3 Patent Examination Practices (Description Requirements) —Description Requirements in the Biotechnology Field—

The description requirements for descriptions, etc. have been gaining attention in recent years. Given the various arguments going on concerning the description requirements, this study was carried out by a subcommittee on the Study on Description Requirements in the Biotechnology Field, which conducted examinations dedicated to the biotechnology field, and a subcommittee on Study on Desirable Descriptions, which conducted examinations without limiting the technical field. In the Study on Description Requirements in the Biotechnology Field, the relevant subcommittee investigated and examined court judgments and Board of Appeal decisions concerning description requirements in the biotechnology field and conducted a questionnaire survey and an interview survey concerning such requirements. Its aim was to identify any differences between the determinations on the description requirements in Japan and such determinations in Europe and the United States, in the biotechnology field, and to clarify the cause for such differences.

I Introduction

In discussions held by the Project Team on Protection and Utilization of Intellectual Property in the Life Sciences, which was set up in the Expert Panel on Management of Intellectual Properties, Council for Science and Technology Policy, it was pointed out that, in the biotechnology field, determinations on the description requirements in Japan may be stricter than those in Europe and the United States. However, no specific examples were given as to which aspects of Japanese description requirements were stricter that those in Europe and the United States, and the actual situation is not quite clear.

Thus, this study was conducted with the aim of identifying any differences between the determinations on the description requirements in Japan and such determinations in Europe and the United States, in the biotechnology field, and clarifying the cause for such differences.

II Comparative Analysis of Cases (Boards of Appeal Decisions/Court Judgments) in Japan, the United States and Europe

In this study, an investigation was first conducted on guidelines, etc. concerning the description requirements in the biotechnology field in Japan, the United States and Europe. In Japan, the ideas of the description requirements in the biotechnology field are indicated in "Biological Inventions," Chapter 2, Part VII in the "Examination Guidelines for Patent and Utility Model in Japan." In the United States, requirements, including the written description requirement and the enablement requirement, are explained using examples in the biotechnology field in the "Manual of Patent Examining Procedure" (MPEP). In addition, the "Synopsis of Application of Written Description Guidelines" provides explanations using specific examples of genes and antibodies. However, in Europe, the "Guidelines for Examination in the European Patent Office" and other documents provide no explanations dedicated to the biotechnology field, except explanations on deposit of biological material. Therefore, a comparative analysis of these guidelines is not enough to examine specific differences between the determinations in Japan and those in Europe and the United States, and the causes for such differences.

Accordingly, in this study, a comparative analysis was conducted on court judgments in Japan and the United States and decisions by the EPO Boards of Appeal that made

determinations on the description requirements in the biotechnology field, and determinations made in the examinations and boards of appeal decisions for the corresponding applications filed with other patent offices, while making reference to Japanese, U.S. and European guidelines.

1 Comparative analysis of major Japanese court judgments and determinations for the corresponding European and U.S. applications

Japanese Case 1 (2003 (Gyo-Ke) No. 220) is a case of a patent application relating to a composition comprising a combination of hepatitis C viral (HCV) antigens for detecting anti-HCV antibodies. In this case, the patent in question was invalidated in a trial for patent invalidation in Japan, due to violation of the enablement requirement. Further, in the subsequent litigation for rescission of the trial decision, the claim was dismissed and the trial decision of invalidation was upheld. However, the corresponding U.S. application was patented after an examination, although the patent claims slightly differed from those for which patent validity was disputed in Japan. As for the corresponding European application, the portion at issue was determined to satisfy the enablement requirement, and the patent was maintained. In this case, the determinations on the enablement requirement differed between Japan and Europe, although the claim statements of both applications included the same following expression: "antigen comprising an epitope from the ... domain." The difference in determinations on the enablement requirement concerning the outer limit of the invention, that is, whether it is necessary to specify all antigens comprising an epitope or it is sufficient to be able to screen them rationally, is considered to have derived different outcomes between Japan and Europe.

Japanese Case 2 (1998(Gyo-Ke) No. 95) is a case of a patent application relating to beta subunits of the T-cell antigen receptor in mammals. In this case, the patentability of the application in question was denied in Japan on the basis of violation of the enablement requirement in a trial against the examiner's decision of refusal, and this trial decision was upheld in the subsequent litigation for rescission of the trial decision. As for the corresponding U.S. application, the first Office Action was notified in the examination phase, but the applicant submitted a notice of appeal and declarations by experts. After subsequent interviews, the enablement requirement was found to be satisfied. Also for the corresponding European application, an opposition was filed after the decision to grant a European patent, and the patent was revoked due to lack of novelty and other grounds, but the enablement requirement was determined to be satisfied. In this case, Japan, the United States and Europe all determined that "it is doubtful whether all fragments are biologically active" at least once for the claim statement, "at least eight amino acids," but their final determinations were divided.

Japanese Case 3 (1997 (Gyo-Ke) No. 249) is a case of a patent application relating to the mammalian granulocyte-macrophage colony-stimulating factor (GM-CSF). The description contained only working examples of mouse GM-CSF, and claimed a mammalian GM-CSF gene. In Japan, the patentability of the application was denied for claims relating to DNA encoding mammalian GM-CSF, which were limited by the sequence, in a trial against the examiner's decision of refusal due to violation of the enablement requirement. In the subsequent litigation for rescission of the trial decision, the applicant submitted a Japanese translation of the declarations that were submitted in the United States, but the trial decision was upheld. With regard to the corresponding U.S. application, the first Office Action was issued in relation to violation of the description requirements. However, after amendments and submission of declarations by experts, the patent was finally granted for claims relating to DNA encoding mammalian GM-CSF without sequence limitations. In the case of the corresponding European application, the

patent was granted for claims relating to DNA encoding mammalian GM-CSF with sequence limitations.

Japanese Case 4 (1998(Gyo-Ke) No. 393) is a case of a patent application relating to peptides with natriuretic activity. The description at the time of the filing had contained statements on identification of human BNP and other matters, but its natriuretic activity had not been confirmed. In Japan, the applicant indicated in the opposition proceedings that a specific peptide included in the claimed peptides actually has natriuretic activity, and contended that the description of a later application filed by a third person at around the same time also contains statements to the effect that said specific peptide has natriuretic activity, but the patent was revoked on the basis that the invention was incomplete. This decision on opposition was upheld in subsequent court proceedings. However, the corresponding U.S. application was determined to satisfy the enablement requirement after interviews with the examiner and submission of declarations by experts, and was patented. The corresponding European application was also patented with no reasons for refusal as to violation of the description requirements. In this case, although there was the difference that the incompleteness of the invention was the point at issue in Japan and the enablement requirement was the point at issue in the United States, differences were found between Japan and the United States in whether or not experiment results and declarations by experts submitted after the filing were adopted.

Japanese Case 5 (2005 (Gyo-Ke) No. 10712) is a case of a patent application relating to a CDR-grafted antibody. In Japan, the patentability of the application was denied in a trial against the examiner's decision of refusal due to violation of the enablement requirement, and this trial decision was upheld in the subsequent litigation for rescission of the trial decision. With regard to the corresponding U.S. application, although the first Office Action was issued in relation to violation of the enablement requirement, the application was patented after a counterargument. The corresponding European application faced opposition on the basis of violation of the enablement requirement, etc., and the patent was revoked due to the addition of new matter without a determination on the enablement requirement. One cause for the different outcomes derived in Japan and the United States is that, in Japan, a detailed study was made as to the presence or absence of any deficiency in the theoretical or experimental support of the claimed invention by working examples.

In this manner, although the five Japanese cases examined in this study cannot be compared easily due to differences in the levels of appeal, it was found that the determinations in Japan tended to be stricter than the determinations in Europe and the United States.

2 Comparative analysis of major U.S. court judgments and determinations for the corresponding Japanese and European applications

U.S. Case 1 (Monsanto Co. v. Scruggs) is a case of a patent application relating to a chimeric gene, which is expressed in plant cells. In the United States, Monsanto, the patentee, sued Scruggs for patent infringement, and Scruggs asserted the defense of patent invalidity based on violation of the written description requirement and the enablement requirement. The Court of Appeals for the Federal Circuit (CAFC) determined that, although no specific DNA sequence was disclosed in the description, the written description requirement and the enablement requirement were satisfied because the sequences of CaMV promoters were well-known at the time of the filing and the CaMV strains could be acquired from the American Type Culture Collection. The corresponding applications in Japan and Europe were both determined to satisfy the description requirements, as in the United States.

U.S. Case 2 (Capon v. Eshhar) is a case of a patent application relating to a chimeric receptor in which a cytoplasmic domain and a transmembrane domain are joined to a different kind of extracellular ligand-binding domain. The Board of Patent Appeals and Interferences (BPAI) of the United States Patent and Trademark Office (USPTO) determined that neither the Capon patent nor the Eshhar application satisfied the written description requirement. However, the CAFC remanded the case, holding that the BPAI did not determine the statements in the description and the known science at the time of the filing. On the other hand, the corresponding Japanese application was patented without being subjected to any notice of reasons for refusal concerning violation of the description requirements. The corresponding European application was opposed on the basis of lacking sufficiency of disclosure, etc., but it was determined that the disclosure was sufficient, and this decision by the Opposition Division was upheld by the Board of Appeal.

U.S. Case 3 (University of Rochester v. G.D. Searle & Co. Inc.) is a case of a patent application relating to a method for selectively inhibiting PGHS-2 (COX-2) activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product. While the description contained statements on the method of evaluating the PGHS-2 activity, it contained no specific statements on the non-steroidal compound that selectively inhibits PGHS-2 activity. In the United States, the University of Rochester sued G.D. Searle & Co. Inc. and Pfizer, Inc. for patent infringement, but the CAFC determined that the patent was invalid due to violation of the written description requirement, since the patent did not provide any guidance for obtaining the compounds that can be used to carry out the claimed methods (compounds that selectively inhibit PGHS-2 activity) and there was no pre-existing awareness in the art of any such compound. In Japan and Europe as well, no patent was granted for a method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product.

In this manner, although the three U.S. cases examined in this study cannot be compared easily due to differences in the levels of appeal, it was found that the determinations by the U.S. CAFC concerning the description requirements were similar to the determinations in Japan and Europe.

3 Comparative analysis of major EPO Board of Appeal decisions and determinations for the corresponding Japanese and U.S. applications

European Case 1 (T 0973/03) is a case of a patent application relating to a composition used as a therapeutic agent against chronic viral hepatic diseases. The composition relating to the invention comprised a combination of a polypeptide sequence having one or more antigenic T cell-activating epitopes and a carrier capable of presenting the epitope sequence(s) bound to each other by covalent or hydrophobic bonding, and the description only contained working examples concerning hepatitis B virus (HBV). In Europe, a decision to grant a patent was made for the application, without being restricted to hepatitis B. However, in opposition proceedings, it was determined that the invention was enabled only for hepatitis B, and this decision on opposition was upheld by the Board of Appeal. With regard to the corresponding Japanese application, a patent was granted for claims as limited to treatment of hepatitis B, after a trial against the examiner's decision of refusal. The corresponding U.S. application was also patented after the claims became limited to treatment of hepatitis B. The determinations in Japan, the United States and Europe coincided in that they all found the invention to be patentable as long as it was limited to treatment of hepatitis B, but they differed as to the extent to which the "antigenic T cell-activating epitopes" and "carrier" needed to be specified in the patent

claims. The Japanese patent claims specified a narrower scope of antigenic T cell-activating epitopes than that in the U.S. and European patent claims, and contained more detailed limitations concerning the carrier than those in the U.S. and European patent claims.

European Case 2 (T 0446/99) is a case of a patent application relating to a neutralized polypeptide that can be used as vaccine ingredient against pertussis toxin. Although the description did not contain statements that the biological activity of the polypeptide as a vaccine has been confirmed, it contained working examples concerning the ability to bind to a toxin-neutralizing antibody and its ADP-ribosyltransferase activity, which serves as a marker of toxic activity. In Europe, an appeal was filed with the Board of Appeal against a decision by the Opposition Division to maintain the patent, but the Board of Appeal also determined that the enablement requirement was satisfied, based on the statement in the description. The corresponding Japanese application also faced a trial for patent invalidation, but was determined to satisfy the enablement requirement. The corresponding U.S. application was subjected to an Office Action concerning the enablement requirement, etc., but after making amendments to add claim limitations and making responses, the application was determined to satisfy the enablement requirement and was patented. In this case, the amino acid which substitutes the "arginine at the ninth position from the N-terminus" in the claim statement was not limited in Japan and the United States, but in Europe, it was limited to lysine, the same as that indicated in the working example.

In this manner, in the two European cases examined in this study, the scope of the patent claims in Japan was narrower than that in Europe for European Case 1, but the scope of patent claims in Japan was broader than that in Europe for European Case 2. Therefore, the determinations in Europe were not found to be consistently looser than the determinations in Japan.

III Description Requirements in Japan, the United States and Europe from the User Point of View

In this study, a questionnaire survey and interview survey were conducted to collect user opinions, given that there is the above-mentioned indication that, in the biotechnology field, determinations on the description requirements in Japan may be stricter than those in Europe and the United States.

1 Questionnaire survey

A questionnaire survey of domestic users was conducted on the following two topics for each technical field (physics, mechanical, chemical, biotechnology, electric, and information and communications), targeting regular member companies of the Japan Intellectual Property Association (JIPA):

(i) Differences between determinations on the description requirements in Japan and those in Europe and the United States for each technical field; and

(ii) Applicants' views on determinations on the description requirements in Japan for each technical field.

The results of the questionnaire survey showed that, in the biotechnology field, determinations on the enablement requirement and the support requirement in Japan tend to be stricter than those in Europe and the United States. However, the same tendency was observed for other technical fields as well, and it could not be concluded that the biotechnology field is the only field in which the determinations in Japan are stricter than those in Europe and the United States.

In addition, determinations on clarity in the biotechnology field in Japan were also stricter than those in Europe and the United States, similar to those in other technical fields. On the other hand, it was found that, in the biotechnology field, a higher percentage of applicants found the determination on clarity in Japan to be slightly looser than those in the United

States, compared to the other technical fields.

With regard to determinations on the description requirements in the biotechnology field in Japan, about 40% of the applicants responded that they found the determinations to be "problematic" or "rather problematic," indicating that the percentage of applicants who found the determinations to be reasonable is lower compare to the other fields. The reasons for finding the determinations to be problematic were mainly attributed to the determinations on the description requirements in Japan being strict, but there were a few applicants who found the determinations on the description requirements in Japan to be problematic due to being loose.

2 Interview survey

An interview survey of applicants (companies, universities and public research institutes) and patent attorneys was conducted with the aim of collecting detailed information concerning differences between determinations of the description requirements in the biotechnology field in Japan and those in Europe and the United States.

As a result of the interview survey, the major opinion on the determination of the description requirements in the biotechnology field in Japan, the United States and Europe was that the determinations in Japan were stricter than those in Europe and the United States, similar to the results of the questionnaire survey. However, some responded that, in the patent examinations in Japan, "the determinations are less varied between examiners" and "examiners point out violations of the description requirements in detail and in an easy-to-understand manner." With regard to certified experiment results, there was an opinion that "in Japan, certified experiment results, etc. submitted after the filing are less likely to be adopted as the basis for satisfaction of the description requirements, compared to Europe and the United States."

As for views on determinations of the description requirements in the biotechnology field in Japan, among company applicants, 36% found that the "determinations in Japan are reasonable" and 32% thought that the "determinations in Japan should be looser." On the other hand, among university and public research institute applicants, 50% thought that the "determinations in Japan should be looser" and none of the applicants found that the "determinations in Japan are reasonable."

As the points to note by applicants and patent attorneys in the biotechnology field, many respondents mentioned basic matters for satisfying the description requirements, such as "including plenty of working examples in the description at the time of the filing" and "sufficiently stating the specific modes of the invention in the description."

IV Handling of Certified Experiment Results, etc. with Regard to Description Requirements

When a reason for refusal has notified that the application is in violation of the description requirements in an examination of a patent application, applicants often counter by submitting certified experiment results relating to experiments that were not stated in the description, etc. at the time of the filing. In this regard, it was pointed out in the interview survey conducted in this study that, in the biotechnology field in Japan, when a reason for refusal has been notified to the effect that the application is in violation of description requirements, particularly in respect to portions other than the working examples that are included in the claimed inventions, certified experiment results are hardly adopted in the counterargument to such notice.

Thus, this chapter first reviews the enablement requirement and the support requirement in the biotechnology field in Japan, and then reviews the handling of certified experiment results with regard to violation of the enablement requirement or

the support requirement in Japanese examination guidelines and court judgments. Based on these, considerations are made on the cases where it would be appropriate to adopt certified experiment results as the basis for counterargument when violation of the enablement requirement or the support requirement has been given as a reason for refusal.

Comparing the enablement requirement and the support requirement, the two are alike in that a claimed invention may include portions other than the working examples that are stated in the description, as long as such inclusion is permissible based on the statements in the description, etc. and the common general technical knowledge at the time of the filing. However, the two differ in that the former prohibits a claimed invention that includes portions that may not be worked based on the statements in the description, etc. and the common general technical knowledge at the time of the filing, and the latter prohibits a claimed invention that includes portions exceeding the scope of statements that allow a person of ordinary skill in the art to recognize, based on the statements in the description, etc. and the common general technical knowledge at the time of the filing, that the task of the invention may be solved.

However, when the task of the invention is to provide a product that has a specific function, the "portions that may be worked based on the statements in the description, etc. and the common general technical knowledge at the time of the filing" in the former and "scope of statements that allow a person of ordinary skill in the art to recognize, based on the statements in the description, etc. and the common general technical knowledge at the time of the filing, that the task of the invention may be solved" in the latter would coincide.

In such cases, it would not run contrary to the statements in the examination guidelines or holdings in court judgments to adopt certified experiment results that have been submitted as the basis of counterargument against violation of the enablement requirement or the support requirement in respect to portions other than the working examples that are included in the claimed inventions and that relate to results of experiments conducted based on the statements in the description, etc. and the common general technical knowledge at the time of the filing.

Therefore, it would be appropriate, both for the case of the enablement requirement and the support requirement, to adopt certified experiment results that have been submitted as the basis of counterargument against violation of the enablement requirement or the support requirement in respect to portions other than the working examples that are included in the claimed inventions, if they relate to results of experiments conducted based on the statements in the description, etc. and the common general technical knowledge at the time of the filing.

V Summary

In order to keep the right of biotechnology-related inventions within a certain appropriate scope, while providing them full protection under patent law, the description requirements will continue to be important in the future. This is because, while such patentability requirements as novelty and an inventive step indicate the attitude of patent law on how to deal with overall inventions, the description requirements, such as the enablement requirement and the support requirement, are intended for granting a patent for the scope which the inventor possesses and keeping the right based on the statements of the claims within an appropriate scope supported by the disclosure in the description.

This study found basic commonalities in practices and operations in Japan, the United States and Europe, but at the same time, it also found some cases where outcomes differed between them. Although a conclusion should not be derived easily without making detailed considerations of the invention

background, technical contents, and the common general technical knowledge relating to each case, such differences found in this study are expected to provide important suggestions for future studies.

Granting of right of the appropriate scope is extremely important for the development of industry. By accumulating studies on the significance and function of the description requirements in the future, it would become possible to grant a right of the scope suitable for inventions relating to various biotechnology achievements.

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