pharmaceutical Co., Ltd.

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#### 1. Introduction

In the past, there have been various discussions and interpretations concerning the doctrine of equivalents in Japan. On February 24, 1998, the Supreme Court rendered a decision that explicitly recognized the possibility of finding infringement under the doctrine of equivalents and specifically set out five requirements for establishing equivalence (in the Ball Spline Bearing Case Decision). This resulted in a tentative solution. However,

these five requirements were not necessarily clear. Specifically, there have been conflicting theories regarding the interpretation of the first and fifth requirements, and their interpretation and application have not been particularly unified at the lower courts.

The decision in the present case (the "Decision") was rendered against such a backdrop. This case is an appeal of a decision in a patent infringement action concerning a process for the synthesis of

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vitamin D and its derivatives that can be used as a medicine. The Intellectual Property High Court (the "IP High Court") supported the finding of the court of prior instance of infringement under the doctrine of equivalents. This case has attracted attention as it is the first time a finding of infringement has been made under the doctrine of equivalents in the field of medicine, an area where there have been few such cases. It has also attracted great interest because the IP High Court handled the case as a Grand Panel case (despite the fact that it did not change the result) and presented detailed methods for determining the first and fifth requirements for establishing equivalence, as a general theory. In other words, this case was chosen to be examined as a Grand Panel case, not for the purpose of verifying the propriety of the decision in the prior instance, but for the purpose of indicating a uniform standard for the interpretation of the requirements for the establishment of equivalence to be used in the future.

As background of the Decision, this article will first describe the position of the IP High Court Grand Panel in past cases in Japan and the practice trends in cases relating to infringement under the doctrine of equivalents. Then we will introduce an outline of the Decision, focusing on the parts in which the court rendered a holding as a general theory. Finally, we will examine the effect, etc., of the Decision on future practice.

### 2. Background information relating to the Decision

### 2-1. The Grand Panel system at the IP High Court

In the past, appeals of decisions in

intellectual property right infringement actions and actions for the rescission of a Japan Patent Office ("JPO") decision have been handled mainly by the divisions at the Tokyo High Court specialized in intellectual property. However, the IP High Court was established on April 1, 2005, as a court specializing in intellectual property-related cases, for the purpose of further enriching and expediting court proceedings for such cases. The Grand Panel system was launched as a Special Division, which is based on a panel of five judges, one year before the establishment of the IP High Court for the purpose of handling only intellectual property-related cases relating to patent rights and other technology-related actions. At the IP High Court, ordinary cases are handled by any one of the First to Fourth Divisions and are in principle examined by a panel consisting of three judges, including the chief judge of the relevant division. On the other hand, the Grand Panel Division in principle consists of the chief judges of each of the four ordinary divisions (First to Fourth Divisions) of the IP High Court and one senior judge. A decision rendered by an ordinary division has no binding force on other divisions. Even within the same division, if the divisional chief judge has been replaced, a decision may be rendered based on a totally different standard. On the other hand, a decision rendered by the Grand Panel Division is regarded as a unified determination of the IP High Court as a whole, and is practically binding on subsequent determinations of the ordinary divisions. Therefore, Grand Panel decisions have a markedly greater as precedents than ordinary value division decisions, and naturally have a significant influence on subsequent intellectual property practice.

In relation to the Supreme Court, the Grand Panel Division is considered to be a division of a lower court and, as such. determinations by the Supreme Court override those of the Grand Panel Division on the same issue. However, under the new Code of Civil Procedure that came into force on January 1, 1998, a violation of a law or regulation that affects the conclusion has ceased to serve as a reason for filing an appeal, and whether to accept an appeal for such a reason is now left to the Supreme Court's discretion. As a result, cases that cover an important point at issue under the Japanese Patent Act (the "Patent Act") on which the Supreme Court will a substantial determination have become dramatically restricted. Therefore, the Grand Panel Division of the IP High Court can also be considered to play a role in making determinations that are final and are binding as precedents, on behalf of the Supreme Court, for patent-related cases that require specialized determinations (however, as also mentioned later, there are cases where the Supreme Court will reverse or modify a decision of the IP High Court Grand Panel).

The Grand Panel Division has handled 10 cases so far, including the present case, comprising seven civil cases concerning patent infringement and three cases for the rescission of a JPO decision. As one of those cases was withdrawn, this case is the ninth case on which the Grand Panel Division rendered a decision. Taking into account that the IP High Court renders over 100 decisions on patent-related cases every year, nine cases in the 12 years since the inception of the Grand Panel Division cannot be considered to be large. However, most of the

cases that have been handled by the Grand Panel Division have addressed issues that are important in terms of patent practice, such as exhaustion theory, interpretation of the scope of rights of a product-by-process claim, requirements for the acceptance of a disclaimer, determination standards for the support requirements, and requirements for the patent term extension of a medicine whose active ingredient is not novel and the scope of rights thereof. These Grand Panel decisions have attracted a great deal of attention (before the Decision, there had been no cases in which the IP High Court indicated specific determination standards while considering the doctrine of equivalents as a major issue).

Of those decisions, the Grand Panel decision on November 11, 2005, was rendered on a case relating to the issue of determination concerning the fulfillment of the support requirement in relation to a parameter invention. The Grand Panel indicated a general determination standard for the support requirement, and that determination standard is considered still to serve as a standard in patent practice.<sup>1</sup> In addition, in the Grand Panel decision of May 30, 2008, the Court set out the requirements for accepting a statement of a claim that excludes prior art that is not stated in the description. This decision plays an important role in the current examination and trial practice for patent applications.

On the other hand, there are the cases where an IP High Court Grand Panel decision has been reversed or modified by the Supreme Court. In particular, the Grand Panel decision of January 27, 2012, attracted considerable attention as the Court advocated a new theory whereby product-by-process claims are classified

into true product-by-process claims and untrue product-by-process claims based on the advisability or difficulty of identifying the product without being based on the process, and the scope of rights is interpreted based on respective standards. However, in the Supreme Court decision on the same case, which was rendered on June 5, 2015, the Court set a determination standard that the advisability or difficulty of identifying the product without being based on the process should be taken into account in relation to the clarity requirement while fundamentally being based on the product identity theory, and completely denied the theory adopted in the aforementioned Grand Panel decision. As a result, the Court reversed the decision of prior instance. Therefore, the standard adopted in this Supreme Court decision is now a standard for patent practice, and the aforementioned Grand Panel decision has come to have almost no significance in terms of practice. Moreover, in the Grand Panel decision of January 31, 2006, the Grand Panel advocated a detailed theory concerning the types of cases where a defense of exhaustion is accepted and the distribution of the burden of proof in such cases. However, as a determination that modified this theory was subsequently made in a Supreme Court decision (although the Supreme Court maintained the conclusion), the importance of said Grand Panel decision was significantly reduced.

In this manner, some of the IP High Court Grand Panel decisions become standards for subsequent patent practice while others are reversed or modified by the Supreme Court and come to have almost no significance in terms of practice. The present case is also currently pending at the Supreme Court, and there is a possibility that the Supreme Court will reverse the Grand Panel's determination and advocate a new theory. Therefore, it is necessary to pay close attention to future trends. However, the Decision is not one that advocates a new theory as in the aforementioned decision, and instead only sets out the standard for interpreting the requirements for equivalence that were previously presented by the Supreme Court. Therefore, many consider that the Decision is not likely to be significantly modified.

# 2-2. Idea of infringement under the doctrine of equivalents in Japan and relevant determination standards

Article 70, paragraph (1) of the Patent Act provides that, "The technical scope of a patented invention shall be determined based upon the statements in the scope of the claims attached to the application." There is no clear legal ground for the establishment or nonestablishment of the doctrine of equivalents. Therefore, in the past, some were of the opinion that the doctrine of equivalents should not be recognized in any case, but the standpoint that recognizing the doctrine of equivalents does not conflict with the aforementioned provisions of the Patent Act has become more prevalent. In fact, there are many lower court decisions in which the Court made a finding of infringement under the doctrine of equivalents on the premise that infringement under the doctrine of equivalents can be established. However, various determination standards were used in such cases.

Under these circumstances, in the Supreme Court decision of February 24, 1998 (the Ball Spline Bearing Case deci-

sion), the Court explicitly recognized the doctrine of equivalents and clearly indicated the relevant determination standards as follows<sup>2</sup> (requirements [i] to [v] mentioned below are referred to as the "first requirement" and so on in practice).

Even if, within the structure stated in the scope of the claims, there is a part that is different from a product manufactured, etc., or a process used by the other party (hereinafter referred to as the "subject product, etc."), it is reasonable to understand that the subject product, etc., falls under the technical scope of the patented invention as an equivalent to the structure stated in the scope of the claims if the following requirements are fulfilled:

[i] said part is not an essential part of the patented invention;

[ii] even if said part is replaced with a part in the subject product, etc., the purpose of the patented invention can be achieved and the same function and effect can be obtained;

[iii] a person ordinarily skilled in the art to which the invention pertains (a person ordinarily skilled in the art) could have easily conceived of the aforementioned replacement at the time of the manufacturing, etc. of the subject product, etc.:

[iv] the subject product, etc., is neither identical to art publicly known at the time of the filing of the patent application for the patented invention nor one that a person ordinarily skilled in the art could have easily conceived of at the time of said filing based on such publicly-known art; and

[v] there are no special circumstances, such as the fact that the subject product, etc., falls under inventions that were intentionally excluded from the scope of the claims in the patent application procedures for the patented invention (hereinafter requirements [i] to [v] above are referred to as the "First Requirement" to the "Fifth Requirement" in order of precedence).

As the Supreme Court of Japan often shows a negative attitude toward adopting a theory that does not have a ground that is explicitly stated in law, the Supreme Court was very innovative in recognizing the doctrine of equivalents and setting out all of the requirements for equivalence in the case. As a result, these standards have become standards in subsequent patent practice. Since then, lower courts have come to determine equivalence based on these five requirements. In this manner, the Ball Spline Bearing Case decision caused the debate over the doctrine of equivalents to reach a tentative solution. However, as described in more detail in the next section, there are some issues concerning the interpretation of the requirements for equivalence, and it cannot be said that lower courts have been putting the requirements into practice in a unified way.

## 2-3. Trends of court decisions after the Ball Spline Bearing Case decision and problems thereof

As mentioned above, lower courts have come to determine equivalence based on the aforementioned five requirements since the Ball Spline Bearing Case decision. There was a lower court decision holding that the patentee has the burden of allegation and proof for the first to third requirements, while the defendant has the burden of allegation and proof for the fourth and fifth requirements. <sup>3</sup> There

has been almost no dispute on this point in practice.

Regarding the first to third requirements that should be alleged and proven by the patentee, fulfillment of the requirements are usually determined in this order. If it is determined that the first requirement is not fulfilled (and, consequently, infringement under the doctrine of equivalents is not established), fulfillment of other requirements for equivalence is often not determined. Moreover, in fact, in about 70% of the court decisions that denied infringement under the doctrine of equivalents, the Court determined that the first requirement was not fulfilled. On the other hand, there has been no court decision in which the Court determined that the second or third requirement was not fulfilled although the first requirement was fulfilled.

During the period from its founding in 2005 until the Decision, there were 54 appeal cases in which the IP High Court made a decision on the fulfillment of requirements for equivalence. Statistical data on these cases is shown below for reference purposes.

- The establishment of equivalence was recognized in 6 cases.
- The establishment of equivalence was denied in 48 cases.

(The fulfillment of the first requirement was denied in 32 cases, the second in 15 cases, the third in 7 cases, the fourth in 4 cases, and the fifth in 17 cases.)

\* The number of requirements denied in total is not the same as the number of cases in which the establishment of equivalence was denied. This is because, in some cases, more than one requirement was found not to be fulfilled when making a decision on the establishment of equivalence.

In this manner, the first requirement plays a very important role in practice for the determination of infringement under the doctrine of equivalents, despite the fact that it is less common in the requirements for equivalence in other countries. Therefore, there is no doubt that the first requirement is a major cause of the peculiar nature of determinations concerning equivalence in Japan.<sup>4</sup> In fact, there is a background that in conventional court precedents and practice, establishment or non-establishment of infringement under the doctrine of equivalents has been determined mainly based on the second and third requirements, i.e. identity of function and effect or replaceability and obviousness or ease of replacement. 5 In other words, the Ball Spline Bearing Case decision can be evaluated as not only having set out the requirements for establishing equivalence but also as having substantially switched the major factor in the requirements for the establishment of equivalence and significantly converted conventional practice. In addition, as the first requirement concerns the question of whether the difference between the invention and the subject product is an "essential part of the patented invention," and is thus an abstract requirement that seems to assume the answer in advance, the conclusion can significantly differ depending on the manner of understanding the "essential part." However, the relevant determination standard has not been necessarily unified among lower court decisions after the Ball Spline Bearing Case decision, and it can be said that the first requirement has been frequently used as a shortcut method for denying infringement under the doctrine of equivalents for that reason

In this regard, determination standards for the second and third requirements are more specific, and there are no major issues as with the first requirement. However, the positioning of each requirement significantly differs depending on the order of in which determinations concerning these three requirements are made. That is, if determinations are made in numerical order, i.e. from the first to third requirements, as adopted in many court decisions, most of the elements to be determined in terms of the second and third requirements are substantially more likely to be determined in terms of the first requirement in advance, and the roles of the second and third requirements must be limited. On the other hand, if determinations are made in the order of the second, third, and first requirements, as adopted in some IP High Court decisions, 6 the second and third requirements play a central role in determinations concerning equivalence, and the first requirement will function as a supplement for the purpose of preventing the scope for which equivalence is established from becoming excessively broad due to those requirements.<sup>7</sup>

On the other hand, the fourth and fifth requirements are matters that are examined only in response to the defendant's defense, as mentioned above. If the requirements are alleged by the defendant, the fulfillment thereof is determined separately from the first to third requirements. Therefore, there are many cases in which the court first determines non-fulfillment of the fourth or fifth requirement and does not make any determination concerning the first to third

requirements. In this manner, the first to third requirements and the fourth and fifth requirements are independent of each other. However, the relationship between the first requirement and the fourth requirement sometimes becomes an issue when taking into account publicly-known art. In so doing, the court often considers the relationship not in terms of the fourth requirement, which clearly specifies publicly-known art, but in relation to the consideration of publicly-known art in finding the essential part in the first requirement.<sup>8,9</sup> Moreover, regarding the relationship between the first requirement and the fifth requirement, there are many cases in which an issue that should have been discussed originally as an issue of estoppel in the fifth requirement are determined as issues concerning an essential part in the first requirement and equivalence is thereby such as cases where denied. applicant's allegation or amendment becomes an issue in the examination process and cases where a numerical limitation that is hardly considered to be distinctive becomes an issue.

In this manner, the first requirement has been used for convenience as a requirement that includes elements that should be originally determined in terms of other requirements, but such method is likely to cause the expanded application of the requirement to a scope so wide that there would originally be no need to restrict the application of the doctrine of equivalents. Therefore, it is very important to make clear the standard for the interpretation of "essential part" in the first requirement and restrict the scope to which the requirement is applicable to an appropriate range in the sense of not restricting wrongfully the

where the doctrine of equivalents is applicable and enhancing legal stability by securing the objectivity of establishment or non-establishment of infringement under the doctrine of equivalents. 10

Furthermore, regarding the fifth requirement, which is used as a ground for denying infringement under the doctrine of equivalents, following the first requirement, it is not necessarily clear what action taken by the patentee causes the case to fall under the "special circumstances." This point has been an issue peculiar to the fifth requirement. That is, as the fifth requirement is specified as "such as the fact that ... fall under those that were intentionally excluded from the scope of the claims in the patent application procedures," it is typically applied in cases where an amendment is made to exclude an embodiment that includes the subject product in response to a reason for refusal of lack of novelty or an inventive step in the patent application examination process and cases where the party alleges that the embodiment of the subject product is not included in the scope of the claims. There is no dispute in practice over the point that the fifth requirement matters in such cases. However, the phrase "in the patent application procedures" does not necessarily specify just office actions after the filing of an application, and there have been disputes over the issue of whether the fifth requirement is applicable in cases where the embodiment of the invention is stated in the description as of the filing date but is not stated in the scope of the claims or cases where the embodiment of the subject product is not stated despite the fact that it was easy to include said embodiment based on common general technical knowledge as of the filing date. 11

It is considered to be very meaningful that the IP High Court clearly described determination methods for the first and fifth requirements, which have a significant influence on practice, in the form of a Grand Panel decision under the circumstances as mentioned above. Therefore, the Decision is explained below with a focus on determination methods for the first and fifth requirements.

#### 3. Explanation on the Decision

#### 3-1. Outline of the case

The appellee (plaintiff in the first instance), who holds the patent right in question for an invention entitled "Intermediates for the synthesis of vitamin D and steroid derivatives and a process for preparation thereof," alleged that the process (Appellant's Process) for the preparation of maxacalcitol preparations, etc. (Appellants' Products), imported and sold by the appellants (defendants in the first instance) is equivalent to the invention claimed in claim 13 of the patent in question and that the sale, etc., of the Appellants' Products constitutes infringement of the patent right in question. Based on this allegation, the appellee filed this case against the appellants to seek an injunction against import, assignment, etc., of the Appellants' Products and disposal thereof. The structure of the invention in question is as follows (segmentation of the invention into constituent features is as described in the Decision).

"[A-1] A process for preparing a compound having the following structure:

$$X$$
 $Y - (CH_2)_n$ 
 $R_2$ 
OH

[A-2] in the formula, n is  $\underline{1}$ ;

[A-3]  $R_1$  and  $R_2$  are methyl;

[A-4] each of W and X is independently hydrogen or methyl;

[A-5] Y is <u>O</u>; and

[A-6] Z is

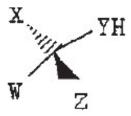
a steroid ring structure of the formula:

or a vitamin D structure of the formula:

wherein each of the structures of Z may optionally have one or more protected or unprotected substituents and/or one or more protective groups, and wherein any ring of the structure of Z may optionally have one or more unsaturated bonds);

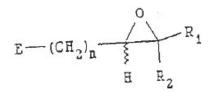
[E] which comprises:

[B-1] [a] the step of reacting a compound having the following structure:



(in the formula, W, X, Y and Z are as defined above)

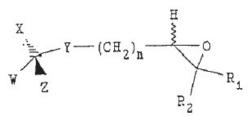
[B-2] in the presence of a base, with a compound having the following structure:



or

(in the formula, n,  $R_1$ , and  $R_2$  are as defined above, and E is an eliminating group)

[B-3] to produce an epoxide compound having the following structure:



[C] [b] the step of treating the epoxide compound with a reducing agent to produce the compound; and

[D] [c] the step of recovering the compound so produced."

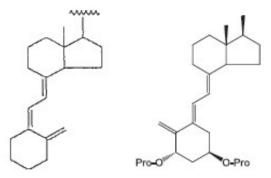
The corrected invention is outlined as a process for preparing a compound wherein the objective substance is produced by reacting the starting material with a specific reagent to prepare an

intermediate and treating the intermediate with a reducing agent. The Appellant's Process fulfills the constituent features of the corrected invention concerning the reagent and objective substance (Constituent Features [A], [B-2], [D], and [E]) but does not fulfill the constituent features of the corrected invention concerning the starting material and intermediate (Constituent Features [B-1], [B-3], and [C]) in that the carbon skeletons of the starting material and intermediate do not have a cis-form vitamin D structure but have a trans-form vitamin D structure, which is a geometric isomer of the cisform vitamin D structure.

More specifically, as mentioned below, the Appellant's Process does not fulfill Constituent Feature [B-1] of the corrected invention in that the carbon skeleton of Starting Material A in Step I is not a "cis-form vitamin D structure" (cis (5Z) secosteroid structure) that has two protected substituents among "Z" of Constituent Feature [A-6] cited in Constituent Feature [B-1] of the corrected invention but is a *trans*-form vitamin D structure, which is a geometric isomer of the *cis*-form vitamin D structure.

(Vitamin D structure of Z in the corrected invention)

(Carbon skeleton of Starting Material A for the Appellant's Process)



(Z may have one or more protected substituents.)

In addition, the Appellant's Process does not fulfill Constituent Features [B-3] and [C] of the corrected invention in that the carbon skeleton of Intermediate C in Steps I and II is not a *cis*-form vitamin D structure but a *trans*-form vitamin D structure, as mentioned below.

The parties disputed the establishment of infringement under the doctrine of equivalents through specific application of the five requirements described in the aforementioned Ball Spline Bearing Case decision. The court of prior instance recognized that the Appellant's Process is equivalent to the corrected invention and upheld the appellee's claims. Therefore, the appellants filed an appeal against the decision of prior instance (in addition to the doctrine of equivalents, the parties also disputed the invalidity of the patent, but this point is omitted in this article).

## 3-2. Outline of the Decision (portions that relate to a general theory for determining equivalence)

#### 3-2-1. Introduction

In the Decision, the Court also determined infringement under the doctrine of equivalents based on the five requirements indicated in the aforementioned Ball Spline Bearing Case decision, in the same manner as in the prior instance. As

mentioned above, the Decision is considered to be very meaningful in that it described determination methods in detail, especially for the first and fifth requirements as a general theory. Therefore, the portions of the Decision setting out determination methods for infringement under the doctrine of equivalents as a general theory, which are considered to be important, are introduced in advance of the parts indicating a specific determination concerning this case. Incidentally, the parts cited from the Decision are indicated in italics, and underlining in the cited parts have been added by the author unless otherwise noted.

### **3-2-2.** The burden of proof for the five requirements for equivalence

Regarding the burden of alleging and proving the fulfillment of the first to fifth requirements, it is reasonable to understand as follows, taking into account that the doctrine of equivalents should be applied within the scope of inventions that are found to be easily conceived of by a person ordinarily skilled in the art as one that is substantially identical with the statements in the scope of the claims beyond the scope of the literal interpretation of said statements: a person who alleges that a subject product, etc., is equivalent to a patented invention should be considered to have the burden of allegation and proof for the first to third requirements, which are the facts required for the subject product, etc., to be recognized as falling within said scope, while a person who denies the applicability of the doctrine of equivalents in relation to the subject product, etc., has the burden of allegation and proof for the fourth and fifth requirements, which are related to

cases where the doctrine of equivalents should not be applied, even if the subject product, etc., is within the aforementioned scope.

### **3-2-3.** The first requirement for equivalence

The substantial value of an invention that the Patent Act intends to protect exists in the disclosure, with a specific structure, to society of a means for solving a technical problem that could not have been solved by prior art that is based on a unique technical idea that has not been seen in prior art. Therefore, an essential part of a patented invention should be understood to be a characteristic part that constitutes a unique technical idea, which has not been seen in the prior art, that is in the statements in the scope of the claims of the patented invention.

The aforementioned essential parts should be found by first understanding the problem to be solved and the means for solving the problem of the patented invention ... and its effect ... based on the statements in the scope of the claims and the description, and then determining the characteristic parts that constitute unique technical ideas that are not seen in the prior art in the statements in the scope of the claims of the patented invention. That is, taking into account that the substantial value of a patented invention is defined by the degree of contribution in comparison with the prior art in the relevant technical field, an essential part of a patented invention should be found based on the statements in the scope of the claims and the description, in particular, through comparison with the prior art stated in the description. [i] If the degree of contribution of the patented invention is considered to be more than that of the prior art, the patented invention is found to be a generic concept in relation to part of the statements in the scope of the claims .... [ii] If the degree of contribution of the patented invention is evaluated to be not much more than the prior art, the patented invention is found to have almost the same meaning as stated in the scope of the claims.

However, if the statement of the problem, which is described as one that the prior art could not solve, in the description is objectively insufficient in the light of the prior art as of the filing date ..., a characteristic part that constitutes a unique technical idea of the patented invention that is not seen in the prior art should be found also in consideration of prior art that is not stated in the description. In such cases, the essential part of the patented invention is closer to the statements in the scope of the claims compared to cases where it is found only based on the statements in the scope of the claims and the description, and the scope of application of the doctrine of equivalents is considered to be narrower.

In addition, in determining the fulfillment of the first requirement, i.e. whether
a difference from the subject product, etc.,
is a non-essential part, it is not appropriate to first divide the constituent features
stated in the scope of the claims into
essential parts and non-essential parts
and then consider that the doctrine of
equivalents is not applicable to all of the
constituent features that fall under
essential parts, but it is necessary to first
determine whether the subject product,
etc., commonly has the essential parts of
the patented invention determined as
mentioned above and if the subject

product, etc., is recognized as having said essential parts, the differences should be found to be unessential. Even if the subject product, etc., has a difference other than the characteristic part that constitutes a unique technical idea that is not seen in the prior art, this fact does not become a reason for denying the fulfillment of the first requirement.

### **3-2-4.** The fifth requirement for equivalence

Even if there is another structure that is outside the scope of the claims that a person ordinarily skilled in the art could have easily conceived of as of the filing date as one that is substantially identical to the structure stated in the scope of the claims and the applicant thus could have also easily conceived of that other structure as of the filing date, this fact alone cannot serve as a reason for alleging that the applicant's failure to state said other structure in the scope of the claims falls under the "special circumstances" in the fifth requirement of the doctrine of equivalents.

This is because of the following reasons. [i] As mentioned above, the substantive value of a patented invention extends to the art that a person ordinarily skilled in the art can easily conceive of as one that is substantially identical to the structure stated in the scope of the claims based on said structure, even if it is a structure other than the structure stated in the scope of the claims. This principle does not change at all in relation to any art that a person ordinarily skilled in the art could have easily conceived of as of the filing date. If it is not at all permitted to allege the doctrine of equivalents only for the reason that a structure could have been easily conceived of by a person

ordinarily skilled in the art as of the filing date, the scope to which the substantial value of a patented invention extends will differ from the aforementioned scope. [ii] In addition, taking into account that an applicant should first disclose his invention to the public by stating it in the description and then clearly specify the scope of the exclusive right in the scope of the claims, the applicant should state the scope of the claims in just proportion within the scope of the invention disclosed in the description while fulfilling the requirements, such as the support requirement under Article 36, paragraph (5) of the Patent Act and paragraph (6), item (i) of said Article and the clarity requirement under item (ii) of said paragraph. However, in some cases, it is considered to be harsh to require the applicant to prepare a scope of the claims that contains all the expected infringements and the description supporting such scope of the claims within a limited period of time, taking into account the fact that, under the first-to-file system, applicants are generally required to prepare the scope of the claims and the description and file applications within a limited period of time. On the other hand, in many cases, a third party who has received the disclosure of an invention as described in the description pertaining to a patent application can easily conceive of one that has an essential part of the patented invention but also includes features that are not within the literal interpretation of the scope of the claims, based on the statements in the scope of the claims and the description, etc., during the duration of the patent. The doctrine of equivalents is applicable because if any third party can easily escape the exercise of rights by the patentee, includ-

ing an injunction, through replacement of a non-essential part of the patented invention, this will diminish the incentive to invent in general, which not only goes against the purpose of the Patent Act, i.e. contributing to the development of industry through protection and encouragement of inventions, but also goes against social justice and runs counter to the principle of fairness. In the light of the aforementioned situation, even if a person ordinarily skilled in the art could have easily conceived of another structure that is outside the scope of the claims as of the filing date, it is not reasonable to exclude said other structure from the application of the doctrine of equivalents only for the reason of such fact without exception.

However, even in such a case, if the applicant is objectively and externally recognized as having recognized another structure that is outside the scope of the claims as a replacement for a different part in the structure stated in the scope of the claims as of the filing date (for example, where the applicant can be considered to have stated the invention based on said other structure in the description or where the applicant stated the invention based on another structure that is outside the scope of the claims in a paper. etc., which was published as of the filing date), the applicant's failure to state said other structure in the scope of the claims is considered to fall under the "special circumstances" in the fifth requirement.

This is because in the aforementioned cases, it can be understood that the patentee intentionally excluded said other structure from the scope of the claims, i.e. the patentee acknowledged or behaved in a way to be objectively considered to have acknowledged that said

other structure does not fall under the technical scope of the patented invention. The trust of a third party who understands as such should be protected. Therefore, the patentee is not permitted to subsequently allege the application of the doctrine of equivalents in relation to a subject product, etc., that is based on said other structure in contradiction of such protection in the light of the doctrine of estoppel.

### 3-3. Outline of the Decision 2 (determination concerning this case)

#### 3-3-1. Introduction

In the Decision, the Court first considered the fulfillment of the first to fifth requirements for equivalence in numerical order, and then determined that the Appellant's Process fulfills all five of the requirements and recognized the establishment of infringement of the invention claimed in Claim 13 (Corrected Invention) of the patent in question under the doctrine of equivalents. The details of the specific holdings for each requirement are as follows

### **3-3-2.** The first requirement for equivalence

The Corrected Invention makes it possible to prepare its objective substance through a new preparation route that was not available in the prior art, and its degree of contribution to the art is large. ... The Corrected Invention made it possible ... to industrially manufacture maxacalcitol for the first time ... In the light of the problem to be solved and the means for solving the problem of the Corrected Invention and its effect as mentioned above, the essential part of the Corrected Invention ... is recognized as existing in finding that a side chain

having an epoxy group by an ether bond can be introduced through one step by having an alcohol compound at the 20position of a vitamin D structure or steroid ring structure react with an epoxy hydrocarbon compound of Constituent Feature [B-2], which has an eliminating group at its end, and in making it possible to introduce a maxacalcitol side chain into an alcohol compound at the 20-position of a vitamin D structure or steroid ring structure through a new route of first going through an intermediate that is a vitamin D structure or steroid ring structure into which a side chain having an epoxy group by an ether bond is introduced through such one step and then opening the ring of the epoxy group of the side chain. ... The Appellant's Process ... is considered to have the characteristic part that constitutes a unique technical idea that has not been seen in the prior art in the statements in the scope of the claims of the Corrected Invention.

On the other hand, in the Appellant's Process, the point that the vitamin D structure that corresponds to "Z" of the starting material and the intermediate is not a cis form but a trans form, which is different from the Corrected Invention, is not an essential part of the Corrected Invention ....

Therefore, the Appellant's Process is recognized as fulfilling the first requirement of the doctrine of equivalents.

### 3-3-3. The second requirement for equivalence

In ... Starting Material A and Intermediate C in the Appellant's Process, the carbon skeleton that corresponds to Z in the Corrected Invention is a trans-form vitamin D structure, and the Appellant's Process differs from the Corrected Inven-

tion in that the carbon skeleton of Z of the starting material ... and the intermediate ... of the Corrected Invention is a cisform vitamin D structure. However, the starting materials and intermediates in both the Appellant's Process and the Corrected Invention have the same function and effect of being capable of preparing maxacalcitol by a process of going through an intermediate that is a vitamin D structure into which a side chain having an epoxy group is introduced by an ether bond through one step by having an alcohol compound at the 20-position of a vitamin D structure react with the same epoxy hydrocarbon compound. It is recognized that the same purpose as that of the Corrected Invention can be achieved and the same function and effect are produced even if the aforementioned starting material and intermediate having a cis-form vitamin D structure in the Corrected Invention are replaced with the aforementioned starting material and intermediate having a transform vitamin D structure in Appellant's Process. ... Therefore, the Appellant's Process is recognized as fulfilling the second requirement of the doctrine of equivalents. ... The Corrected Invention also includes the step of converting a steroid ring structure to a vitamin D structure. A difference in the total number of steps (fewer steps), including the conversion step, is not particularly recognized as a difference from the prior art. Taking this into account, the function and effect of the Corrected Invention cannot be found to be the reduction in the total number of steps for preparing the objective substance, such as maxacalcitol, compared to the prior art.

### 3-3-4. The third requirement for equivalence

The following facts are recognized: [i] ... it was a widely-known process to obtain a cis-form vitamin D derivative by using a compound having a trans-form vitamin D structure as the starting material in preparing a desired vitamin D derivative and converting the trans-form vitamin D structure into a cis-form vitamin D structure by light illumination after introducing a side chain as appropriate ...; [ii] It was also known that the trans-form vitamin D structure that corresponds to Starting Material A of the Appellant's Process is used for the synthesis of maxacalcitol ...; [iii] Even in the case of using a compound having a cis-form vitamin D structure as the starting material, it was generally accepted to adopt processes wherein the compound is converted into a trans form at the time of introducing a substituent, etc., or removing a protective group in the course of preparation and is reconverted into a cis *form* ....

Moreover, ... the hydroxyl group with which the alcohol compound at the 20-position of a vitamin D structure, which is the starting material, reacts upon the introduction of a maxacalcitol side chain is far from the position of the double bond (5-position) of the vitamin D structure, which differs between a trans form and a cis form. ... Taking this into account, it is natural for a person ordinarily skilled in the art not to consider that the reaction, in the course of introducing the maxacalcitol side chain in the Corrected Invention, would differ as a result of the difference between a trans form and a cis form in the position of the double bond.

In that case, it is recognized that a person ordinarily skilled in the art could have easily conceived of the Appellant's Process ... based on the Corrected Invention at the time the Appellant's Process was carried out (when the patent right was infringed).

### 3-3-5. The fourth requirement for equivalence

Said allegation of the appellants is unacceptable as held in No. 4, 4.(1) to (6) in "Facts and reasons" in the judgment of prior instance. The relevant part is cited.

### **3-3-6.** The fifth requirement for equivalence

The Corrected Description does not refer to a trans-form vitamin D structure at all. For example, it does not describe the step of converting a trans form to a cis form. There is no statement concerning an invention pertaining to a manufacturing process using a trans-form starting material in the Corrected Description.

Given these circumstances, it cannot be considered, based on each of the aforementioned statements in the Corrected Description, that an invention using a compound having a trans-form vitamin D structure as the starting material of the Corrected Invention is stated in the Corrected Description. In addition, said statements are not sufficient to objectively and externally recognize that the applicant recognized a trans-form vitamin D structure as a replacement for the starting material of the Corrected Invention as of the filing date. Therefore, it is not recognized that a trans-form vitamin D structure was intentionally excluded from the scope of the claims. ... Even based on the other allegations of the appellants, it is not recognized that the special circumstances of the fifth requirement of the doctrine of equivalents exist.

### 3-4. Commentary on the Decision 3-4-1. Introduction

As also mentioned at the beginning of this article, the Decision has also attracted attention in the sense that the Court found infringement under the doctrine of equivalents for the first time in the field of medicine, a field in which there have been few relevant cases in the past. Originally, a major cause of difficulty in finding infringement under the doctrine of equivalents in the fields of chemistry and medicine seems to be the low predictability of functions and effects.

However, in this case, whether the double bond that is distant from the reaction site is a trans form or cis form is hardly considered to affect the reaction for introducing the side chain, and it can be easily presumed from common general technical knowledge of persons ordinarily skilled in the art that the same intermediate as specified in the Corrected Invention can also be obtained by the Appellant's Process. In addition, taking into account the fact that it is known that a cis-form vitamin D derivative is obtained by converting a trans form into a cis form after reaction and that it is easy to eventually achieve the same objective, it is considered that a trans form, which is not literally specified as Constituent Feature [A-6], is only used to avoid infringement of the patent in question (although normally it would be logical in terms of the purpose to use a cis form). The issue in this case is, after all, how to evaluate the fact that the patentee did not make a broader statement to include a trans form

#### as Constituent Feature [A-6].

However, it does not seem to be a significant error that the patentee did not state (failed to state) an embodiment that is identical to the patented invention as a technical idea but is less efficient in terms of the purpose of the invention. Also, the doctrine of equivalents is a theory intended to protect those items that are identical to a patented invention in terms of purpose and function and effect and can be replaced with the patented invention and for which such replacement is easy if they do not literally fulfill constituent features, in cases where a constituent feature is not literally fulfilled for such reason. Therefore, it should be considered to be a very reasonable determination in terms of the purpose of the doctrine of equivalents that the Court found infringement under the doctrine of equivalents in this case. Rather, if the Court did not find infringement under the doctrine of equivalents in such a case, the existence of the theory of the doctrine of equivalents itself would seem to have almost no meaning.

The major aim of handling this case as a Grand Panel Case, despite being such a case, seems to be to maintain the matters mentioned in sections 3-2-2. to 3-2-4. above as a general theory for future practice. Therefore, explanations are given below with a focus on these holdings.

### 3-4-2. The burden of proof for the five requirements for equivalence

As indicated in section 3-2-2. above, the person who alleges that a subject product, etc., is equivalent to a patented invention (i.e. the patentee) has the burden of proof for the first to third requirements while the person who denies the applicability of the doctrine of equiva-

lents in relation to the subject product, etc. (i.e. the defendant) has the burden of proof for the fourth and fifth requirements. Although an objection is advocated in this regard, in the research law clerk's explanation of the Ball Spline Bearing Case decision, 12 this practice can be considered to have become almost fixed practice through the accumulation of lower court decisions after the Ball Spline Bearing Case decision. Therefore, the Decision is in the form of conforming to this practice, and it can thus be said that this holding will not change the past practice.

### **3-4-3.** Regarding the first requirement for equivalence

Regarding the definition of "essential part" in the first requirement, the court held that an essential part of a patented invention is a "characteristic part that constitutes a unique technical idea that is not seen in the prior art in the statements in the scope of the claims of the patented invention." Such a definition conforms to the interpretation that has been adopted in recent lower court decisions, and it has significance in indicating that a determination is made based on the identity of technical ideas.

Furthermore, the Decision attracts attention in that it held as follows in relation to the determination method: "It is not appropriate to first divide the constituent features ... into essential parts and non-essential parts and then consider that the doctrine of equivalents is not applicable to all of the constituent features that fall under [the category of] essential parts, but rather it is necessary first to determine whether the subject product, etc., commonly has the essential part of the patented invention, determined

as mentioned above and if the subject product, etc., is recognized as having said essential parts, the differences should be found to be unessential." In the past, methods for determining whether a constituent feature is included in essential parts have been roughly divided into two ideas, specifically, the idea of first dividing constituent features into essential parts and non-essential parts and then considering that the doctrine of equivalents is not at all applicable to the constituent features that fall under essential parts (essential part theory), and the idea of first determining the characteristic principle in the means for solving the problem of the patented invention through comparison between the patented invention and prior art and then making a determination from the perspective of whether the means for solving the problem of the subject product belongs to the principle that is substantially identical to the principle for solving the problem of the patented invention (technical idea identity theory). 13

Of these theories, the essential part theory is convenient in that a conclusion about whether infringement under the doctrine of equivalents is established can be drawn by mechanically classifying constituent features into essential parts and non-essential parts without specifically considering the relationship between the patented invention and the subject product. In particular, lower court decisions that seem to have denied establishment of equivalence based on this idea were prominent immediately after the Ball Spline Bearing Case decision.<sup>14</sup> However, as is obvious from the provisions of Article 36, paragraph (5) of the Patent Act, "The scope of the claims ... shall state a claim or claims and state for each claim all matters necessary to specify the invention for which the applicant requests the grant of a patent," all of the structures stated in the scope of the claims are matters that are recognized as necessary to specify the invention, and are specified with some technical significance. Therefore, for all of the structures, reasons for choosing them and reasons other structures are unfavorable are stated the description in many cases. Mechanically interpreting those statements, structures pertaining to differences are determined to be the essential parts of the invention in most cases, and there will be almost no meaning in finding infringement under the doctrine of equivalents.

Therefore, it seems to be reasonable to adopt the technical idea identity theory. However, it can be said that the Decision is meaningful in that the Court clearly denied the essential part theory and made clear the adoption of the technical idea identity theory. Incidentally, this idea conforms to the statements in the research law clerk's explanation in the Ball Spline Bearing Case decision. 15 In practice, the same determination method has been adopted in many court decisions since the aforementioned interlocutory decision on the Hollow Golf Club Head Case. 16 Consequently, the Decision follows this trend of recent lower court decisions, but it can be considered to be meaningful in having clearly denied the essential part theory and brought an end to the past argument.

Incidentally, the Court held as follows in the Decision: the essential parts of a patented invention should be found through comparison with the statements in the scope of the claims and the description, in particular, the prior art stated in the description; if the statements of prior art in the description are insufficient, prior art that is not stated in the description can also be taken into account. It is natural that the statements in the description are important in finding the essential parts, and it has been recognized in lower court decisions that the items cited in the description serve as elements for finding the essential parts. Therefore, there seems to be no special objection regarding this point. However, it seems that the items are cited in a limited manner in consideration of the sharing of roles between the first requirement and the fourth and fifth requirements (see section 3-4-5 for further details).

Moreover, if the degree of contribution of a patented invention is large, some of the statements in the scope of the claims are found to be a generic concept, while if the degree of contribution thereof is not so large, the statements in the scope of the claims are understood as they are. In this regard, there is no conventional court decision that indicates this as a general theory, and the Decision can be evaluated as having made an in-depth determination. 17 However, granting better protection for inventions that make larger contributions, i.e. those for which there are less alternative art and whose inventive steps are greater, fits in with the purpose of the Patent Act, and it can be considered intuitively to make sense. Moreover, it is considered that the higher the level of the technical idea pertaining to the essential part, the less important other parts (non-essential parts) of the invention are. Therefore, this holding also theoretically makes sense.

Looking at past court decisions, for example, the court can be evaluated as having found the essential part by making the term directly stated in the scope of the claims, "suture material," into a generic concept and thereby having found infringement under the doctrine of equivalents in the aforementioned interlocutory decision on the Hollow Golf Club Head Case.

In the present case, it is not necessarily clear how this holding affected the determination concerning the first requirement. However, the court can be evaluated as having permitted making the structure of the vitamin D skeleton into a generic concept to the extent that it does not have a significant effect on the reaction because of the greatness of the contribution of having found a new route for obtaining an intermediate into which a side chain having an epoxy group by an ether bond is introduced through one step.

### **3-4-4.** The fifth requirement for equivalence

As mentioned above, in the Decision, the Court held that even if there is another structure that is outside the scope of the claims that a person ordinarily skilled in the art could have easily conceived of as of the filing date as one that is substantially identical to the structure stated in the scope of the claims, and the applicant could thus have also easily conceived of such other structure as of the filing date, this fact alone does not fall under the "special circumstances" in the fifth requirement. In this regard, as long as the fifth requirement specifies the "special circumstances, such as the fact that the products fall under those that were intentionally excluded from the scope of the claims," it is reasonable to consider that the mere existence of another material that produces the same effect as of the filing date does not fall under the "special circumstances" mentioned here. In addition, as long as the ease of replacement at the time of infringement is specified in the third requirement for equivalence, if lack of ease of replacement as of the filing date is set as a requirement in the fifth requirement, infringement under the doctrine of equivalents will never be established unless the technical level concerning ease of conceiving of the replacement changes during the brief period between the filing date and the time of infringement, and it will become very unlikely for the court to find infringement under the doctrine of equivalents (actually, in the Decision, the court also found the ease of replacement based on the filing date in its determination concerning the third requirement, and ease of conceiving of the replacement as of the filing date are fulfilled in this case).

Therefore, the aforementioned holding is reasonable, and there has been no court decision that explicitly recognizes the ease of conceiving of the replacement as of the filing date as a ground for satisfaction of the fifth requirement. <sup>18</sup> Consequently, the content of the holding brings no significant change to the existing practice, but it is considered to be meaningful in that it clearly denied the idea that was also advocated in the research law clerk's explanation in the Ball Spline Bearing Case decision. <sup>19</sup>

However, in the Decision, the Court held that "if the applicant is objectively and externally recognized as having recognized another structure that is outside the scope of the claims as a replacement for a different part in the structure stated in the scope of the claims as of the filing date," the case is considered to fall under the aforementioned "special circumstances." Furthermore, as specific

examples, the Court cited cases "where the applicant can be considered to have stated the invention based on another structure in the description" and cases "where the applicant stated the invention based on another structure that is outside the scope of the claims in a paper, etc., which was published as of the filing date."

Regarding cases "where the applicant can be considered to have stated the invention based on another structure in the description," there is a court decision in which the court held to this extent, 20 but this idea is not one that has been generally adopted in past lower court decisions (rather, these are considered to be matters that have been often determined in relation to the first requirement). However, as the act of stating a description can also be considered to be part of the patent application procedures, it does not seem particularly strange that the statements in the description can be an example of "those that were intentionally excluded from the scope of the claims in the patent application procedures."

On the other hand, the court has rendered no holding regarding cases "where the applicant stated the invention based on another structure that is outside the scope of the claims in a paper, etc., which was published as of the filing date," and such holding is one that can narrow down the scope of establishment of equivalence based on the fifth requirement. In this regard, originally, if an "invention based on another structure that is outside the scope of the claims" is stated in a paper, etc., that the applicant published as of the filing date and it fulfills the first to third requirements in relation to the patented invention, the patent is not established on the grounds that the invention involves no

inventive step in relation to the invention stated in the paper, etc., that the applicant published, or the patent is invalidated through a trial for invalidation, as an issue before making a determination concerning equivalence. Moreover, even if the doctrine of equivalents becomes an issue, the issue will be cleared up as an issue relating to the fourth requirement in most cases. Therefore, literally interpreting cases "where the applicant stated the invention based on another structure that is outside the scope of the claims in a paper, etc., that was published as of the filing date" in a limited way, this requirement has almost no meaning. On the other hand, if this requirement is interpreted in a manner that it is expanded to some extent (for example, if an "invention based on another structure that is outside the scope of the claims" is not required to fulfill all of the "essential parts" of the relevant invention), it will have some meaning as a new requirement that limits the establishment of requirement. This point requires attention. In fact, this holding is merely an example of the case where "the applicant is objectively and externally recognized as having recognized another structure that is outside the scope of the claims as a replacement for a different part in the structure stated in the scope of the claims as of the filing date." Therefore, there seems to be room to interpret this holding with some degree of flexibility.

In this manner, in the Decision, the Court explicitly denied the ease of conception as of the filing date, but held that cases where the applicant is considered to have recognized an invention based on said other structure fall under special circumstances, without being limited to the statements in the description as

of the filing date and the content of written opinions and written amendments in the examination stage. The standards for determining the cases that are included in the special circumstances are not clear at present. Therefore, the accumulation of future court decisions is expected in relation to determinations concerning this point.

## 3-4-5. The relationship between the first requirement and other requirements

First, regarding the relationship between the first requirement and the second and third requirements, the Court made determinations concerning these requirements in this order in the Decision. In this regard, although such method of making determinations in numerical order is a general method adopted in court practice, the IP High Court adopted a method wherein determinations concerning the second and third requirements were made before that concerning the first requirement in some of its decisions, including the interlocutory decision on the Hollow Golf Club Head Case. There is also a statement that is in line with such method in the research law clerk's explanation in the Ball Spline Bearing Case decision.<sup>21</sup> In this regard, as mentioned above, such determination method seems to be reasonable to some extent, taking into account that the term "essential part" in the first requirement is abstract and difficult to interpret and also has a risk of extremely limiting the cases where infringement under the doctrine of equivalents is found because it is broadly interpreted in a manner creating distance from the second and third requirements.<sup>22</sup> However, as a method wherein determinations are made on the requirements in

numerical order was adopted in the Decision, the same method may be adopted in more lower court decisions in the future. <sup>23</sup> Therefore, the first requirement will continue to play an important role in the future practice as the center of determination concerning equivalence.

However, even in such a case, an adverse effect, i.e. excessive restriction on infringement under the doctrine of equivalents, becomes less likely to occur by considering the first requirement not as a requirement that is separate from and independent of the second and third requirements but close, particularly, to the second requirement. Actually, if the "technical idea identity theory" adopted in relation to the interpretation of "essential part" in the first requirement, a determination is made based on whether or not the means for solving the problem of the subject product belongs to a principle that is substantially identical with the principle for solving the problem of the patented invention. However, if the means for solving the problem of the subject product is substantially identical with the principle for solving the problem of the patented invention, the function and effect of the subject product can also be evaluated as being identical with those of the patented invention. This is close to the second requirement (replaceability).<sup>24</sup> In the present case, the Court found the fulfillment of both the first and second requirements based on the commonality that a maxacalcitol side chain is introduced by a process of going through an intermediate that is a vitamin D structure or steroid ring structure into which a side chain having an epoxy group by an ether bond is introduced through one step and then opening the ring of the epoxy group of the side chain. The Court can be evaluated as having adopted a close determination. As long as such a determination method is adopted, even if the fulfillment of the first requirement is determined first, it is highly likely that the first requirement will not to be applied in a manner such that it is expanded to the scope where there is no need to restrict the application of the doctrine of equivalents. However, there was no explicit statement as such in the Corrected Description in relation to the function and effect, and the appellant alleged regarding the second requirement that the only effect stated in the corrected description is reduction of the number of steps and that processes do not have the same function and effect if the total number of steps differs. In response to this, the Court cast aside the aforementioned allegation by ruling that the patented invention is not an invention for which a difference in the total number of steps (fewer steps), including the conversion step, is recognized as being different from prior art, and broadly interpreted the scope of identity of function and effect pertaining to the second requirement in a manner that is advantageous to the right holder. This point is also worthy of attention.<sup>25</sup>

Moreover, the Decision includes a holding that is worthy of attention in terms of the relationship between the first requirement and the fourth and fifth requirements. That is, as mentioned above, in the Decision, the Court cited the statements in the scope of the claims and the description (in particular, comparison with prior art stated in the description) as elements used for finding the essential parts of the patented invention, and held that it is also permitted to take into account prior art that is not stated in the description if the statements in the scope

of the claims and the description are objectively insufficient in light of prior

In the past lower court decisions, the court has naturally recognized that the scope of the claims and the description should be taken into account, but there have been many cases in which the court found prior art by being relatively free in taking into account the statements in publicly-known documents without being limited, particularly, to the description.<sup>26</sup> However, in many such cases, the court took into account such statements with the aim of denying the fulfillment of the first requirement. In that sense, the Decision attracts attention in that the Court held that prior art should be found in principle through comparison with the prior art stated in the description and that it is also exceptionally permitted to take into account prior art that is not stated in the description if the prior art stated in the description is objectively insufficient in the light of the prior art. Needless to say, this holding is considered not to be intended to prohibit the finding of prior art based on the statements in publiclyknown documents in relation to the fourth requirement, and it can rather be evaluated as indicating the sharing of roles, that is, publicly-known art that is not stated in the description should be in principle determined in relation to the fourth requirement. As mentioned above, the fourth requirement imposes a hurdle, specifically, equivalence can be denied based on publicly-known art only after the subject product is determined not to be novel or presumed not to be easily conceived of based on the assumption that it is included in the scope of the claims. Therefore, if there are an increasing number of cases in which prior art is

found only based on the statements in the description in a determination concerning the first requirement, the scope in which infringement under the doctrine of equivalents is found will be substantially broader. Consequently, the degree of detail of the statements of prior art in the description that is required to fall under the cases where the statements "are objectively sufficient in the light of prior art as of the filing date" becomes an issue. However, the Decision does not indicate any specific standard therefor. If statements of prior art fall under the cases where the statements are "objectively insufficient in the light of prior art as of the filing date" unless the statements include the detailed statements of any and all kinds of prior art relating to the invention, this cannot be considered to be realistic in the light of common sense of patent practice, and the holding in the Decision that prior art should be in principle found based on the description comes to have no substantial meaning. In this regard, there is an Intellectual Property High Court decision that was rendered after the Decision, which can be considered to be using whether or not the relevant art is well-known art as a standard for determining whether or not it should be stated as prior art, and the decision attracts attention.<sup>27</sup> At any rate, the method of finding publicly-known art in making a determination concerning the first requirement affects the establishment of equivalence. Therefore, accumulation of court decisions is expected to guide future practice.

In addition, in conventional lower court decisions, prosecution history is often cited as an element for finding essential parts, as well as the scope of the claims, description, and prior art. In fact,

it is not uncommon for a court to find essential parts based on the prosecution history and determine non-establishment of equivalence based on the first requirement. 28 In this regard, it is considered that, in the Decision, the Court chose not to cite the prosecution history as an element taken into consideration in terms of the essential part for the purpose of making clear the sharing of roles by defining the prosecution history as an element that is taken into consideration in relation to the fifth requirement. In practice, the content of an amendment and the statements in a written opinion at the time of the amendment are largely taken into account with the aim of limiting the scope of identity of essential parts more than can be understood only based on the statements in the description. Therefore, the Court's intent to interpret the scope of application of the first requirement in a limited way can be seen in this regard.

Moreover, as mentioned in section 3-4-4. above, the fact that cases "where the applicant can be considered to have stated the invention based on another structure in the description" are specified as cases where fulfillment of the fifth requirement is denied can also be regarded, in some way, as specifying the sharing of roles between the first requirement and the fifth requirement. This point is explained below by using a numerical limitation invention as an example.

In Japan, there has been no court decision in which the Court found infringement under the doctrine of equivalents for an invention that includes a numerical limitation in relation to the subject product that is outside the numerical scope of the invention. Although the fifth requirement is sometimes cited as a

reason for denying infringement under the doctrine of equivalents for such an invention, the first requirement is most commonly used. For some inventions, there are cases in which the solution of a problem is attempted based on the numerical scope thereof and novelty and an inventive step is recognized in the numerical scope, but, realistically, there are many cases in which a numerical scope that is considered to be desirable in the prior art is specified without any direct relationship with the principle for solving the problem of the invention in order to fulfill the enablement requirement. In this regard, if fulfillment of the first requirement is determined based on the technical idea identity theory in accordance with the Decision, even if the subject product is outside the numerical scope, it is highly likely to be determined to fulfill the first requirement in the latter case, putting aside the former case. Therefore, for most of the cases where the subject product does not fulfill a numerical limitation, establishment of the doctrine of equivalents will be determined based on the fifth requirement in the future.

In this regard, the act of setting a numerical limitation itself can also be seen as intentionally excluding other numerical scopes in the description. Therefore, it may not be easy to find infringement under the doctrine of equivalents in the light of the aforementioned standard. However, there have actually been cases where a numerical scope that has been considered to be unrealizable at the technical level as of the filing date becomes realizable at the time of infringement with the advancement of technology that is not related to the technical problem of the invention, and it becomes

easy to avoid infringement (for example, the applicant specified the scope of the particle size that was realizable at the technical level of the time, in relation to an invention for the composition of a particle, for which the size of the particle itself is not an essential part, but it had become possible to realize a finer particle at the time of infringement). There seems to be room for the finding of infringement under the doctrine of equivalents in such cases. Therefore, future court decisions are expected in this regard.

## 4. Influence of the Decision on actual practice and points to note in future practice

As mentioned above, the Decision as a whole is roughly in line with the idea that has been adopted in recent lower court decisions, and the Decision is not expected to change the trend of the future court decisions significantly. Even so, it can be considered to be a court decision that has great significance in the future practice because it followed the direction in which court decisions have been converging after the twists and turns since the Supreme Court decision in the Ball Spline Bearing Case and also includes holdings that go into more depth than before.

In particular, it is expected that there will be fewer further decisions in which the court denies the establishment of equivalents through excessive expansion of the first requirement, particularly, such as in the lower court decisions immediately after the Ball Spline Bearing Case Supreme Court decision, because the Court clearly indicated that it embraces the technical idea identity theory in relation to the first requirement and interpreted the elements taken into

account in relation to the first requirement in a limited way. On the other hand, regarding the fifth requirement, the Court made a determination in the direction of expanding the scope of application toward denying infringement under the doctrine of equivalents, compared to the idea that has been adopted in conventional practice. Therefore, cases in which the establishment of equivalence is denied based on the fifth requirement may increase while the cases in which equivalence is denied based on the first requirement may decrease. Therefore, it is currently not clear whether the cases in which infringement under the doctrine of equivalents is found will increase or decrease on the whole. At any rate, it is important to sufficiently understand the purport of the Decision from perspectives of right holders and third parties, respectively. Therefore, points to note in practice at the moment are mentioned below.

First of all, from the perspective of right holders, there is still a major hurdle to the establishment of infringement under the doctrine of equivalents in Japan, even in the light of the Decision. Therefore, applicants should state the scope of the claims and the description creatively so that they can allege literal infringement. For that purpose, it is important to closely consider what parts fall under characteristic parts that do not exist in the prior art through comparison between prior art and the new invention and to state the parts that are the same as those in the prior art in as abstract a form or as generic a concept as possible (needless to say, it is also necessary to leave room for restriction to a more specific concept through amendment in preparation for reasons for refusal). In doing so, the

applicant should state, in particular, materials, etc., stated in publications of unexamined applications pertaining to his applications in the past and published papers, etc., without omission because fulfillment of the fifth requirement is likely to be denied even if they are not stated in the description. However, it is necessary to note that fulfillment of the fifth requirement is likely to be denied if an applicant states such materials only in the description but does not state them in the scope of the claims (in particular, if the applicant makes a negative statement regarding such materials or numerical scope).

Moreover, it is also important to enrich the statements in the description in order to make it easier for a finding of infringement under the doctrine of equivalents. In particular, if the statement of the problem that has not been solved by prior art is insufficient, prior art that is not stated in the description is also taken into account, and fulfillment of the first requirement is more likely to be denied compared to cases where prior art is found only based on the statements in the description, etc. This point requires attention. Furthermore, as it is a natural prerequisite for recognizing the fulfillment of the first requirement that the technical idea or function and effect of the invention can be understood from the statements in the patent description, it is also important to enrich the statements of the technical idea or function and effect (the decisions in which the court has permitted taking into account the experimental data that was submitted after the filing of the application in determining replaceability in the second requirement but showed a negative attitude toward using such data in finding that essential

parts are prominent<sup>29</sup>).

From a third party's perspective, it is necessary to pay more attention to infringement under the doctrine of equivalents than ever. Because of circumstances such as the fact that there have been few court decisions finding infringement under the doctrine of equivalents in Japan, it is not rare that a third party does its best to avoid literal infringement and does not sufficiently consider establishment or non-establishment of infringement under the doctrine of equivalent after excluding the constituent features of a relevant invention. In addition, it is difficult to determine the fulfillment of the first requirement based on the technical idea identity theory because it is necessary to consider not only the statements in the description but also the relationship with the subject product, and it is often difficult to predict what determination the court will make. Because of these circumstances, it may be effective to consider the prosecution history, statements in the description, and statements in the past publications of unexamined application and papers, etc., of the same applicant to seek materials that can be used for alleging the non-fulfillment of the fourth or fifth requirement if there is no decisive factor in relation to the non-fulfillment of the first requirement.

In this manner, for the time being, it seems to be safe to take the actions mentioned above in the light of the Decision. However, as mentioned in section 2-1. above, this case is now pending at the Supreme Court, and there remains a possibility that the Supreme Court will advocate a new theory. Therefore, it is also necessary to pay attention to the future trends.

#### (Notes)

- However, there is a criticism that the determination standard causes determinations concerning the support requirement to be excessively hard on right holders, and there have been IP High Court decisions in which the court interpreted the range covered by said decision in a limited manner and made a determination concerning the fulfillment of the support requirement based on a standard that differs completely from said standard. However, in recent years, it has been common that all of the divisions of the IP High Court make flexible determinations that are not excessively strict on right holders while fundamentally being based on this standard.
- However, in said Supreme Court decision, the Court denied the establishment of infringement under the doctrine of equivalents on the ground of non-fulfillment of the fourth requirement and thereby reversed the decision at prior instance that found infringement under the doctrine of equivalents. Therefore, in Japan, there has been no case in which the Supreme Court found infringement under the doctrine of equivalents. Incidentally, when said decision was rendered, a defense set forth in Article 104-3 of the Patent Act (a defense of patent invalidity) had not been provided by law, and it was a major method to interpret the scope of rights in a limited way based on a "defense of publicly-known art" if the scope of the claims includes publicly-known art. At present, such issue is often determined not in terms of the framework of the requirements for equivalence but in terms of the establishment or nonestablishment of a defense of patent invalidity. There are few cases in which infringement under the doctrine of equivalents is denied on the grounds of non-fulfillment of the fourth requirement.
- This was first held in the Tokyo District Court decision of October 7, 1998, *Hanji*, No. 1657, at 122 (Load Device System Case), and similar determinations have been made in subsequent court decisions.
- In this regard, the following is stated in Iimura and Shitara, ed., *Chitekizaisan kanren soshō* (Intellectual property-related lawsuits): "The reason for requiring the first requirement is that if the second and third requirements alone are considered as requirements, the scope in which equivalence is established becomes excessively broad in relation to the point that the standard time for the determination of ease of replacement was defined as the time of

- infringement. Infringement under the doctrine of equivalents is denied based on the first requirement in many cases likely because the first requirement functions as a "restriction" on the expansion of infringement under the doctrine of equivalents.
- Regarding practice before the Ball Spline Bearing Case decision, the following is stated in Yoshifuji, Tokkyohō gaisetsu [dai 13 ban] (Overview on the Patent Act (13th edition)): "If art in which some of the constituent features of a patented invention are replaced with other elements (art expressed by a product or a process) is identical to the patented invention in terms of purpose as well as function and effect (function) (identity of function and effect or identity of function), the patented invention can be replaced with said art (replaceability) and a person ordinarily skilled in the art as of the filing date can naturally conceive of such replacement itself based on the statements of the structure of the patented invention (obviousness (ease) of replacement), said art is equivalent to the patented invention; the definition of equivalence indicated in court decisions and theories (commonly accepted theories) up until the present is almost the same as this."
- The interlocutory decision of the IP High Court of June 29, 2009, Hanji, No. 2077, at 123 (interlocutory decision on the Hollow Golf Club Head Case) can be considered to be the leading case of those decisions, and there have occasionally been IP High Court decisions in which the court made a determination concerning the second or third requirement before making a determination concerning the first requirement. Incidentally, in the first instance of the Hollow Golf Club Head Case, the court made a determination that dismissed the plaintiff's claims on the ground of non-fulfillment of the first requirement.
- In this regard, the following is stated in Iimura, "Tokkyoken no kintōshingai no seihi ni kansuru 2,3 no ronten" (A few points at issue concerning establishment or non-establishment of infringement of a patent right under the doctrine of equivalents), Patent 2014, vol. 67, no. 3: "There is no need to point out that there have been many court decisions that denied equivalence because lower courts applied the first requirement, 'the different part is not an essential part,' in a considerably extended manner immediately after the Supreme Court decision on the Ball Spline Bearing Case." In a note on this statement, it is stated that, "It is

- presumed that the cause also exists in that the 'non-essential part' requirement was set as the first requirement."
- In this regard, the following is stated in Iimura, supra Note 7: "Looking at actual practice, since the Supreme Court decision on the Ball Spline Bearing Case, the court rarely makes a determination concerning the fourth requirement in a case concerning equivalence, and there has been no court precedent in which the fourth requirement affected the conclusion. The reason for this is as follows. The exclusion of publicly-known art, etc. (fourth requirement), and a non-essential part (first requirement) have the commonality in that they focus on the comparison between publicly-known art as of the filing date of a patent application and the patented invention. However, as the first requirement has been conventionally applied in an expanded manner in practice beyond the purpose of its establishment as a requirement in the Supreme Court decision on the Ball Spline Bearing Case, there is no more room to deny equivalence through application of the fourth requirement."
- Regarding this reason, the following is stated in Tamura, "Saibanrei ni miru kintōron no honshitsutekibubun no ninteihōhō" (Methods of finding an essential part under the doctrine of equivalents that are seen in court decisions), Kurēmu kaishaku wo meguru shomondai (Kenkyūhōkoku dai 23 gō) (Problems in claim interpretation (research report No. 23)) (Central Research Institute of Intellectual Property of the Japan Patent Attorneys Association, December, 2008), 13: "The court prefers to take into account publicly-known art not in relation to the fourth requirement but in relation to the first requirement for the following reasons: If publicly-known art is taken into account in relation to the fourth requirement, it is necessary to examine whether the relevant claim fulfills the novelty and lack of ease of presumption requirements in comparison with the publicly-known art on the assumption that the allegedly infringing product is claimed in the claim, and there is a hurdle that equivalence can be denied for the reason of existence of the publicly-known art only if the fulfillment of said requirements is denied. However, in relation to the first requirement, publiclyknown art can be flexibly taken into account without such hurdle. However, such flexibility can be cut both ways with predictability, and it may restrict equivalence to an extent that is unnecessary."

- In this regard, the following is stated in Otomo, Bessatsu jurisuto tokkyohanrei hyakusen VIII [dai 4 han] (Jurist separate volume: 100 selected patent precedents VIII [4th edition]), 141, which was written as a commentary on the aforementioned interlocutory decision on the Hollow Golf Club Head Case: "Also taking into account the fact there is a difference in the interpretation of the requirement in the decision of prior instance and that in the decision in this case, the first requirement is considered to function as a requirement that is convenient for judges, which can be determined in any way depending on the anticipated conclusion of the court. As a result, the second and third requirements become relatively less important, and the desirable way of determination concerning equivalence will be questioned."
- For example, the court held as follows in the IP High Court decision of September 26, 2012, Hanji, No. 2072, at 106 (Medical Visible Image Generation Process Case): "If the applicant chooses to state a specific structure alone in the scope of the claims although another candidate structure is disclosed in the description and the applicant can easily state said other structure, application of the doctrine of equivalents to said other structure does not fulfill the fifth requirement for the doctrine of equivalents, and it should be considered to be impermissible to do so." This court decision is also cited in this case as a support for the appellant's allegation.
- Regarding the burden of allegation and proof for the fourth requirement, the following is stated in Mimura, Saikōsaibansho hanrei kaisetsu (minjihen) heisei jū nendo (jō) (Explanation on Supreme Court precedents (civil cases) fiscal 1998 (1)), 161: "It is considered reasonable to understand that if the other party first alleges and proves the existence of specific publicly-known art as of the filing of a patent application and then alleges non-fulfillment of requirement (4) in relation to said publicly-known art, the patentee is required to prove the fulfillment of requirement (4) ...." This idea is criticized as follows, for example, in Suevoshi, Bessatsu jurisuto tokkyohanrei hyakusen VIII [dai 4 han] (Jurist separate volume: 100 selected patent precedents VIII [4th edition]), 137: "From a general understanding of the burden of proof ..., the idea that a person who has the burden of allegation and the person who provides proof are separated is hard to understand"; "There is a question about the reasonability of the theory that the patentee

has the burden of proof for requirement (4) ...." Actually, it is a clear direction adopted in the past lower court decisions to consider that the patentee has the burden of proof for the first to third requirements while the defendant has the burden of proof for the fourth and fifth requirements, in the same manner as in the aforementioned Load Device System Case.

In this regard, for example, the following is stated in Tamura, supra Note 8: "Classifying constituent features into essential parts and non-essential parts without looking at the replacement embodiment of the alleged infringer can theoretically lead to making it necessary to assume quite a lot of replacement embodiments. It is nothing more than unnecessary work to study closely embodiments that are not related to the solution of the case, and the latter theory (the technical idea identity theory) that focuses on the replacement embodiment of the alleged infringer should be considered to be right." In this manner, there are many opinions that support the technical idea identity theory.

<sup>14</sup> For example, the Tokyo District Court decision of September 28, 2007 (2006 (Wa) 15809), available on the Supreme Court's website, is a court decision that denied the fulfillment of the first requirement based on such an idea. The IP High Court decision of September 8, 2008 (2007 (Ne) 10085), which was rendered on the appeal instance thereof, available on the Supreme Court's website, is also based on the

same idea.

The following is stated in Mimura, *supra* Note 12, 142: "In this decision, the court used the expression, the 'essential parts' of the patented invention, probably because it chose not to use the expression, 'identity of technical ideas,' in consideration of the criticism to the effect that 'Evaluating technical ideas as identical with each other is synonymous with finding equivalence, and citing identity of technical ideas as a requirement for equivalence causes a tautology." The author made it clear that he embraces the technical idea identity theory.

For example, it is considered that the same determination method was also adopted in an IP High Court decision of June 23, 2011, Hanji, No. 2131, at 109, in which the Court found infringement under the doctrine of equivalents.

In this regard, the following method is advocated in Makiyama, "Tokkyoshingaisoshō ni okeru kintōron no tekiyō" (Application of the doctrine of equivalents in patent infringement lawsuits), Patent 2012, vol. 65, no. 11; 41: "Regarding determination concerning the

fulfillment of the first requirement, [i] a determination is made as to whether a different part is a constituent feature that is related to the solution of the problem of the patented invention through comparison between the matters necessary to specify the invention (constituent features) of the patented invention and the means for solving the problem of the allegedly infringing product, [ii] if the different part is a constituent feature that is related to the solution of the problem of the patented invention, said constituent feature is made into a generic concept based on the matters stated or suggested in the description as of the filing of the patent application, and [iii] if the allegedly infringing product is included in the constituent feature that has been made into a generic concept, a determination is made on whether the principle for solving the problem (technical idea) that is understood from the structure that has been made into a generic concept is identical to publicly-known art.

In the aforementioned Medical Visible Image Generation Process Case, the court held as follows: "If the applicant chose to state only a specific structure in the scope of the claims despite the fact that he/she could easily state another structure, application of the doctrine of equivalents to said other structure does not fulfill the fifth requirement for the doctrine of equivalents, and it should thus be considered to be impermissible." However, in this case, the court found that a candidate for another structure was disclosed in the description. Therefore, it is not reasonable to regard the decision on this case as a court decision in which the court recognized the ease of conceiving of another structure as of the filing date as a ground for the fifth requirement, as a general theory.

The following is stated in Mimura, supra Note 12, 148: "If the applicant chose neither to include a structure in the scope of the claims as of the filing date nor to include it the scope of the claims through amendment in the application process though a person ordinarily skilled in the art can easily conceive of doing so, the applicant is considered to have intentionally excluded the structure from the scope of the claims in the patent application procedures or have behaved as if he/she is externally acknowledged so in relation to the requirement (5) (special circumstances, such as intentional exclusion) cited in this court decision, and such case is often considered to be the cases where there is a circumstance that prevents the establishment of equivalence."

The aforementioned Medical Visible Image Generation Process Case.

The following is stated in Mimura, *supra* Note 12, 144: "In the light of the fact that fulfillment of requirement (2) is determined in general terms to some extent on the basis of the statements in the description, it seems to be rather reasonable to determine first the fulfillment of requirement (2) (replaceability) and then determine the fulfillment of requirement (1) in determining the establishment of equivalence in relation to specific cases in practice."

In this regard, the following is stated in Iimura, *supra* Note 7, 135-136: "In practice, it is very difficult to determine the fulfillment of non-essential parts (first requirement), and it cannot be necessarily said that there is predictability. In order to eliminate inconvenience in this regard, even if only slightly, examination and determination concerning compliance with the second and third requirements, i.e. examination and determination concerning whether the replaced part of the defendant's product, etc., is 'replaceable or not' and 'easily replaced or not' under the technical level as of the time of infringement, should be conducted in advance."

<sup>23</sup> However, in an IP High Court decision of June 29, 2016 (2016 (Ne) 10017), available on the Supreme Court's website, which was rendered after the Decision, the court made a determination that equivalence is not established, based only on its determinations concerning the second and fifth requirements (although the first requirement also seems not to be fulfilled in this case). Incidentally, in an IP High Court decision of June 29, 2016 (2016 (Ne) 10007), available on the Supreme Court's website, which was rendered by the same panel on the same date, the court made a determination that equivalence is not established, based only on determinations concerning the first and fifth requirements. In this manner, the court also seems to consider that it is desirable to make a determination concerning the second requirement before making a determination concerning the first requirement. Therefore, the order of making a determination from the first to third requirements in the Decision is considered not to function as a clear constraint on the subsequent court decisions.

In this regard, the following is stated in in Iimura, supra Note 7, 136: "The subject of examination of replaceability (second requirement) is whether or not the principle for solving the problem (function and effect) of the

patented invention and that of the defendant's product can be evaluated as identical with each other. The essential and characteristic part of the patented invention in making a determination on non-essential parts (first requirement) has commonality in terms of the position in which the principle for solving the problem (function and effect) of the patented invention is placed. In that case, whether a part is a non-essential part should not be necessarily independently determined, and it is considered to be reasonable to determine it through comparison with other requirements (second and third requirements)."

In this regard, the following is stated in Mimura, supra Note 12, 143-144: "It is not reasonable to determine the fulfillment of requirement (2) while considering effects that are additionally recognized and functions and effects that are peculiar to working examples, as well as the solution of the problem, as the 'purpose' or 'function and effect' of the patented invention as mentioned in said requirement, from among the effects of the patented invention stated in the description. If the subject product, etc., is required to realize such additional functions and effects and effects that are peculiar to working examples, which go beyond the solution of the problem of the patented invention, in the same manner as the patented invention, there will be almost no room for the establishment of equivalence." In the present case, it is reasonable to consider a reduction of the number of steps as a secondary or additional function and effect associated with the finding of a new route for obtaining an intermediate into which a side chain having an epoxy group by an ether bond is introduced through one step.

In particular, regarding the trends of court decisions immediately after the Ball Spline Bearing Case decision, the following is stated in Tamura, supra Note 8, 13: "Whether publicly-known art that is taken into account when determining essential parts is limited to prior art that is disclosed in the description can become an issue. However, in many conventional court decisions, the court took into account publicly-known art without especially sticking to this point"; "It seems to be sufficient to discuss the relationship with such publicly-known art that is not disclosed in the description not in terms of essential parts but only under the hypothetical claim theory of the fourth requirement."

<sup>27</sup> In the aforementioned IP High Court decision of June 29, 2016 (2016 (Ne) 10007), available on the Supreme Court's website, which was rendered after the Decision, the Court found well-known art based on another publiclyknown document when making a determination concerning the first requirement and permitted the taking into account of prior art that was not stated in the description by ruling that, "What is stated in this description as a problem that could not have been solved by prior art is objectively insufficient in the light of the prior art. Therefore, the essential part of the invention in question should be found through comparison with the aforementioned wellknown art, which is prior art as of the priority date, in addition to the statements in the description."

In particular, regarding the trends of court decisions immediately after the Ball Spline Bearing Case decision, the following is stated in Tamura, *supra* Note 12, 13: "The fact that the applicant alleged, in response to a reason

for refusal that was issued on the ground that the invention is identical to prior art or an invention stated in the gazette of an earlier application, that adopting the claimed structure is the feature of the invention, with an amendment ... is taken into account in the direction of understanding that the product does not have the essential part if the structure is replaced with a different structure or a combination"; "According to a commonly accepted view, the fact might not have to be considered in relation to the essential part requirement, which is regarded as the statement of claim, and might suffice to be considered only in relation to the fifth requirement."

<sup>29</sup> The IP High Court decision of March 27, 2007 (2006 (Wa) 10052), available on the Supreme Court's website, is a court decision in which the court did not recognize the finding of an essential part based on the experimental data that was submitted at the time of the infringement action.