

## Overview of Examination Guidelines at the Japan Patent Office

Ariga International Patent Office seeks to provide our clients with as much information as possible regarding the procedures under which applications are examined by the Japan Patent Office (JPO), so that our clients understand what is involved in drafting an application that stands the best chance of being granted as seamlessly as possible.

Much of what makes a strong application is making sure the application fits within the Examination Guidelines of the JPO. On September 18, 2015, the JPO published their updated "Examination Guidelines for Patents and Utility Models" and "Examination Handbook for Patents and Utility Models". In this overview, we will first describe the basic concepts used by the JPO in determining whether a patent or utility model application conforms to the Patent Law or the Utility Model Law. Afterwards we will briefly cover how the updated/revised "Examination Guidelines for Patents and Utility Models" and "Examination Handbook for Patents and Utility Models" have affected the preparation of applications and techniques used to respond to Office Actions. In April 2018, the JPO published a revised edition of the "Handbook for PCT International Search and Preliminary Examination in the Japan Patent Office". An English version of this handbook can be found on the JPO website ([https://www.jpo.go.jp/tetuzuki\\_e/t\\_tokkyo\\_e/pct\\_handbook\\_e.htm](https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pct_handbook_e.htm)).

This overview will be broken down into several sections, each of which explains the basic concepts behind various aspects of how patent and utility model applications are handled at the JPO.

Section I. Description and Claims Requirements

Section II. Unity of Invention

Section III. Industrially Applicable Inventions

Section IV. Determination of Novelty and Inventive Step

## I. Description and Claims Requirements

### A) Description Requirements (corresponding to Article 36(6) (i) of the Patent Law)

The invention stated in the claims is compared to the invention described in the detailed description (explanation) of the invention. This is referred to as *Support Requirements*. There must be a substantial correspondence between the invention in the claims and the invention in the detailed description. The expressions used to describe the relationship between both must be consistent and the elements necessary to solve the problem must be recited.

The application is examined as to whether the invention described in the claims exceeds the scope described in the detailed description of the invention and as to whether the claims reflects the means for solving the problem(s) described in the detailed description of the invention.

When the content disclosed in the detailed description of the invention cannot be expanded nor generalized to the scope of the claimed invention, the description is considered to be in violation of the support requirements.

### B) Claims: Clarity Requirements (Corresponding to Article 36(6) (ii) of the Patent Law)

A person skilled in the art must be able to clearly define the invention from one claim in order to determine whether there is novelty and inventive step, and in order to understand the technical scope of the invention.

If the claim contains statements which are unclear or ambiguous (including clerical errors) which make the scope of the invention unclear, technically incorrect statements, or the category of the invention is unclear, the description is considered to be in violation of the clarity requirements.

Note that, terms such as "use"/"utilize" denote processes.

If the claim describes matters specifying the invention which are not related to one another, the claim is considered to be in violation of the clarity requirements.

For example: "A transceiver transmitting a specific encoded signal" only shows the function of a transceiver, and there is

no relation between the transceiver and the encoded signal.

Claims containing expressions such as "except", "slightly", "much", "easy to", "hard to", claims containing only one of the upper limit or the lower limit of a substance, or claims containing expressions where the scope cannot be identified, such as "essentially", "substantially", "about", etc., make the scope of the claimed invention unclear.

Claims containing optionally additional matters or selective matters, such as "If necessary", "when desired", etc., are considered to be in violation of the clarity requirements. However, if the optionally additional matters are stated so that it is understood that they are optional, the scope is clear, and if the selective matter can be understood to mean a generic concept, the scope is clear.

Claims containing a numerical limitation in which zero (0) is included, i.e., "from 0% to 15% Ca", are unclear, as is a claim which refers to a drawing (as drawings tend to be ambiguous representations).

The claim should describe the invention based on the invention's characteristics, properties, functions, etc. If these cannot be clearly understood, the claim is considered to be unclear.

#### C) Claims: Enablement Requirements (Corresponding to Article 36(4) (i) of the Patent Law)

A person skilled in the art could carry out the invention on the basis of the description of the features in the description and drawings.

For example, if the invention pertains to a process or method for manufacturing or producing a product, a person skilled in the art should be able to use the process or method to manufacture or produce the product without having to resort to unnecessary trial and error or an unreasonable amount of complicated experimentation to do so.

How the product may be used must also be described, and in the case of the invention of a chemical substance, the purpose

of the substance must be described.

Describing the technical means in a functional or abstract manner, failing to clearly describe the correspondence between the technical means which form the invention, and failing to describe the specific numerical values associated with the production and testing of the invention shall be deemed to be violations of the enablement requirement.

Additionally, if the claim is not supported in the detailed description of the invention, it is considered to be in violation of the enablement requirements.

The above would include the cases when the claim is directed to a general concept, while only a narrow concept is described in the detailed description of the invention; the case when the claim is described in Markush-form, but only the mode to carry out part of the dependent claims is described in the detailed description of the invention, or the case when the claim describes a product defined by the result or effect obtained by a specific mode is described in the detailed description of the invention.

In summary, if the invention is

- 1) a product, then there must be a description that enables the product to be made and a description that enables the product to be used,
- 2) a process, then, there must be a description that enables the process to be used, or
- 3) a process for producing a product, then there must be a description that enables the product to be produced by the process.

#### D) Claims: Conciseness Requirement

The applicant should seek to balance the Clarity Requirements with some standard of brevity in order to facilitate the understanding of the invention by a third party. Should the claims contain numerous statements essentially repeating the same contents; the statements will be deemed to be excessively redundant. This shall not apply to cases when the "repeated contents" are indispensable matters for satisfying the patentability requirements or description requirements.

If the claims are expressed as alternatives, as is often

the case for chemical compounds and pharmaceutical compositions in Markush-type claims, the number of alternatives should not become so great that it is no longer possible to envision the invention due to a loss of conciseness.

## II. Unity of Invention

Two or more inventions which are to be the subject of a single application must be recognized as having a technical relationship to each other (among each other). It must be obvious that the inventions are "linked so as to form a single, general inventive concept by having the same or corresponding special technical features among them" (Japan Patent Office).

The special technical feature(s) must make a contribution over the prior art, and the contents of the description, claims and drawings and the common general knowledge as of the filing date of the application are reviewed by the Examiner in order to determine the above.

Some examples of claims which are deemed to have the same special technical feature is as follows:

[Claim 1] A metallic particle (a substance having improved strength and durability properties).

[Claim 2] A surface coating material composed of the metallic particle.

The metallic particle is a special technical feature which is judged to make a contribution over the prior art. The inventions claimed in claims 1 and 2 have the same special technical feature.

[Claim 1] A pharmaceutical product made by adding X to Z.

[Claim 2] A pharmaceutical product made by adding Y to Z.

While claim 1 and claim 2 include different technical features (X or Y), both claims are directed to solving the same unsolved problem (making a pharmaceutical product), and thus, have the same special technical feature.

It may be deemed that it is efficient to examine other inventions of the application along with the inventions having the same or corresponding special technical feature. These other inventions must include all matters specified in the invention according to claim 1. These other inventions must be inventions which can be examined without having to conduct an additional prior art search.

### III. Industrially Applicable Inventions

An invention is defined as being "an advanced creation of technical ideas utilizing the laws of nature" (Japan Patent Office)

The basic concept is that by applying a law (or laws) of nature, a novel technical idea can be created which leads to the advancement of technological thought and innovation. The claimed invention as a whole must utilize a law of nature.

An invention is examined to make sure that it is not in itself or the result of any of the following:

- a law of nature or counter to the laws of nature.
- an artificial arrangement which does not utilize a law of nature, a mental activity, the use of a law other than a law of nature, etc.
- a personal skill such as being able to juggle which is acquired through personal experience and practice.
- the discovery of a new organism existing in nature.

Examples of the above include, but are not limited to a language for programming a computer; a business method or a mathematical method for calculating a total cost by multiplying a subtotal by a tax rate in the absence of a hardware resource; a sculpture or painting; and the simple presentation of information.

A. In Japan, a method for treating a human body by surgery, therapy, and diagnostic methods practiced on a human body are NOT industrially applicable.

Surgery includes cosmetic surgery which is not therapeutic and the preparation and procedures prior to surgery, i.e., anesthetics.

Therapeutic treatments include a method for injecting or administering medicine for treatment or prophylaxis of disease, and therapy. This also applies to methods of preventative medicine, such as receiving a fluoride dental treatment.

Diagnostic methods include measuring the internal or external conditions of a patient in order to determine the physical health of a patient.

While a medical device and a medicine itself may be patentable, the operation of the medical device or the actual use of the medicine generally is not patentable. The device or medicine must not be deemed to be methods of treatment

If it is specifically indicated that the invention is practiced on animals which do NOT include human beings, the invention may be industrially applicable.

The JPO has deemed that a method for treating a sample, such as blood, urine, cells, etc., which was extracted from a human body and methods for obtaining data by analyzing the sample are not "methods of surgery, therapy or diagnosis of humans", unless the sample is to be returned to the same human body after being processed, then the method does correspond to "methods of surgery, therapy or diagnosis of humans". This would include dialysis or the application of skin grafts obtained from the same human body.

However, the following cases (1-4) are not deemed to be "methods of surgery, therapy or diagnosis of humans", even if the sample is to be returned to the same human body, and hence, may be patentable:

- 1) Method for manufacturing a medicinal product such as a vaccine, a genetically modified formulation, or a blood preparation utilizing a raw material(s) obtained from a human body.
- 2) A method for manufacturing an artificial medical material which is can be substituted for a part of the human body, such as an artificial bone, etc., utilizing a raw material(s) obtained from a human body.
- 3) A method of manufacturing an intermediate product(s) for a medicine or a medical material, such as the methods for the induction or purification of cells, utilizing a raw material(s) obtained from a human body.
- 4) A method of analyzing a medicine or a medical material, or an intermediate product(s) thereof which is manufactured utilizing a raw material(s) obtained from a human body.

Additionally, methods for obtaining information by



measuring the functions or the structure of the organs in a human body are not considered to be methods of diagnosis unless they include the steps of judging the physical condition of the human body; the mental condition of a human; or treatment/surgery plans related to these conditions. Thus, a method for obtaining an image of an internal organ by X-rays may be patentable.

Other inventions which are not deemed to be patentable include, but are not limited to methods for contraception and delivery of a child, methods for the drawing of blood, methods for transplanting or implanting artificial internal organs or artificial limbs, and methods for preventing disease.

B. Inventions which were created for personal use, academic, or experimental purposes, and which are clearly commercially inapplicable also are not industrially applicable inventions.

C. Inventions which are not practical, such as a Dyson sphere, are not industrially applicable inventions.

D. Computer Programs (software) are patentable as products, and generally, the criteria that the invention be the creation of a technical idea utilizing a law of nature is satisfied by "concretely realising the information processing performed by the software by using hardware resources". To put it simply, there must be a readily understandable connection between the computer program (software) and the hardware system of the computer.

## Section IV. Determination of Novelty and Inventive Step

### Novelty (Article 29(1) of the Patent Law)

If an invention was publicly known, publicly worked, and described in distributed publications, or made publicly available through a mode of telecommunications in Japan or other country prior to the filing of the patent application of the invention in question, the invention is generally deemed to NOT possess novelty.

#### I. How the JPO determines novelty.

The JPO performs an investigation to initially interpret the claimed invention and determine what is actually described in the invention(s) cited in the prior art or cited by an International Searching Authority (ISA) in an International Search Report (ISR). Then the claimed invention is compared with the cited invention(s) to determine the similarities and differences.

#### Interpretation of the Claimed Invention

The descriptions in the claims are the basic material by which the claimed invention is to be understood; however, as the terms stated in the claims are defined further in the description and the drawings, they should also be examined to provide a deeper understanding of what is being claimed.

#### Determination of what the Cited Invention(s) describes

Publicly known facts, common general knowledge, inventions and matters described in the publication are used to determine whether the cited invention is a publicly worked or known invention and whether a person skilled in the art can or cannot manufacture the product or use the process described in the cited invention.

The Examiner(s) compare all of the features of the claimed invention with those of the cited invention(s) to determine the features which are identical and which are different. If no differences are found, it is deemed that the claimed invention is not novel. If the features of the claimed invention are described as an alternative, and none of the alternatives are

different relative to the cited invention(s), it is deemed that the claimed invention is not novel. An example of an alternative would be a Markush-type formula with a multiple dependent claim in which two or more other claims are cited, or claims in which statement such as "a carboxyl group having 2 to 24 carbons".

Note:

If the patent application is filed within six (6) months (grace period) of the introduction of the invention by the inventor in a printed publication, through electronic communication means, or in a written presentation to a scientific organization designated by the JPO, the disclosure of the invention against the inventor's or right holder's will, or the display of the invention at certain types of exhibitions, the invention of the patent application may still possess novelty. Any of the above cases are referred to as Exceptions to Lack of Novelty of Invention.

In this case, it is necessary to submit documents proving that the disclosure was made in such a manner which corresponds to one of the abovementioned exceptions. Such a document and its Japanese translation must be submitted within 30 days from the filing of the application (with the exception of disclosure against the will of the inventor(s) or right holder(s)).

However, if the invention is publicly known or worked, or described in any publication, the invention shall be deemed to lack novelty under Article 29(1) of the Japan Patent Law. For example, an oral explanation of the invention without a confidentiality agreement between the parties will result in the invention being considered as prior art, and will be covered by the six-month grace period.

#### Use of the six-month Novelty Grace Period

A request for a six-month grace period may be requested for 1) a PCT application designating Japan with the request for the grace period being made when the application enters the Japanese national phase, or 2) a patent application directly filed with the JPO prior to six-months from the disclosure which would destroy

the novelty of the invention.

Novelty Part II (Article 29-bis of the Patent Law)

A claimed invention of an application filed after a previous application which discloses the same invention (no new technical matter) was filed is unpatentable, regardless of when the previous application was published. The filing date serves as the basis which determines that the previous application is that which may be patentable.

The same is true in the case when there is a difference between the claimed invention and the previous application, but it is judged to be a minor difference, and thus, the two inventions are substantially identical.

The above shall not apply in the cases when the same inventor(s) and/or the same applicant(s) filed the claimed invention and the previous application.

## Inventive Step (Article 29-2 of the Patent Law) Non-Obviousness

If a person skilled in the art would have easily made, conceived of, or arrived at the claimed invention on the basis of the cited invention(s), the claimed invention is unpatentable.

A person skilled in the art is any person who comprehends the technical elements in the state of the art, possesses the skill of what is deemed to be general common knowledge and the skill to use the ordinary technical means in research and development in the art to which the invention pertains at the time the application was filed. A person skilled in the art is one who has the creativity to anticipate simple changes in design and has the ability to select basic materials, both of which do not contribute to inventive step.

### Process for determining inventive step by a person skilled in the art

The claimed invention is examined for an inventive step after the presence of novelty has been determined. A publicly known and worked cited invention(s), which may also include non-patent literature, such as academic documents, brochures, etc., is sought using the description of the claim (in the case of patent literature) or using the defining matters which define the invention or discovery stated in the academic documents, etc. This cited invention(s) is compared with the claimed invention.

The Examiner searches for common grounds in the matters defining both the claimed invention and the cited invention. The wording and phrasing of the matters may differ, yet, still remain virtually identical to each other, and this shall be stated in the development of the reasoning. The Examiner attempts to provide reasoning that a person skilled in the art would have easily arrived at the claimed invention on the basis of the similarities to the cited invention(s).

The judgment of whether the cited invention involves an inventive step, which is an effect beyond that which would be anticipated by a person skilled in the art, is performed based on the reasoning that the person skilled in the art would have easily produced the claimed invention on the basis of the cited invention is made by ascertaining what the person skilled in the

art would do based on their understanding of the state of the art in the field to which the application of the cited invention pertains. This is referred to as the "reasoning".

The reasoning itself can be derived from numerous aspects including small changes made to the cited invention to arrive at the claimed invention, and understanding the cause or motivation by determining how the fields, problems, functions, suggestions in the cited invention, and advantageous effects are related between the cited invention and the claimed invention.

A) Small changes and modification of design

If it can be judged that the difference between the claimed invention and the cited invention is merely a small change such as the selection of a more optimal material or an optimal range to which a composition is added or a temperature at which a reaction is performed, a modification to the design, or a simple aggregation of features contained in the cited invention which a person skilled in the art could have easily conceived of, then the claimed invention shall be deemed to lack an inventive step.

B) Motivation

If it can be judged that the claimed invention merely applies a technical means to a field which is clearly related to that in the cited invention, and hence, is merely the exercise of the normal creative abilities of a person skilled in the art, then the claimed invention shall be deemed to lack an inventive step. The same is true if it is deemed that the problem to be solved is obvious based on the cited invention.

If it can be shown that the application of one cited invention to a second cited invention due to the similarity of technical fields or the problem(s) to be solved would easily result in the claimed invention, then the claimed invention shall be deemed to lack an inventive step.

Example 1. Motorcycles and automobiles are both related to the technical field of vehicles which comprise engines, thus applying a publicly known fuel control valve for a motorcycle in an automobile would be easily done by a person skilled in the art.

Additionally, the problem of regulating the flow of fuel is common in both motorcycle engines and automobile engines.

The fact that the technical field and/or problems to be solved are similar or related serves as motivation for combining a cited invention with a second cited invention to arrive at the claimed invention. Thus, the claimed invention would not comprise an inventive step.

If the problem to be solved by the invention is an obvious problem which could be easily solved by a person skilled in the art, then the claimed invention shall be deemed to lack an inventive step. For example, merely attempting to produce a product at a lower cost and with fewer steps is obvious and is a general problem of all methods and inventions. A person skilled in the art could apply a cited invention which was produced at a lower cost and with fewer steps to a second cited invention to achieve the same goal, and thus, arrive at the claimed invention.

#### C) Function

If it can be judged that the claimed invention has the same mode of operation and function as that of the cited invention(s), then the claimed invention shall be deemed to lack an inventive step.

Example 2. Cited invention 1 is equipped with an outlet for spraying a liquid for cleaning a tube and Cited invention 2 has a tapered nozzle for directing a cleaning fluid towards a glass surface to be cleaned. There is little difference between the outlet of Cited invention 1 and the tapered nozzle for directing a fluid towards a glass material to be cleaned of Cited invention 2, thus, the Examiner can reason that converting an outlet into a tapered nozzle is within the range which would be easily conceived of by a person skilled in the art.

#### D) Suggestions

If it can be judged that the claimed invention was actually suggested in the cited invention, then the claimed invention shall be deemed to lack an inventive step. A cited reference which

suggests that Cited invention 1 may be applied to Cited invention 2 is deemed to be the motivation for applying Cited invention 1 to Cited invention 2.

#### E) Advantageous Effects

If it can be judged from the description and the drawings of the claimed invention that a novel advantageous effect is brought about compared to the cited invention(s), then the following should be considered. The advantageous effect may be a different effect than that seen in the cited invention or may be the same effect as that in the cited invention, however the degree or extent of the effect in the claimed invention is significantly improved relative to the claimed invention.

Is the advantageous effect remarkable or could a person skilled in the art have easily arrived at the claimed invention based on the cited invention(s)? In the case of the former, a judgment that there is inventive step may be rendered.

The advantageous effect is described within the specification or can be clearly and unambiguously inferred from the description or drawings.

In some fields, the effect of an invention can be predicted from its structure. In such cases, the effect is not so much a factor in whether the structure could have easily been produced by a person skilled in the art. In fields such as chemistry, where the effect of the claimed invention cannot be easily determined based solely on the structure of the compound, etc., a separate statement describing that the compound has an advantageous effect is necessary in order to indicate that there is indeed an inventive step.

If the effect is within the range which would be anticipated by a person skilled in the art, then the effect does not support the presence of an inventive step.

If the effect of newly derived Compound X is remarkable relative to that of the conventional Compound X, the claimed invention has an inventive step over the cited invention(s), provided that the effect could not have been easily anticipated by a person skilled in the art with reference to the cited



invention(s).

If the advantageous and remarkable effect is only brought about by the combination of the constituent components and the combination of the constituent features and the effect brought about thereby could not have been easily anticipated by a person skilled in the art even though the cited invention(s) may disclose each of the constituent components, the claimed invention has inventive step.