

4 The Examination and Implementation of Use Inventions in Major Countries

Major patent offices have not conformed to each other in terms of the interpretation and implementation of special claims relating to a use invention, as represented by product-by-use claims and use claims. Especially in Japan, a variety of claim forms are admitted in relation to use inventions of a publicly known chemical compound or a composition, and there are thus many problems that are peculiar to each industrial field. With that, claim forms, requirements for patentability, judicial precedents, and the scope of the right for use inventions were organized, and problems with the examination and implementation of use inventions were extracted with respect to each industrial field with high needs for use inventions, through comparison with the results of overseas research in the United States and Europe. Specifically, there are the problem of special use claims in the pharmaceutical field, the problem of the description requirements for pharmacological mechanisms and pharmacological data, the particularity of examination in the cosmetic field, the problem relating to descriptions limiting a product by use in the chemical fields, and the problems of claims defining a product by property and overlapping rights in the alloy field. Solutions to these problems were considered. Toward international harmonization, problems were raised and proposals were given in relation to desirable ways to examine and implement use inventions in Japan.

I Purposes and Outline of the Study

The purpose of this study is firstly to clarify problems relating to the examination and implementation of use inventions, and secondly to make proposals for desirable ways to examine and implement use inventions in Japan based on the consideration of solutions to these problems.

In order to clarify problems, analysis was conducted on the overall picture of the requirements for patentability, judicial precedents, and the scope of the effect of a patent right in relation to use inventions. At the same time, four technical fields-the pharmaceutical, cosmetic/food, chemical, and alloy fields-were selected as major industries with high needs for use patents, and problems in each industry were extracted.

Next, research was conducted on the examination and implementation of use inventions in general in the United States and Europe respectively as well as on specific problems extracted in each of the above-mentioned technical fields, for the purpose of gaining an understanding of the present situation of examination and implementation in major foreign countries. Solutions to these problems were considered through comparison of examination and implementation in Japan, the United States, and Europe based on the overseas research results.

Incidentally, for this study, "inventions of which claims contain a description relating to some sort of use" in a broad sense, including inventions that are not purely use inventions, were defined as "use-related inventions."

II Use-Related Inventions

With respect to use-related inventions, differences in relevant provisions and in handling in examinations, appeal/trial decisions, and court decisions among Japan, the United States, and Europe, were considered from the viewpoint of the handling of "use inventions," novelty (including identity), inventive step, clarity, the enablement requirement, and the support requirements. Then, proposals were made with a view to harmonization that is defined as "one invention is provided with equal protection in Japan, the United States, and Europe."

Specifically, the following were proposed.

- (1) Product-by-process claims and product-by-use claims shall be handled in the same way, and shall mean a product suited to the limitation. On that basis, "a product shall not be novel unless its structure or composition is different from those publicly known." However, the pharmaceutical and cosmetic fields where process claims are not available shall be regarded as exceptions to this.
- (2) In the United States, there are many decisions of the lack of novelty due to inherency, for example, the one in the Claritin Case. But this point should be unified among Japan, the United States, and Europe.
- (3) With respect to limitation by a mechanism in use claims, a mere clarification of a mechanism shall not create novelty. However, the pharmaceutical field where process claims are not available shall be regarded as an exception to this, and limitation by a mechanism that is different from well-known mechanisms shall create novelty.

(4) Decision standards for the inventive step of a "product" or a "composition claim" should be unified among Japan, the United States, and Europe.

(5) For appropriate protection of inventions, clarity test in Japan shall be made to conform to that in Europe.

(6) In Japan, the requirement of "utility (though the meaning of the word is not clear)" shall be separated from Section 36(4) and it shall be integrated into the "industrial applicability" in the main paragraph of Section 29. On the other hand, the requirements of "how to use" and "how to make" shall be left in Section 36(4) to clarify provisions.

(7) The concept of "predictability" shall be introduced into the enablement requirement in Japan to create the appropriate standards.

(8) The handling of biological data shall be unified among Japan, the United States, and Europe.

III Judicial Precedents Relating to Use-Related Inventions in Japan

According to judicial precedents in Japan, the existence of use inventions (or use-related inventions) has been recognized, though "use invention" is considered to be a scholarly term. A generally accepted interpretation is that a use invention is "an invention that focuses attention on one property of a product and is to be used solely for a particular use based on the property, which has not been known in the past."

Regarding such use-related inventions, this report introduced relevant judicial precedents in relation to novelty, inventive step, and the description requirements for a specification, respectively. As for novelty, according to judicial precedents, even if a product is well-known or publicly known, it may be deemed to be patentable if its use involves novelty. In this report, consideration was also given to judicial precedents that ruled that incomplete inventions should not be deemed to have the effect of eliminating later applications. In addition, after introducing judicial precedents relating to the determination of the inventive step of use inventions, deliberation was conducted on a judicial precedent that found that the description of pharmacological test data is required for a medical use invention from the viewpoint of both the description requirements for a detailed description of the invention and those for the scope of claims, as a judicial precedence relating to the description requirements for a specification.

IV Scope of the Effect of a Patent Right for a Use-Related Invention

The basic idea of the scope of the effect of a patent right for a use-related invention was confirmed, and consideration was given on scholarly ideas and interpretations in judicial precedents. As for the interpretation of the scope of the effect of a patent right for a use-related invention, past discussions are considerably limited both in theories and judicial precedents. In the present circumstances, all of them, including specific problem-raising and theoretical analysis, do not go beyond ambiguous, fragmentary discussions.

Discussions through the following two stages are required in the process of delimiting the scope of the effect on the premise of a patent right for a use-related invention.

(i) Determining the correspondence of the claims of a patent right for a use-related invention to the categories of inventions under the Patent Law

(ii) Interpreting each claim of a use-related invention

It can be said that problems to be discussed exist in both stages. Needless to say, theories that should be applied in each stage can be said to be based on the framework of the Patent Law in general. However, since the details of how to reflect the particularity of use-related inventions have not yet been sufficiently worked out, a method for delimiting the scope of the effect of a patent right for a use-related invention still remains unclear. That is, it can be concluded that the greatest challenge is the point of how to clarify the interpretation standards for the stage of category classification and claim interpretation for inventions. In particular, the clarification of the interpretation standard of "how to interpret matters relating to use described in the claims of a use-related invention" and the provision of the legal grounds thereof are considered to be the largest challenges.

More generally, this means that further detailed review should be conducted on the point of whether there is some sort of gap between the handling (examination standards and implementation) of claim descriptions of a use-related invention at the stage of granting of a right and the idea of the claim interpretation of a use-related invention at the stage of exercise of the right or whether there is room for such a gap. On the condition that the possibility for such a gap arises, it should be brought into view to make possible appropriate adjustments to the handling at the stage of granting of the right (specifically, in the form of alterations in examination standards and implementation).

V Problems and Solutions Relating to Use-Related Inventions in Each Technical Field

A. Problem in the Pharmaceutical Field (I) Impact of Special Use Claims on the Medical and Pharmaceutical Industries and the Possibility of Solution of the Problem

Research and study were conducted on the actual conditions of special use claims in the pharmaceutical field. The examples of special claims that are affecting the industry of this field were collected, and their origins were analyzed. In cases where an application was transferred to the national phase in Japan claiming the priority of a corresponding European application or U.S. application, there are divergences between claims in Japan and those in Europe or the United States. Comparing these claims with the description of the essence of the invention in the specification of Japanese application or patent, claims in Japan were not considered to sufficiently cover the essence of the invention unlike claims in Europe or the United States. If these cases are divided into categories, there is a common tendency that claims are different from the essence of the invention when relating to a treatment method or a therapeutic use. In such cases, registration was made by product claims or process claims that are not relating to treatment. In addition, in many cases involving claims for treatment, a reason for refusal as stated in the main paragraph of Section 29 of the Patent Law was found in the examination process. Due to these results, it was considered that 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 treatment in the pharmaceutical field. It was thought that the use of process claims in the pharmaceutical field should be considered as a solution to these special use claims.

B. Problem in the Pharmaceutical Field (II)

First of all, comparative consideration was conducted on the question of how two inventions that are specified 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," are examined in Japan, the United States, and Europe. For the former claim, novelty may be denied in the United States, as the event "R-receptor antagonism" that occurs in vivo is considered to be inherent in compound X. In Europe, since the word "R-receptor antagonist" contains unspecified number of pathologic conditions and diseases to be alleviated, it is considered unclear. The latter claim is

considered unclear both in the United States and in Europe on the ground that it does not structurally limit the compound at all. Contrary to this, the Examination Guidelines in Japan do not indicate how to describe the names of diseases and pathologic conditions in the claims of a medical use invention. It is appropriate not to recognize an invention as one for medical use unless it is clearly stated that the invention is used for a particular disease that specifically appears as a human pathologic condition. For the latter claim, it is considered difficult to maintain clarity also in Japan. However, the collection of examples includes some examples that confuse this understanding. It is desirable to allow claiming an invention as a compound with "R-receptor antagonistic" action without specifying any specific compound only when the invention cannot be appropriately specified by expressions other than such, and not to make any exceptions.

Next, through comparative consideration on the question of whether it is allowed to submit pharmacological data to recover from the violation of the disclosure requirement in Japan, the United States, and Europe, it was confirmed that such submission is widely allowed in the United States while it is relatively difficult in Europe. However, how far such submission is allowed in Japan cannot be ascertained even by referring to the Examination Guidelines. Technical matters necessary for the description of the invention differ depending on the type of invention. For medical use inventions, "how to use" should be considered not as the enablement requirement but as the description requirement, and the submission of pharmacological data to cover deficiency in description of "how to use" should not be allowed. On the other hand, submitting test methods or data to recover from the violation of the enablement requirement should be allowed since it will help third parties consider the invention through comparison.

Due to the revision of Section 36 of the Patent Law in 1995 and the publication of the Implementing Guidelines, the freedom of claim description increased, and the unified Examination Guidelines across all industries were established. However, because of this, decision standards in examination rather became difficult to understand in the field of medical use inventions. In order to secure the high validity and predictability of examination results, it is desired that the standards are reasonable and clear as well as easy to understand. In addition, in examination, priority should be given to the protection of clear scope rather than the protection of broad and ambiguous scope.

C. Problems of Use Inventions in the Cosmetic/Food Fields and Consideration Thereof

In the cosmetic/food fields, there are many inventions created based on the discovery of a new function of a publicly known natural material. Such inventions are often described in product claims (agent claims) limited by use due to the problem of novelty arising if they are treated as inventions of product and the problem of industrial applicability arising if they are treated as inventions of process. Looking at recent examples of patent claims in the field in question, patents have been granted based on claims limited by use at various levels, from the specific effect that can recall the final product to an action mechanism of expression of an active substance. However, the examination standards for such use inventions, especially the decision standards for identity when comparing two or more uses, cannot be said to be clear in Japan. In addition, there is room for discussion on the validity of a form of expression called "agent claim."

In this overseas research, answer was received from both Europe and the United States that for the same active substance, novelty may be recognized in the second cosmetic use (whitening) even if the first cosmetic use (moisturizing) is publicly known. In particular, it was made clear that in the United States, the identity of the means and timing of application of an active substance has nothing to do with the determination of novelty and does not serve as a ground for refusal based on the inherency doctrine, with respect to a use invention that is expressed by a process claim. On the other hand, it was indicated that limitation by use based on action mechanism (inhibition of enzyme Z) would be refused due to inherency in the publicly known final use (treatment of disease Y). When considering two requirements for inherency (unexpressed claimed elements (i) necessarily exist in the prior art and (ii) are recognizable for persons skilled in the art) with reference to corresponding European practice, it can be said to be sufficiently realistic to adopt these requirements as decision standards in Japan. Here, "recognition" by persons skilled in the art should be made a requirement in principle both in determining the fulfillment of the requirements for patentability and in interpreting the technical scope after registration. However, it is possible to adopt the handling in which "recognition" requirement shall, exceptionally, not be applied to limitation by use based on action mechanism.

If the essence of a use invention exists in a process element, i.e. using an active substance that brings about a particular effect with the intent to achieve the effect, it is appropriate to directly express the process element by a process claim, and it is desirable to recognize that an invention of process for nonmedical treatment is industrially

applicable (as with the practice in Europe). In addition, it is considered desirable to further unify the forms of expression even though the current practice of agent claims is maintained at the moment.

D. Consideration Regarding the Protection of Use-Related Inventions in the Chemical Field

In the chemical field, there are considerable claim descriptions that refer to the use of a chemical substance relating to an invention. However, there are not so many applications for "use patent" in a strict sense. Thus, it seems that no very serious problems have occurred in practice even under the current Examination Guidelines relating to use inventions in Japan. If the Japanese Examination Guidelines are revised in the future to those closer to the practice in Europe and the United States from the viewpoint of international harmonization, it is desirable to ensure the freedom of claim description and to give consideration so as to keep room for the obtainment of rights for use inventions in the form of product claim.

E. Problems in the Alloy Field

The wording "property or/and use" is still described in many claims of applications in the alloy field for which the past Examination Guidelines by industry provided that "the property or/and use of the alloy must be expressed in the scope of claims."

Despite the fact that the wording described as matters specifying the invention plays an important role when determining the technical scope of the invention, the wording "property or/and use" may sometimes be interpreted several ways with respect to inventions in the alloy field, which were examined according to the current Examination Guidelines and granted patents. However, since there is no means of reasonably confirming how the examiner has understood the wording, gaps are easy to occur among the applicant's intent, the examiner's determination, and the third party's interpretation, which makes it significantly difficult to determine the scope of the right in the present circumstances.

In this report, the meaning of the descriptions of "property" and "use" as matters specifying the invention in the alloy field was verified on the basis of the Examination Guidelines, appeal/trial decisions, and judicial precedents in the past, and problems with determining the scope of the right by applying the current Examination Guidelines were indicated. In addition, a method of solving these problems by the same standards as for other fields was examined in consideration of the particularity of inventions in the alloy field.

VI Overseas Research Report

In the United States, use inventions are treated as processes (process claims), and claims limiting a publicly known substance by use (product-by-use claims) are examined as pure product claims, and are not deemed to involve novelty in the examination practice. In Europe, except in the pharmaceutical field, a discovery of a novel use of a publicly known product is not considered to give novelty to the product itself. Article 54(5) of the European Patent Convention is a special rule that allows product claims relating to the first medical use of a publicly known substance or composition. The discovery of the second medical use is deemed to involve novelty in Swiss-type claims (Article 54 is planned to be revised to protect the second medical use in the same way as the first medical use). Regarding use inventions in fields other than the medical field, both process claims and use claims are accepted in general.

Japan adopts the examination practice that permits claiming a publicly known product as a product limited by use, and there are thus various forms of claims, such as agent claims, process claims, and use claims. In the case where international harmonization is aimed at in the future, Japan, the United States, and Europe have to compromise with one another, and it is considered necessary to review in the future the decision standards for novelty for "2) a product that is to be used solely for the purpose" in the current Examination Guidelines. The following is a list of possible revisions of the Examination Guidelines.

(1) Accept only process claims for use inventions relating to a publicly known product, regardless of the industrial field, as with the United States (this seems to be impossible in the present circumstances).

(2) Permit claims in the form of limiting a product by use only in the medical field as an exception and accept only process claims for other fields, as with Europe (it is questionable whether such an exception is possible).

(3) Adopt the implementation that permits, as in the past, claims in the form of "pharmaceutical product for...", "cosmetic for ...," and "agent for ...," of which the term itself contains the meaning of use but deems claims that end with "compound," "composition," "resin," "alloy," or "material" to mean only raw materials and thus does not recognize them as claims limiting by use (definitions of terms are necessary).

(4) Accept only process claims and Swiss-type claims (an idea that avoids making an exception as mentioned in idea (2) and defining terms as mentioned in idea (3)).

(5) Adopt conventional implementation, and eliminate varieties in implementation and

interpretation among technical fields by making clear standards for "a product that is to be used solely for the purpose" (product-by-use claims are transmitted from Japan as claims based on a new concept).

VII Conclusion

The overseas research results revealed anew differences in handling claims limiting a product by use between the United States/Europe and Japan. In Japan, there are individual examination standards and examination practice with respect to each technical field, including pharmaceutical, cosmetic, chemical, and alloy fields, and different examination and implementation are carried out. This constitutes a main cause of the recognition that examination and implementation in Japan are unclear and vary depending on the industrial field. Numerous discussions seem to be still necessary in the future before a reasonable conclusion is drawn.

Next, there are considerable divergences between the United States/Europe and Japan in relation to the basic concept and implementation of use inventions (and use-related inventions). The main differences are in terms of (1) industrial applicability, (2) the description requirements, (3) the enablement requirement, and (4) examination, implementation, and interpretation of the right for products and processes limited by use, property, or function. It is considered necessary to conduct further concentrated considerations from the viewpoint of international harmonization and better protection with a view to legal revision in the future.

Setting aside the future direction of the Examination Guidelines and the revisions of relevant laws, this report pointed out various problems with examination and implementation in each of the pharmaceutical, cosmetic, chemical, and alloy fields, which are deep problems at present, and proposed a variety of solutions to them. It is considered necessary to develop these proposals into the revision of the Examination Guidelines in the future.

Although this research report left many problems, it delved into problems in promoting improvements in examination and implementation, and thus will serve as an informative source of information for further considerations in the future.

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