2 Desirable Ways to Examine and Implement Use Inventions

There is a growing need for claims regarding use inventions along with the progress in technology development in pharmaceutical and other technical fields and diversification of technical fields. This study aimed to categorize problems extracted from the previous year's study and sufficiently discuss desirable ways to examine and implement use inventions in Japan, thereby contributing to the process for revising the Examination Guidelines.

Use inventions are described with diverse claim expressions. The novelty of a use invention described by a product claim may be determined by distinction by use or distinction by form. Study was conducted as to "a claim of a raw material defined by the use thereof" and "limitation by use and property in the alloy field." As for a medical use invention that may not be described by a process claim, it was deemed to be appropriate to determine its patentability on the condition that either the product defined by the process or the use defined by the process is acknowledged as being novel. Study was also conducted regarding how to satisfy the description requirements including the enablement requirement and submitted pharmacological test data. Analysis was also conducted from the perspective of international comparison and of legal matters.

Ⅰ Background and Purpose of the 2004 Study

There is a growing need for claims regarding use inventions along with the progress in technology development and diversification of technical fields where patent protection is demanded. However, protection of a use invention differs among major countries, and multilateral conferences have been held with the aim of developing common guidelines for the interpretation and implementation of special claims including a claim defining a product by its particular use (product - by - use claim). Furtheremore, under the Examination Guidelines in Japan, there are no clear provisions on how to handle use inventions and only general guidelines have been provided. The various industries demand more concrete and easer-to-understand examination guidelines for use inventions.

As a recent movement in this respect, the "Task Force on the Protection of Patents of Medical-Related Acts" in the Strategic Council on Intellectual Property, in its arrangement as of November 22, 2004, indicated a major policy for the examination and implementation of use inventions. The study group also discussed the possibility of protecting pharmaceutical inventions as inventions of products in the form of claims for use inventions. Under such circumstances, the importance of use inventions will be intensified in the future.

In 2003, the "Study on the Examination and Implementation of Use Inventions in Major Countries" was conducted to specify problems relating to use inventions in individual technical fields, analyze judicial precedents, and understand the current practices at the patent offices in the United States and Europe. However, this study failed to adequately discuss desirable ways to interpret and implement use inventions in Japan, by pointing out existing problems based on the survey results and proposing solutions thereto. The study in 2004 aimed to discuss desirable ways to examine and implement use inventions based on the results of the 2003 study, thereby making it possible to start the process for revising the examination guidelines for use inventions.

Ⅱ Summary of the 2003 Study and the Purpose of the 2004 Study

1 Problems Extracted from the Results of the 2003 Study

In Japan, a use invention is an invention (which can be either an invention of a product or an invention of a process) based on a discovery of a new method of using a product focused on a particular property of the product. It may be described by a product-by-use claim, process claim, or use claim (a medical use invention cannot be described by a process claim or use claim). In the United States, a use invention is handled only as an invention of a process, and a medical use invention is described by a process claim. In Europe, a use invention in non-pharmaceutical fields may be described by a process claim or use claim whereas in the medical field, first medical use inventions are accepted in the form of product-by-use claims as an exception, and second medical use inventions are expressed in the form of Swiss-type claims.

In Japan, when the novelty of a use invention is examined, the provisions of the Examination Guidelines for Patent and Utility Model, Part II, Chapter 2 Novelty and Inventive Step 1.5.2(2) "Claim statements defining a product by its use (limitation by use)" shall be applicable. However, since the comments in the guidelines are abstruse and unclear, more concrete and easier-to-understand guidelines are desired.

The 2003 study focused on four technical fields—pharmaceutical, cosmetic/food, chemical and alloy fields, and extracted the following problems and needs.

[1] Pharmaceutical field

- Separately from conventionally known special use claims that are based on the wording in claims, there are special use claims that occur to avoid process claims relating to medical treatment.
- Examination guidelines are unclear with regard to the claim description requirements for inventions that are defined by a pharmacological mechanism called "R-receptor antagonism," that is, "R-receptor antagonist composed of compound X" and "therapeutic agent for disease Y composed of R-receptor antagonistic compound."
- In Japan, pharmacological test data on medical use inventions are required upon the filing of patent applications, and it shall not be accepted if it is submitted thereafter. The trilateral patent offices are not harmonized on whether it is allowable to submit pharmacological test data after the filing of patent applications in order to recover from the violation of the disclosure requirement.

[2] Cosmetics/food fields

- In the cosmetic/food fields, inventions created based on the discovery of a new function of a publicly known natural material are often expressed in agent claims. Forms of expressions of such claims should be unified.
- If an invention claimed as a "method of make-up" is judged to fall under the scope of "surgical, therapeutic or diagnostic methods," it shall be excluded from the scope of "industrially applicable inventions."

[3] Chemicals field

- There seem to be no practical problems.

[4] Alloy field

- The former Examination Guidelines by industry provided that the use (or property) of the invention must be described in the claim. In accordance with this provision, inventions relating to alloys are still claimed with limitation by use, irrespective of whether they are novel alloys or publicly known alloys.
- Where an invention relating to an alloy is claimed with limitation by its particular property, e.g. "heat-resistant alloy having a composition of…," the scope of right for the invention would be unclear and two or more use patents that are defined by properties or functions would be established with respect to an alloy with a particular composition/constitution.

2 Line of the 2004 Study

The 2004 study categorized the problems extracted from the 2003 study, by causes, into "problems arising from the existence of diverse claim expressions," "problems arising from the non-acceptance of process claims in the pharmaceutical field," and "problems relating to the description requirements."

[1] Diverse claim expressions

A use invention can be expressed as either "an invention of a product" or "an invention of a process." There are diverse types of claims, and this makes the interpretation of claims complicated. Problems also arise because claim expressions chosen by applicants according to their needs are often not accepted as they wish. In the chemical fields (including the cosmetic/food fields) and alloy field, it is unclear from claim expressions whether the claim expressions containing limitation by use signify a use invention or an invention of a new product with limitation by use. In the alloy field, there are inventions of products defined by property in addition to those defined by use, and this may cause problems in terms of the interpretation of claims. Consequently, the 2004 study focused on the following points.

① Existence of diverse claim expressions depending on the categories of inventions
② Approach to obtain patent by claiming a raw material defined by the use thereof in the materials industries
③ Limitation by property and use in the alloy field

[2] Non-acceptance of process claims

In Japan, surgical, therapeutic or diagnostic methods are not included in the scope of industrially applicable inventions, and a medical use invention cannot be claimed as an invention of a process. For this reason, most medical use inventions have been protected in the form of agent claims. However, as more applications are filed for inventions in the fields of medical technology and clinical studies where remarkable

progress has been made in recent years, problems arise from the non-acceptance of process claims for such medical-related inventions. This issue, which is only seen in the pharmaceutical field, was examined in the 2004 study.

[3] Problems concerning the description requirements

The amendment to the Examination Guidelines in 1995 eased the requirements for describing claims. However, the revised guidelines are unclear with regard to claim expressions for use inventions. Study was conducted as to whether or not there were problems in terms of the description requirements. In the pharmaceutical field, focus was placed again on the description requirements for agent claims such as "R-receptor antagonist composed of compound X" and "therapeutic agent for disease Y composed of R-receptor antagonistic compound." that recently appeared along with the discovery of disease-related genes and clarification of pharmacological mechanisms thereof (Section 36(6) of the Patent Law), as well as the requirements for the detailed description of the invention including pharmacological test data (Section 36(4)(i) of the Patent Law).

[4] Analysis from the perspective of international comparison and legal matters

Based on the results of the study of the problems mentioned above, analysis was also conducted from the perspective of international harmonization and of legal matters in the phases of the granting and enforcement of patent.

Ⅲ Diverse Claim Expressions Depending on the Categories of Inventions

As the criteria for defining use inventions and determining the novelty thereof, the comments in 1.5.2(2) of the Examination Guidelines should be further clarified, by explicitly distinguishing ② "a product that is to be used solely for the purpose," which seems to be directed to use inventions, from ① "a product that is particularly suitable for the stated use." Whether the claimed invention falls under ① or ② should be judged while taking into account the substance of the invention or technical idea. If the gist of the descriptions is questionable, third party confidence should be protected by broadly interpreting the scope of claims.

A use invention expressed in a product claim may be basically interpreted from two different perspectives. A use invention may be defined by the development of the new use of a product, and its novelty may be acknowledged if such use can be distinguished, based on the limitation in the claim, from the publicly known use of the product (distinction by use). A use invention may also be defined by the structure or form of a product that is particularly suitable for the stated use, and its novelty may be acknowledged if the product with such structure or form can be distinguished from the product with the structure or form that is suitable for other use (distinction by form). Although both perspectives have both good and bad points, it seems to be appropriate to adopt the theory of distinction by use if importance is to be basically placed on maintaining the conventional way of protection. On the other hand, if the aim is to correct the examination practices with the objective of achieving harmonization in the provisions of the Examination Guidelines, the theory of distinction by form may be adopted (in the non-pharmaceutical fields); however, in this case, sufficient explanation should be given to applicants and other parties concerned.

Under the theory of distinction by use, controversy may occur over the appropriateness of the method of judging whether or not the claimed use is different from the publicly known use based on the difference in terms of the "scope of application." In this respect, consideration should be given to allowing substantial examination as to whether or not it is possible to technically distinguish between the uses. On the other hand, should the theory of distinction by form be adopted, there might be no need to provide for "Claim statements defining a product by its use" [1.5.2(2)②] separately from "Claim statements defining a product by its function, characteristics, etc." [1.5.2(1)] under the Examination Guidelines. Another possible approach would be to acknowledge, in accordance with the theory of distinction by form, the novelty of a use invention as an invention of a product with a particular indication (e.g. a label), while regarding such indication as part of the form of the product, but this would not be appropriate as a general approach. Nevertheless, it may be unreasonable, at least in respect of a medical use invention, to always require substantial difference in the claimed invention from the publicly known invention as a product, while rejecting such constructive difference made by a particular indication.

"Agent claims," which are often adopted for use inventions, should be considered as a type of product claims, because it is difficult to adopt different criteria for determining the novelty of inventions described by agent claims. As for process claims (including use claims), it is reasonable to acknowledge the novelty if the claimed use can be distinguished from the publicly known use, irrespective of the criteria for product claims.

Ⅳ Problems in Individual Technical Fields and Solutions Thereto

A Patent Protection by Claimes of a Raw Material Defined by the Use thereof in the Materials Industries

In the case of a use invention relating to a publicly known substance Z, by claiming the invention as "product Y consisting of substance Z" the company that manufactures and sells product Y can obtain patent to directly protect its own product. Similarly, if the company that manufactures and sells a material product successfully obtains patent claiming the material with limitation by use for a use invention relating to its own product, by adopting a claim form that starts with the substance of its own product (e.g. compound Z for pesticide) or claim form that starts with the ingredient or composition consisting of the substance, the company can enforce the patent directly against its competitors (other materials manufactures). Such claim forms will satisfy the needs of manufacturers in the materials industries.

In Part II, Chapter 2, Section 1.5.2(2) of the current Examination Guidelines, which explains the criteria for determining the novelty, the comments concerning "compound Z for pesticide" are unclear because they set some conditions for the determination. Since "compound Z" is the proper name of a chemical substance and no adjective or modifier would change its chemical structure, it cannot be deemed to fall under ① "a product that is particularly suitable for the stated use." Consequently, it is necessary to examine whether or not it falls under ② "a product that is to be used solely for the purpose," but the Examination Guidelines indicate no concrete requirements and leave this issue to the determination by individual technical fields.

When a use invention is claimed as "an invention of a product," it is often expressed as an unspecified product for a specific use consisting of a specific product that is publicly known (e.g. composition for pesticide consisting of compound Z). When this approach is adopted, the scope of such unspecified product can be limited by the two specific requirements. However, the scope of "a substance with a proper name that is already specified," such as "compound Z," cannot be further narrowed. In this respect, study was conducted as to whether or not it would be appropriate to require the product, the use of which was limited in the claim, to be an unspecified product that was usually described with a general noun.

If a use invention can be distinguished by the form (e.g. type of agent), package or indication applied for or attached to the product, its novelty can be determined by examining whether or not it falls under ① above, but it may not be substantially distinguished from the product per se that is not defined by the newly discovered use. In such case where a use invention cannot be distinguished in terms of the structure of the product, its novelty is determined by examining whether or not it falls under ② "a product that is to be used solely for the purpose." In this respect, ② can be regarded as the criterion directed to use inventions. In this respect, consideration was conducted as to whether or not it would be appropriate to regard a use invention as "a product that is to be used solely for the purpose," if the claimed use could be distinguished from the publicly known use in terms of the scope of application of the product.

B Problems Arising from Limitation by Property and Use in the Alloy Field

Most inventions of materials are created as results of R&D activities that are aimed to bring about the targeted chemical or physical properties. In the alloy field, most inventions are created similarly, and they are claimed with limitation by "use" and "property." Following the previous year's study, the 2004 study examined the consistency between the meanings of these terms and the Examination Guidelines for limitation by use.

The concept of a use invention is not only applicable to particular fields, but some inventions in the alloy field also meet the developmental pattern of use inventions. Even from the descriptions of the claims or the specification, it is usually impossible to determine whether or not an invention relating to an alloy meets the developmental pattern of a use invention, i.e. "an invention based on a discovery of a new method of using a product focused on a particular property of the product." In the case of an invention relating to an alloy, the product is often defined by its use or property. Consequently, as in other technical fields, there are "inventions of patentable products for uses newly discovered" and "inventions of patentable products for common uses," and also "inventions of patentable products defined by the use" in the alloy field. In this respect, study was conducted as to whether it would be possible to appropriately express an invention in the alloy field, without describing the "use" of the product or by assuming that the product was not defined by the use.

Another question was how to interpret the wording of ② "a product that is to be used solely for the purpose," which is provided in the Examination Guidelines for limitation by use. This question was examined in terms of the consistency with inventions recognized as being novel because of the distinctive status of use, and the difference between inventions of compounds

and other inventions.

The current Examination Guidelines under which "property" is regarded as "use" are appropriate for examining inventions of alloys, but it is impossible to determine, by appearance, whether or not the description of the property defines the product. A proposal was made as to how to solve this problem under the Examination Guidelines, which are applicable to all technical fields.

C Problems Specific to the Pharmaceutical Field

Following the previous year's study, the 2004 study analyzed the causes of disparity between the substance of a medical use invention and its technical scope in the case of a patent relating to a medical use invention where a process element was present in the claim, and examined the possibility and limit for solving this issue.

The approach taken for this study was to analyze the claims for patented use inventions that had technical features relating to ways of using medicine. More specifically, the structure of the claim for each patented invention was analyzed and compared with the substance of the invention, and the results of the analysis and comparison were examined.

The results of the study can be outlined as follows. A patent relating to a medical use invention is defined by the product claim, and it consists of three elements, i.e. product, use, and process, with the use and process elements defining the invention of the product. However, due to lack of clear guidelines on how to define the technical scope of a medical use invention by the process element, the technical scope for such invention cannot be clearly defined, which causes instability to the right. Problems are also found in the way of claiming a medical use invention as an invention of a product while using such terms that are not directly relevant to the substance of the invention. A medical use invention is defined by the selected product and process, and therefore importance lies in the relationship between the invention and these elements. Although there are no clear provisions in the Examination Guidelines on how to handle each element in the claim of a medical use invention, the analysis of judicial precedents suggests that courts regard a use invention as an invention based on a discovery of a particular property of a product, and this implies that a use invention can be acknowledged as being novel if either the product or the use thereof is novel. The process element cannot be treated as a property of a product due to lack of clear provisions in the guidelines to that effect, but considering that any limitation of the process has a significant impact on the use, the process element and the use element should be regarded as being inseparable from each other in defining a medical use invention. A use invention should be acknowledged as being novel if either the product defined by the process or the use defined by the process is acknowledged as being novel. However, this approach does not seem to be applicable to the examination of patentability of all use inventions. There is also a view that the novelty of an invention of a product should only be determined based on the product or property thereof. Consequently, study should also be conducted as to how to protect medical use inventions that are defined by processes.

Ⅴ Problems Relating to the Description Requirements

The 2003 study pointed out that the current Examination Guidelines for use inventions were not sufficiently clear. The 2004 study took up the most suitable cases relating to use inventions in individual technical fields and clarified the interpretation and implementation of the Examination Guidelines, with the aim of proposing revisions to the guidelines for achieving high predictability and stability in the examination.

In the current Examination Guidelines, use inventions are addressed in Part II, Chapter 2, 1.5.2(2), but the provisions in this section indicate rules on how to determine the difference between products, and they cannot be directly applied to use inventions. It is rather necessary to provide for new guidelines specifically for use inventions by which the difference between use inventions relating to the same product is determined by the difference in the use of the product. If a use invention is considered to be an invention that includes a series of general ways of using the product, when it is modified by a special way of use of the same product, which is beyond the range of general ways of use, it can be expressed as an invention relating to a specific concept of use that is subordinate to the generic concept of use. For instance, an invention relating to a particular "usage or dose" of a medical product can be regarded as a selection invention relating to the use of the medical product.

Meanwhile, in order to prevent the granting of a patent for which the scope is not clearly defined, examples should be provided in the Examination Guidelines for individual technical fields in terms of expressions of the claims that clearly indicate that the claimed inventions are use inventions. A claim form that is expressed with a pharmacological mechanism should be deemed to be unclear unless it is obvious based on technical common knowledge that the product is to be used for treating a specific disease. Also,

a claim that is expressed only with the function or characteristics of a compound, without defining its structure, should be accepted only in the case where the invention cannot be expressed otherwise, and there should be no more exceptions.

Under the current Examination Guidelines that only require the descriptions of "how to use" and "how to make" an invention so as to satisfy the enablement requirement, it might be argued that it would suffice to give detailed instructions on how to make a trial of the invention. However, the support requirement should be implemented in addition to the enablement requirement in order to ensure a use invention will be sufficiently disclosed based on necessary pharmacological test data.

The author of this report recommends handling the support requirement separately from the enablement requirement, for the primary reason that the author believes that such separation will reasonably explain to what extent the pharmacological test data submitted after the filing of a patent application should be taken into consideration. Based on the recognition that whether or not an invention has completely been made should be the criterion for determining the satisfaction of the description requirements, the author suggests considering revisions to the guidelines in order to allow additional pharmacological test data to be submitted after the filing of a patent application to a certain extent, so that for a use invention that has already been completely made or satisfied, the support requirement will also be able to satisfy the enablement requirement.

Ⅵ Analysis from the Perspective of International Comparison

The 2003 study already presented international comparison in terms of patentability requirements. The 2004 study made further analysis from the perspective of international comparison regarding the Examination Guidelines for Medicinal Invention, which are under development for the first time at the Japan Patent Office (JPO). There is a difference between Japan and other countries in terms of the handling of the support and enablement requirements, and further discussion will be needed from the perspective of harmonization in this respect.

Ⅶ Analysis from the Legal Perspective

1 Positioning of Use Invention under the Japanese Patent Law

Although the discussion had yet to reach a specific recommendation and had only summarized basic issues, useful suggestions were made based on the analysis of the pharmaceutical field and other fields in this study. In the future, we should continue concrete discussion from the legislative perspective, while taking international harmonization into account.

2 Pharmaceutical Issues

(1) Study was conducted as to the interpretation and direction of the political consensus for granting patents to medicinal inventions as "inventions of products," which was indicated in the arrangement of the "Task Force on the Protection of Patents of Medical-Related Acts" in the Strategic Council on Intellectual Property. The necessity of providing by law the grounds for unpatentability and immunity for medical practitioners was also pointed out.
(2) Study was also conducted as to problems in the phase of the granting of patents for medicinal inventions (novelty/inventive step). It was deemed to be a reasonable approach, in the examination of a medicinal invention, to regard it as a use invention of a product, and then, if the medicinal invention could be defined by a technical idea relating to a process, determine the patentability of the medicinal invention by examining the novelty and inventive step of the invention as an invention of a product, rather than examining it by applying the condition of "surgical, therapeutic or diagnostic methods applied to the human body." As for a concrete method of evaluating a technical idea relating to a process, it was considered to be appropriate, in light of the significance of a use invention, to judge it by two structural elements, the product and the medical use.
(3) With regard to problems in the phase of the enforcement of patents for medicinal inventions, it was confirmed that uses other than that specified in the claim should be, in principle, excluded from the technical scope of the use invention. Study was also conducted as to joint direct infringement in the scope of direct infringement. As for indirect infringement, it was reported that according to the court judgment that had applied Section 101, Subparagraphs (ii) and (iv) of the Patent Law as amended in 2002, the scope of indirect infringement was broadened drastically.

3 Other Discussion

The 2003 study already examined legal matters on use inventions, including court judgments in Japan and the overall discussion on the scope of effect of patent. The 2004 study examined other legal matters that have emerged

as to how to treat medical-related inventions as use inventions (VII. 2 of this report). Furthermore, study was also conducted, based on the discussion on other issues in this report, as to whether or not there was any possibility that a use invention should be treated differently by law from a general invention in the granting phase and the enforcement phase or there was any reasonable grounds for such treatment, and what measures could be constructively taken should there be such possibility. The definition of a use invention applied in this report is based on the definition under the current JPO Examination Guidelines, "an invention based on a discovery of a new method of using a product focused on a particular property of the product" (Part II, Chapter 2 Novelty and Inventive Step, 1.5.2 Method of Construing Particular Types of Claim Statements: (2) Claim statements defining a product by its use (limitation by use)).

More specifically, legal study was conducted separately for the granting phase and the enforcement phase, focusing on the issues such as whether or not there was any possibility that a use invention, a specific type of invention, should be treated differently in the interpretation and application of the Patent Law, and if there was such a possibility, in what cases and in which direction the different treatment would be required. As for problems in the granting phase, study was also conducted on the special treatment of use inventions under the current Examination Guidelines in terms of the evaluation on the novelty requirement and the wording in claims, as well as the determination of other patentability requirements of use inventions and how to satisfy the enablement requirement by submitted pharmacological test data. As for problems in the enforcement phase, study was conducted from the perspective of the relationships between diverse claim expressions and categories of inventions, and the interpretation of the scope of effect of patent depending on the categories of inventions.

Conclusions of these studies can be summarized as follows.

In the course of the interpretation and application of the novelty and inventive step requirements for a use invention, it is required by law to appropriately evaluate a technical idea of the invention, focusing on the creativity in the use. In order to achieve this objective, clear provisions should be presented under the Examination Guidelines. However, such provisions will be designed rather flexibly and they will be less legally binding. How to satisfy the description requirements by submitting pharmacological test data should basically be considered not as an issue specific to medical use inventions but as medical-related inventions in general. Under the current Examination Guidelines, "use claims" are categorized fixedly as a type of process claims without clear legal grounds. Considering the enforcement phase, or the possibility that courts will interpret claims differently (e.g. regard a use claim as defining an invention of a product), there seems to be room for slightly relaxing the treatment under the Examination Guidelines.

Ⅷ Conclusion

Problems relating to the treatment of use inventions in Japan were more difficult to understand and solve than initially expected, and heated debates were seen for some of these problems. Although the discussion of some problems failed to reach a uniform conclusion, discussion was nevertheless so enthusiastic and deep that the subsequent results will be of great importance as references for future revisions to the Examination Guidelines and the improvement in the interpretation and implementation of use inventions.

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