# Chapter 1 Requirements for Description

## Section 1 Enablement Requirement (Patent Act Article 36(4)(i))

### 1. Overview

The purpose of the patent system is to encourage inventions by promoting the protection and the utilization of inventions and thereby to contribute to the development of industry (Patent Act Article 1).

The patent system is designed to promote protection of inventions by granting an exclusive right, i.e., a patent right, under predefined conditions for a predefined period of time to a person who has developed and disclosed novel technology or techniques, and to give third parties an opportunity to gain access to the inventions by virtue of disclosure of technical details of the inventions. Such a protection and utilization of inventions are promoted through the description, claims and drawings (hereinafter referred to as "description, etc.") which serve both as a technical document that discloses technical details of inventions and as a document of title that clearly defines the technical scope of patented inventions.

Article 36(4) provides the requirements for the description. Among items of the paragraph, Article 36(4)(i) mainly stipulates the requirement for the description so as to serve as the technical document. If the statement in the description is not clear, its role of the disclosure is undermined, which in turn undermines the very purpose of the patent system. In this sense, Article 36(4) is a very important provision.

Article 36(4)(i) requires that "in accordance with Ordinance of the Ministry of Economy, Trade and Industry, the statement shall be clear and sufficient in such a manner as to enable any person ordinarily skilled in the art (Note) to which the invention pertains to work the invention." The requirement that the statement be "in accordance with Ordinance of the Ministry of Economy, Trade and Industry" as stated in Article 36(4)(i) is referred to as the Ministerial Ordinance requirement (see “Section 2 Ministerial Ordinance Requirement”), and the requirement that the statement be "clear and sufficient in such a manner as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention" as stated in the same item is referred to as "the enablement requirement." This Section deals with the enablement requirement.

(Note) Throughout this Part, the term "a person ordinarily skilled in the art to which the invention

pertains to work the invention" means a person assumed to be one who has the common general knowledge in the technical field of the claimed inventions at the time of filing and satisfies the following conditions (i) and (ii) (hereinafter referred to as "a person skilled in the art" in this Part.):

(i) being capable of using ordinary technical means for research and development (including document analytics, experimentation, analysis, and manufacture); and

(ii) being capable of exercising ordinary creativity such as selection of materials and modification of design.

## 2. Basic Ideas of Determination of Enablement Requirement

(1) **The statement in the description must be so clear and sufficient that a person skilled in the art can carry out the claimed invention.**

Article 36(4)(i) requires that "the statement shall be clear and sufficient in such a manner as to enable any person ordinarily skilled in the art to which the invention pertains to work the invention." The term "to work the invention" in the above provision means "to carry out the claimed invention".

It should be noted that it does not constitute a failure to comply with enablement requirement that inventions other than the claimed invention are not stated sufficiently to meet the enablement requirement, or that extra matters which are unnecessary for carrying out the claimed inventions are stated in the description.

(2) **If a person skilled in the art who intends to carry out the claimed invention cannot understand how to carry out the invention on the basis of teachings in the description and drawings relevant to the invention as well as the common general knowledge (Note) at the time of filing, such a description is regarded as being insufficient for the person skilled in the art to carry out the invention.**

Also, if it is necessary to make trials and errors, and/or complicated and sophisticated experimentation beyond the extent to which a person skilled in the art should be reasonably expected to do so as to find out how to carry out the invention, then such a description is regarded as not being described to such an extent that the person skilled in the art can carry out the invention.

(Note) The term "common general knowledge" refers to the art generally known to a person skilled in the art (including well-known art and commonly used art) or matters obvious from empirical rules. Accordingly, the common general knowledge includes methods of experimentation,

analysis, and manufacture, and technical theories, etc., as far as they are generally known to a person skilled in the art. Whether or not a certain technical matter is generally known to a person skilled in the art should be determined based upon not only the number of documents that describe the matter but also the degree of attention given to the matter by such a person.

The term "well-known art" in this context refers to the art generally known in the technical field such as those described below:

(i) the art, with regard to which, there exist a significant number of publications (see "Part III, Chapter 2, Section 3 Procedure of Determining Novelty and Inventive Step," 3.1.1), or Web pages, etc. (see “Part III, Chapter 2, Section 3 Procedure of Determining Novelty and Inventive Step”, 3.1.2);

(ii) the art widely known in the relevant industries; or

(iii) the art that are known in the technical field so widely that there is no need for providing specific examples thereof.

The term "commonly used art" refers to well-known art that is widely used.

(3) The section titled "description of embodiments" usually contains statements of an invention in order to explain in such a manner that the invention can be carried out by a person skilled in the art. If necessary, specific embodiments are described in "examples" section (see Form 29 relating to Rule 24 of the Regulations under the Patent Act). Examples are specific illustrations of the modes for carrying out the invention.

The examples do not need to be provided in cases when the invention can be explained without using the examples in such a manner as to enable a person skilled in the art to carry out the invention based on the statements in the description and drawings as well as the common general knowledge at the time of filing.

## 3. Detail of Determination of Enablement Requirement

### 3.1 Determination depending on categories of invention

The examiner, based on the identification of the category of the claimed invention (Note), determines whether or not the statements in the description satisfy the enablement requirement.

(Note) There are three categories: an invention of a product, an invention of a process, and an invention of a process for producing a product (Article 2(3)).

### 3.1.1 Invention of a product

In regard to an invention of a product, carrying out the invention means making and using the product in question. Therefore, the description must be stated in such a manner as to enable a person skilled in the art to produce and use the product. Specifically, it must comply with the following requirements (1) to (3).

(1) Clear explanation of the invention

To satisfy this requirement, it is necessary that a person skilled in the art can identify an invention from the recitation in a claim, i.e., a claimed invention can be identified, and understand the invention from the statement in the description.

For example, in a case of an invention of a chemical compound, an invention is normally regarded as being clearly explained when the chemical compound as such is recited in the claim either by the name of the chemical compound or by its chemical structural formula.

Each of the claimed elements (Note) must be stated in the description such that the claimed invention can be understood from the elements as a whole without a contradiction among them.

(Note) The term "clamed elements" refers to "matters necessary to specify the invention for which a patent is sought" (see "Chapter 2 Section 1 Patent Act Article 36(5)").

A claim may recite an operation, function, characteristics or properties of a product (hereinafter referred to as "function, characteristics, etc." in this Part) instead of its specific features such as a shape, structure or composition, etc. (hereinafter simply referred to as "structure, etc." in this Part). Meanwhile, it should be noted that, even in this case, the description must state specific features such as a structure of the product. However, this is not the case when a person skilled in the art can understand the specific features which bring a function, characteristics, etc. based on the description and drawings as well as in light of the common general knowledge at the time of filing.

(2) Statement that enables the product to be made

The way to make the product must be concretely stated in the description. However, this is not the case when a person skilled in the art can make the product

based on the statements in the description and drawings as well as the common general knowledge at the time of filing.

In a case where a claim defines a product by its function, characteristics, etc., and such function, characteristics, etc. are neither standard nor commonly used by a person skilled in the art, the description must state the definition of such function, characteristics, etc., or the method for testing or measurement for quantitatively determining such function, characteristics, etc. in order to state sufficiently for the claimed invention to be carried out.

When the claimed invention pertains to a technical field where it is difficult to predict the structure, etc. of a product from its function, characteristics, etc., and a person skilled in the art cannot understand, even though the statements in the description and drawings as well as the common general knowledge at the time of filing are taken into account, how to make the product defined by its function, characteristic, etc., the statement in the description fails to comply with the enablement requirement, except for products, manufacturing methods of which are concretely stated in the description, or products which can be made from the products stated concretely taking into account the common general knowledge. For example, this is the case when a person skilled in the art who intends to carry out the invention would have to make trials and errors and/or complicated and sophisticated experimentation beyond the reasonably expected extent.

Example: R receptor activating compounds obtained by a specific screening method

(Explanation)

The description does not include any statements as to chemical structures or manufacturing methods of R receptor activating compounds other than the novel R receptor activating compounds X, Y, and Z disclosed as examples, and there is no other clue that infers the chemical structure, etc. Therefore, the enablement requirement is not satisfied.

Also, it is required to state a function, or a role each claimed element has (namely, its operation) when a person skilled in the art needs such information for making the product.

On the other hand, when a person skilled in the art can make the product based on the statements of the structure, etc. illustrated as an example or the common general knowledge at the time of filing, the examiner should not determine that it

constitutes failure to comply with the enablement requirement even in the absence of a statement as to the manufacturing method thereof.

(3) Statement that enables the product to be used

The way of using the product must be concretely stated in the description. However, this is not the case when a person skilled in the art can understand how to use the product without an explicit statement, on the basis of the statements in the description and drawings as well as the common general knowledge at the time of filing.

For example, in a case of an invention of a chemical compound, it is necessary to state at least one particular technically significant use of the compound in order to show that it can be used.

When an invention pertains to a technical field, such as chemical compounds, where it is relatively difficult to understand how to make and use a product on the basis of their structures or names, normally, one or more representative examples are necessary for the description to be stated such that a person skilled in the art can carry out the invention. In addition, in a case of a use invention, e.g., medicine, examples supporting the use in question are usually required.

Also, it is required to state a function, or a role each claimed element has (namely, its operation) when a person skilled in the art needs such information for using the product.

On the other hand, absence of the statement of a use of the product does not constitute failure to comply with the enablement requirement in a case when a person skilled in the art can use the product by taking into account statement of the structure of the invention disclosed as an example and the common general knowledge at the time of filing.

3.1.2 Invention of a process

Since that an invention of a process can be worked implies that it is possible to use the process in question, the description must be stated such that the use of the process is made possible. Specifically, the description must comply with the following requirements (1) to (2).

(1) Clear explanation of the invention

To satisfy this requirement, it is necessary that an invention can be identified from a claim, i.e., the claimed invention can be identified, and can be understood from the statement in the description.

(2) Statement that enables the process to be used

There are various types of inventions of a process other than those for producing a product (so-called "pure process"), such as a method for using a product, a measurement method, and a controlling method, etc. For any type of them, the description must be stated such that a person skilled in the art can use the process on the basis of the statements in the description and drawings as well as the common general knowledge at the time of filing.

3.1.3 Invention of a process for producing a product

If an invention of a process falls under "an invention of a process for producing a product," then that the process can be used implies that it is possible to produce the product by the process. Accordingly, the description must be stated such that it is possible to produce the product by the process. Specifically, the description must comply with the following requirements (1) and (2).

(1) Clear explanation of the invention

To satisfy this requirement, it is necessary that an invention can be identified from a claim, i.e., the claimed invention can be identified, and can be understood from the statement in the description.

(2) Statement that enables the product to be produced by the process

Various types of inventions of a process for producing a product exist such as a method for manufacturing a product, a method for assembling a product, and a method for processing a product, etc. Any of these methods consists of three factors of (i) a starting material, (ii) process steps therefor, and (iii) a final product. With regard to an invention of a process for producing a product, the description must be stated in such a manner as to enable a person skilled in the art to produce the product by using the process. Accordingly, these three factors must be, in principle, stated in such a manner that a person skilled in the art can produce the product based on the statements in the description and drawings as well as the common general knowledge at the time of filing.

Among these three factors, however, statements of the final product may be

omitted in a case where the final product may be understood by a person skilled in the art from the statements of the starting material and the process steps. For instance, an exemplary case of this exception will be a method for assembling a simple device, wherein structures of its components do not change during the process steps.

### 3.2 Types of violations of enablement requirement

#### 3.2.1 Improper statement of embodiment

(1) Abstract and/or functional statement of technical means

The statement in the description does not satisfy the enablement requirement when:

(i) technical means corresponding to the claimed elements is stated merely in an abstract and/or functional manner in the description, and thus a material, apparatus, and/or steps, etc. therefor are unclear; and
(ii) a person skilled in the art cannot understand the material, apparatus, and/or steps, even in light of the common general knowledge at the time of filing, as a result of which such a person cannot carry out the claimed invention.

(2) Unclear relation between technical means

The statement in the description does not satisfy the enablement requirement when:

(i) relationship between individual technical means corresponding to claimed elements is unclear in the statement of the embodiment; and
(ii) the relationship between the technical means cannot be understood even in light of the common general knowledge at the time of filing, as a result of which a person skilled in the art cannot carry out the claimed invention.

(3) No statement of numerical values such as manufacturing conditions

The statement in the description does not satisfy the enablement requirement when:

(i) numerical values such as manufacturing conditions are not stated in embodiments; and
(ii) a person skilled in the art cannot understand the above numerical values such as manufacturing conditions even in light of the common general knowledge at the time of filing, as a result of which such a person cannot carry out the claimed

invention.

3.2.2 Violation of enablement requirement because of part of claimed invention, which cannot be carried out, other than embodiments

(1) Cases where a claim is directed to a generic concept but embodiments only of a part of more specific concepts encompassed by the generic concept are stated in the description in a manner that only the specific concepts can be carried out

The statements in the description do not satisfy the enablement requirement when:

(i) a claim is directed to a generic concept but embodiments only of a part of more specific concepts encompassed by the generic concept are stated in the description in a manner that only the specific concepts can be carried out; and

(ii) there is a well-founded reason to find that other specific concepts encompassed by the same generic concept are not stated clearly and sufficiently in such a manner as to enable a person skilled in the art to carry out the invention of the other specific concepts based solely upon the embodiments directed to the specific concepts stated even in light of the common general knowledge at the time of filing. It should be noted that methods of experimentation and analysis may be included in the common general knowledge.

Example1:

A case where a claim recites "a method for manufacturing a synthetic resin molded product comprising molding synthetic resin and then performing a correction to eliminate distortion," while the description states, as an embodiment, only a process wherein thermoplastic resin is extrusion-molded and then distortion is eliminated by heating and softening the obtained molded product. When the process for the distortion correction by heat softening is found to be inappropriate for a molded product made of thermosetting resin, i.e., a rational reasoning can be established that the distortion correction of the embodiment is inappropriate for thermosetting resin in view of the technical fact that thermosetting resin cannot be softened by heating, the statement of the description fails to comply with the enablement requirement.

(2) Cases where only a particular embodiment is stated in such a manner that a person skilled in the art can carry out the claimed invention

The statement in the description does not satisfy the enablement requirement when:

(i) only a particular embodiment is stated in the description in such a manner that only that embodiment can be carried out; and

(ii) there is a well-founded reason to find that, because of the fact that the particular embodiment is a singularity included in the claimed invention or any other similar reasons, a person skilled in the art would be unable to carry out the other parts of the claimed invention even when the statements in the description and drawings as well as the common general knowledge at the time of filing are taken into account. It should be noted that methods of experimentation and analysis may be included in the common general knowledge.

Example:

A claim is directed to "a lens system for a single-lens reflex camera comprising a lens type consisting of three lenses wherein the lenses are placed in order of a positive, a negative and a positive lens from the object side, wherein an optical aberration of the lens system being corrected so as to be equal to or less than X% in image height h." The description states, as an embodiment, an example of specific combination of refractive indices of three lenses, or in addition thereto a specific conditional formula for the indices so that the particular optical aberration correction can be done.

In the technical field of optical lenses, a technical fact is known that a specific combination of refractive indices, etc. which embodies a particular optical aberration is of singular nature. In addition, that particular statement such as the example of refractive indices or conditional formula and the like do not teach any generalized manufacturing conditions. Thus, a rational reasoning can be established that a person skilled in the art would be unable to understand how to carry out the other parts of the claimed invention other than embodiments stated even when taking into account methods of experimentation, analysis and manufacture generally known to such a person.

(3) When a claim is expressed by the Markush grouping or defined by a result to be achieved, see 5.1 or 5.2, respectively.

## 4. Examination Procedure for Determination of Enablement Requirement

## 4.1 Notice of reasons for refusal

### 4.1.1 Notice of reasons for refusal regarding enablement requirement

When the examiner determines that the statement in the description fails to comply with the enablement requirement under Article 36(4)(i), he/she notifies a reason for refusal. In the notification of reason for refusal, the examiner identifies a claim related to an invention which cannot be carried out and makes clear that the reason for refusal is not a failure to comply with the Ministerial Ordinance requirement but a failure to comply with enablement requirement under Article 36(4)(i). If applicable, the examiner points out particular statements in the description or drawings which constitute the violation of the enablement requirement. The examiner specifically explains the reason why he/she determines that the claimed invention fails to meet the enablement requirement, while showing the grounds for such a determination, e.g., a part of the statement in the description and details of the common general knowledge at the time of filing that he/she has taken into account when making the determination. The examiner is also required to set forth in the notification, to the extent possible, such a clue, e.g., the extent to which the claimed invention can be carried out, that the applicant understands the appropriate strategy for an amendment that should be made in order to overcome the reason for refusal.

For example, it is not appropriate for the examiner to state the reasons for refusal as stated in the following items (i) or (ii) without specific explanation of the reasons, because this may make it difficult for the applicant to present effective arguments and understand the amendments to be made to overcome the reasons for refusal.

(i) The reason only reads as follows: "Even by taking into account the common general knowledge at the time of filing, the description cannot be regarded as stating the invention clearly and sufficiently as to enable any person skilled in the art to carry out the invention," without any other information.

(ii) The statement of the reason reads that the description cannot be regarded as stating the invention clearly and sufficiently as to enable any person skilled in the art to carry out the claimed invention solely relying upon the common belief that "it is difficult to predict in the relevant technical filed."

Further, it is preferable that the reason is presented with citation of a reference document to the extent possible. In principle, only documents which are

known to a person skilled in the art at the time of filing may be cited. However, descriptions of later applications, certificates of experimental result, written oppositions for a patent right, and written opinions submitted by the applicant for another application, etc. can be referred to for the purpose of pointing out that the violation stems from inconsistency between the statements in the description or drawings and a scientific or technical fact generally accepted by a person skilled in the art.

4.1.2 Relation between enablement requirement and support requirement (See "Chapter 2 Section 2 Support Requirement" for the support requirement in detail)

The purpose of the enablement requirement is to prevent a patent from being granted for an invention which cannot be carried out by a person skilled in the art. Under the patent system, an exclusive right is given for an invention, under predetermined conditions for a predefined period of time, to a person who discloses the invention as a compensation for the disclosure. If the statement in the description is not clear and sufficient for a person skilled in the art to carry out the invention, the description cannot play a role of disclosure. Therefore, it is determined whether or not the claimed invention would be carried out by a person skilled in the art on the basis of the statement in the description.

On the other hand, the purpose of the support requirement is to prevent a patent right from being granted for an invention which is not made available to the public. Claiming an invention that is not stated in the description would incur granting a patent for an undisclosed invention. To avoid such a consequence, it needs to be determined whether or not a claimed invention is supported by the description.

As mentioned above, both requirements are different in their purposes and also in determination thereof. Hence, it should be noted that a violation of one of the two requirements does not necessarily mean a violation of the other. With these in mind, the examiner determines whether or not the description and the claims satisfy each requirement.

4.2 Arguments and/or explanation, etc. by applicant

In response to a notice of reasons for refusal involving failure to comply with the enablement requirement, the applicant may present an argument, explanation, etc. by submitting a written opinion, certificate of experimental results, and the like.

For example, the applicant may, in a written opinion, point out the common general knowledge, etc. at the time of filing other than those that were taken into account by the examiner when making a determination, and argue that, in light of such common general knowledge, the statement in the description can be regarded to be clear and sufficient enough for a person skilled in the art to carry out the claimed invention. The applicant may also submit a certificate of experimental results to support such an argument presented in the written opinion.

However, when, due to an insufficient statement in the description, the statement in the description cannot be regarded to be clear and sufficient in such a manner as to enable a person skilled in the art to carry out the claimed invention even in light of the common general knowledge at the time of filing, the reason for refusal cannot be overcome even though the applicant submits a certificate of experimental results after filing of the application to make up for such a deficiency and thereby argues that the statement is clear and sufficient.

### 4.3 Response by examiner to argument and/or explanation, etc. by applicant

When the examiner has been convicted that the statement in the description satisfies the enablement requirement in view of the argument, explanation, etc. (see 4.2), the reason for refusal is resolved. Otherwise, the examiner renders a decision of refusal on the basis of the notified reason for refusal to the effect that the statements in the description do not meet the enablement requirement.

## 5. Claims Including Specific Expressions

### 5.1 Markush grouping

The description fails to comply with the enablement requirement when a claim includes alternatives written with the Markush grouping, only a part of which is stated in the description, and there is a well-founded reason to find that a person skilled in the art would be unable to carry out the rest of the alternatives even when taking into account the statements in the description and drawings as well as the common general knowledge at the time of filing. It should be noted that methods of experimentation and analysis may be included in the common general knowledge at the time of filing.

Example:

The claimed subject matter is a method for manufacturing para-nitro-substituted benzene by nitrating a starting compound of substituted benzene, wherein a substituent group (X) is recited in an alternative form as $CH_3$, OH, or COOH. The description only states, as a working example, a case where the starting compound is toluene, i.e., X is $CH_3$. If a rational reasoning can be established that such a method is inappropriate when the starting compound is benzoic acid, i.e., X is COOH, in view of the technical fact that, for example, considerable difference in the orientation between $CH_3$ and COOH exists, the statement in the description does not satisfy the enablement requirement.

5.2 Definition of product by result to be achieved

The description fails to comply with the enablement requirement in a case where, although a claim recites a definition of a product by a result to be achieved, only a particular embodiment is stated in the description in such a manner that a person skilled in the art can carry out such an embodiment, and there is a well-founded reason to find that a person skilled in the art would be unable to carry out the remaining parts of the claimed invention even when taking into account the statements in the description and drawings as well as the common general knowledge at the time of filing. It should be noted that methods of experimentation and analysis may be included in the common general knowledge at the time of filing.

Example:

"A hybrid car, energy efficiency of which while running on electricity is a% to b%, as measured by an X test method" is recited in a claim, but the description only states an embodiment in which such a hybrid car comprises a particular controller for obtaining the above-identified energy efficiency.

In addition, it is common general knowledge at the time of filing in the technical field of hybrid cars that the above-mentioned energy efficiency is normally about x%, which is far lower than a% and it is difficult to realize higher energy efficiency, such as a% to b%. Furthermore, the statement of the hybrid car comprising the particular controller fails to teach a general solution for achieving the above-mentioned high energy efficiency. Accordingly, the rational reason may be established that a person skilled in the art would not be able to understand how to implement the remaining parts of the claimed invention even when the common techniques in the

relevant technical field are taken into account.

## 6. Points to Note

In the following cases, the enablement requirement is not satisfied only when, in accordance with 3. and 5. above, the description is determined to be not stated clearly or sufficiently as to enable a person skilled in the art to carry out a claimed invention.

(i) Cases where the statements in the description are unclear since they are not accurately stated in the Japanese language (including improper translation)

This includes the following: unclear relation between the subject and the predicate of a sentence, unclear relation between a modifier and the modified word, errors in punctuation, errors in characters (wrong character, omitted character, false substitute character), and errors in reference signs.

(ii) Cases where terms are not used consistently through the description, claims and drawings

(iii) Cases where terms are neither academic terms nor technical terms that are commonly used in academic or technical documents and have no definition in the description

(iv) Cases where trademarks are used for what can be indicated otherwise

(v) Cases where a physical quantity in the description is not indicated in units provided for in the Measurement Act

(vi) Cases where the brief description of the drawings (explanation of drawings and reference signs) has deficiency in relation to the description