Patentability Requirements in Japan/US
- Japanese perspective -

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CONTENTS

• Statutory Subject Matter
• Industrially Applicability
• Utility
• Novelty
• Inventive Step
Statutory Subject Matter
Statutory Subject Matter

Statutory basis

• Article 29(1): Any person who has made an invention which is industrially applicable may obtain a patent therefor...

Definition in the Law

• Article 2(1): “Invention” in this Law means the highly advanced creation of technical ideas utilizing a law of nature.
**Statutory Subject Matter**

**Ineligible subject matter**

- **Law of nature as such**
  - *Example:* a law of preservation of energy, a law of universal gravitation

- Those which are mere discoveries, not creations
  - *Example:* discoveries of natural things like an ore or natural phenomena (cf. Isolated chemical compounds and microorganisms)

- Those which are contrary to a law of nature
  - *Example:* So-called perpetual motion

- Those which do not utilize a law of nature
  - *Example:* Artificial arrangements such as a rule for playing a game or business methods, mathematical methods, mental activities, etc.

(JPO Examination Guidelines, Part II, Chapter 1, 1.1)
Statutory Subject Matter

Controversial subject matter

• Software & Program
• Business methods
• Compounds & Substance
• Biological inventions such as nucleic acids, proteins, antibodies, microorganisms, animals, and plants
Statutory Subject Matter

Software & Program

• Software or program is considered to be eligible subject matter in Japan (1) when an object processed by the software corresponds to a phenomenon utilizing a law of nature.

Example

When the claimed subject matter concretely performs:

• (a) control of an apparatus (rice cooker, washing machine, engine, hard disk drive, etc.), or processing relating to the control; or

• (b) information processing based on the physical or technical properties of an apparatus (rotation rate of engine, rolling temperature, etc.).
Statutory Subject Matter

Software & Program

• Even if an object processed by the software does not correspond to a phenomenon utilizing a law of nature, a software or program is considered to be eligible subject matter (2) when an information processing by the software is concretely realized by using hardware resources.

Example

Example 2-5 (Game machine) of JPO Examination Guidelines (Please see Annex 1)
Statutory Subject Matter

Business methods
• Business methods as such
  - Artificial arrangement
  - Ineligible

• Business methods utilizing computers
  - Eligible as long as an information processing by the software is concretely realized by using hardware resources

Example
Example 2-4 (Points service method) of JPO Examination Guidelines (Please see Annex 2)
Statutory Subject Matter

Compounds & Substance
• Chemical compounds & naturally occurring substance
  - Eligible
  - Specific utility is required

Example
Claim 1: Purified amazonic acid

Background: The Amazonian cherry tree is a naturally occurring tree that grows wild in the Amazon basin region of Brazil. The leaves of the Amazonian cherry tree contain a chemical that is useful in treating breast and colon cancers. Many have tried and failed to isolate the cancer-fighting chemical from the leaves. Applicant has successfully purified the cancer-fighting chemical from the leaves and has named it amazonic acid.

[Example 3 of Nature-Based Product Examples (USPTO 2014 Interim Guidance on Subject Matter Eligibility)]
Statutory Subject Matter

**Biological inventions**

- Nucleic acids
  - Eligible
  - Specific utility is required

**Example**

Claim 1: Isolated nucleic acid comprising SEQ ID NO: 1.

Background: Virginia nightshade is a **naturally occurring plant** that grows wild in the Shenandoah Valley of Virginia. When damaged, the leaves of Virginia nightshade produce a hormone called Protein W, which activates chemical defenses against herbivores. Protein W is naturally encoded by Gene W, which is part of chromosome 3 in Virginia nightshade and has the nucleic acid sequence disclosed as SEQ ID NO: 1.

[Example 7 of Nature-Based Product Examples (USPTO 2014 Interim Guidance on Subject Matter Eligibility)]
Biological inventions

• Proteins
- Eligible
- Specific utility is required

Example

Claim 1: Antibiotic L

Background: Newly discovered Streptomyces arizoneus bacteria produce Antibiotic L, which exhibits antibiotic activity in nature.

[Example 4 of Nature-Based Product Examples (USPTO 2014 Interim Guidance on Subject Matter Eligibility)]
Statutory Subject Matter

**Biological inventions**

- Antibodies
  - Eligible
  - Specific utility is required

**Example**

Claim 1: An antibody to Protein S.

Background: Newly discovered *Staphylococcus texana* bacteria have an antigen called Protein S on their outer surface. The specification describes the discovery of naturally occurring antibodies to Protein S in mice and wild coyotes living in Texas.

[Example 8 of Nature-Based Product Examples (USPTO 2014 Interim Guidance on Subject Matter Eligibility)]
Statutory Subject Matter

**Biological inventions**
- Microorganisms
- Eligible as long as they are *isolated* from the nature world
- Specific utility is required
- Genetically modified microorganisms are also eligible

**Example**
Claim 1: A Bacillus subtilis strain T-169 capable of decomposing dioxin.

Background: A Bacillus subtilis strain T-169 was *isolated* from the sample, which was collected from muddy sediment of seabed of Toyama Bay in Japan, with a method known to a person skilled in the art.

Note: Need to deposit

[JPO Examination Guidelines, Part VII, Chapter 2, 8.1, Example 1-2]
Statutory Subject Matter

**Biological inventions**

- Animals and plants
  - New species found in the nature world is ineligible
  - Animals and plants made by crossbreeding are eligible
  - Genetically modified animals and plants are also eligible

**Example**

Claim 1: An RFG mouse spontaneously developing dermatitis, developing periocular edema as an incipient lesion at 3 weeks old.

Background: In the process of maintaining the strain of BALB/c mouse, a mutant individual which developed periocular edema as an incipient lesion at 3 weeks old and spontaneously developing dermatitis under a clean condition was accidentally obtained. Subsequently, an inbred mouse strain was established from the mutant individual and named "RFG mouse."

Note: Need to deposit

[JPO Examination Guidelines, Part VII, Chapter 2, 8.4, Example 4-2]
Industrially Applicability
Industrially Applicability

Statutory basis

• Article 29(1): Any person who has made an invention which is **industrially applicable** may obtain a patent therefor...

Definition in JPO Examination Guidelines

• The word "industry" is construed in a broad sense, including mining, agriculture, fishery, transportation, telecommunications, etc., as well as manufacturing

• How about medical services?
Industrially Applicability

**Industrially inapplicable invention** (JPO Examination Guidelines, Part II, Chapter 1, 2.1)

- Methods of surgery, therapy or diagnosis of humans
- Commercially inapplicable inventions
  - **Example:** Invention applied only for personal use, such as a method of smoking
- Practically inapplicable inventions
  - **Example:** Method for preventing an increase in ultraviolet rays associated with the destruction of the ozone layer by covering the whole earth's surface with an ultraviolet ray-absorbing plastic film
Industrially Applicability

Inventions not considered to be classified as “methods of surgery, therapy or diagnosis of humans”

• Method for manufacturing a medicinal product or material by utilizing raw material collected from the human body (Revision in 2003)
  • Example: blood preparation, vaccine, genetically modified preparation, cell medicine, artificial bone, cultured skin sheet
  • Before the revision, the method was considered to be an industrially inapplicable invention, as the sample taken out of the human body is to be returned to the same person
Industrially Applicability

Inventions not considered to be classified as “methods of surgery, therapy or diagnosis of humans” (continued)

• Method for controlling the operation of a medical device (Revision in 2005)

• Methods for gathering various kinds of information by, e.g., measuring structures and functions of the various organs of the human body (Revision in 2009)
Industrially Applicability

Medical invention

• Recommendable to formulate product claims
  • Example: Pharmaceutical composition, Therapeutic agent, Diagnostic agent, Medical apparatus, ...
  • Method claims involve methods of surgery, therapy or diagnosis of humans
Utility
Utility

Statutory basis

• Article 29(1): Any person who has made an invention which is industrially applicable may obtain a patent therefor...
Utility

JPO practice

• Mainly required in the fields of chemistry, life science, pharmaceuticals, etc.

• Lack of utility is generally treated as failing to meet the enablement requirement

• General utility is insufficient

• Specific utility is required

• Recommendable to show utility by working example(s) and to include the example(s) in the original specification
Utility

Example - Full length cDNA

Claim 1: A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:9.

Background: The claimed polynucleotide is 2400bp cDNA obtained from human liver cDNA library. It encodes a polypeptide of 800 amino acids of SEQ ID NO:10. As a result of similarity search using a known DNA and amino acid database, the claimed polynucleotide showed 20 to 30% homology to the polynucleotide encoding factor ZZ1 of rat, factor ZZ2 of pig and an antagonist of factor ZZ1 receptor of monkey. Further, the amino acid sequence of SEQ ID NO:10 showed 20 to 30% homology to factor ZZ1 of rat, factor ZZ2 of pig and an antagonist of factor ZZ1 receptor. Therefore, this polynucleotide encodes a human protein related to factor ZZ and may be used to diagnose patients with disease related to factor ZZ.

Office Action: Violation of the enablement requirement

[JPO Examination Guidelines, Part VII, Chapter 2, 6.4, Case 3]
Utility

Example - DNA fragment

Claim 1: A polynucleotide consisting of the nucleotide sequence of SEQ ID NO:13.

Background: A cDNA library was constructed from human liver using oligo (dT) primers. The nucleotide sequence of SEQ ID NO:13 is one of the sequences (500 bp) which were analyzed using an automated DNA sequencer. The polynucleotide consisting of the nucleotide sequence of SEQ ID NO:13 is part of a structural gene, and it can be used as a probe in one of the steps to obtain the full-length DNA. However, there is no working example indicating that the full-length DNA was actually obtained, and there is no description of the function or biological activity of the DNA and its corresponding protein.

Office Action: Violation of the enablement requirement

[JPO Examination Guidelines, Part VII, Chapter 2, 6.4, Case 5]
Novelty
Novelty

Statutory basis

• Article 29(1): Any person who has made an invention which is industrially applicable may obtain a patent therefor, except for the following:

(i) inventions that were publicly known in Japan or a foreign country prior to the filing of the patent application;

(ii) inventions that were publicly worked in Japan or a foreign country prior to the filing of the patent application; or

(iii) inventions that were described in a distributed publication, or inventions that were made publicly available through an electric telecommunication line in Japan or a foreign country prior to the filing of the patent application.

• Article 29-2: Secret prior art provision
  • Unpublished earlier application
  • Self-collision? >>> No!
  • Used in Inventive Step assessment? >>> No!
Novelty

**JPO practice**

- When the invention is *clearly described* in the claims, the claimed invention is identified as it is based on the descriptions of the claims. The claim words are interpreted as the meanings in the normal sense.

- When the invention is *clearly described* in the claims but the meanings of the claim words are *defined or explained in the specification*, the descriptions of the specification are taken into consideration to interpret the claim words.

*(JPO Examination Guidelines, Part II, Chapter 2, 1.5.1)*
Novelty

Functional limitation claims

• Product claims having functional limitations are construed to mean all products having such functions

Example: Wall materials with layers insulating heat

• However, if the functions are inherent in the product, the product claims are construed to mean the product *per se*.

Example: Chemical compound X having anticancer activity.
Novelty

Use limitation claims

• Product claims having use limitations, which are specially adapted for the use, are construed to mean products that provide the shapes, structures, or compositions defined by the use limitation

Example: A hook for use as a crane in the shape of...
Novelty

Use limitation claims (continued)

- Product claims having use limitations which are based on a newly found property are construed as a novel product in light of the use (Secondary use or second medical use)

Example: Compositions for use in antifouling of ship bottoms, comprising a specific quaternary ammonium salt

Example: Pharmaceutical compositions for use in the treatment of asthma, comprising chemical compound Y
Novelty

Use limitation claims (continued)

• Product claims having a new dosage regime such as dosing time, dosing procedure, dosage, administration route are construed as a novel product in light of the medical use

Example: A therapeutic agent for treating asthma comprising compound Y wherein 30-40 μg/kg of compound Y is orally administered to humans once per 3 months (JPO Examination Guidelines, Part VII, Chapter 3, Example 4)
Novelty

Use limitation claims (continued)

• However, compounds having use limitations are construed to mean compounds per se with no use limitations

Example: Chemical compound Z for use as an insecticide

Example: Chemical compound ZZ for use in the treatment of gastric ulcer
Novelty

**Product-by-Process (PBP) claims**

- PBP claims are construed to mean *products per se* which have finally been obtained by the production process (Identical Product Theory)

**Example:** Pravastatin sodium containing less than 0.5% pravastatin lactone and less than 0.2% epiprava, which is prepared by a process comprising the steps of: a)..., b)..., c)..., d)... and e)...  

[Japan Supreme Court Decision on June 5, 2015, Case Nos. 2012(ju)1204 and 2012(ju)2658]
Novelty

Exception to loss of novelty

Exception provision (Article 30) expanded in 2012

- Exception applies to all the inventions defined in Article 29(1) where the disclosure was made by the inventor
- JP application must be filed within six (6) months of the disclosure
- Petition must be filed at the JP filing
- Evidence must be filed within thirty (30) days of the filing date (No extension available)
- Inventor’s disclosure will not be used for novelty and inventive step assessment
Novelty

Exception to loss of novelty (continued)

Example: Disclosure by inventor

Disclosure of A by Mr. X in any place in the world  JP Application for A by Mr. X

JP  6 months  Ineligible as prior art

- Petition
- Evidence
Novelty

Exception to loss of novelty (continued)

Example: Disclosure by third party

Disclosure of A by Mr. X in any place in the world

JP Application for A by Mr. X

6 months

Disclosure of A by Mr. Y

Eligible as prior art
Novelty

Exception to loss of novelty (continued)

Example: Disclosure by third party

Disclosure of A by Mr. X in any place in the world — JP Application for A by Mr. X

JP

6 months

Application for A by Mr. Y

Eligible as prior art
Inventive Step
Inventive Step

Statutory basis

• Article 29(2): Where an invention could easily have been made prior to the filing of the patent application by a person skilled in the art to which the invention pertains, based on an invention referred to in any one of the paragraphs of Subsection (1), a patent shall not be granted for such an invention notwithstanding Subsection (1).
**Inventive Step**

**Basic idea of Inventive Step assessment**

- Inventive Step is assessed based on whether it could be reasoned that a person skilled in the art is able to *easily arrive at* the claimed invention based on the cited prior art inventions, considering the technical field of the claimed invention as of the filing.

- Reasoning may be conducted from *various and broad viewpoints*

*(JPO Examination Guidelines, Part II, Chapter 2, 2.4)*
Inventive Step

Detailed steps of Inventive Step assessment

(1) Identify a claimed invention

(2) Identify invention(s) disclosed in the prior art reference(s)

(3) Compare the claimed invention and the prior art invention(s) to find corresponding point(s) and different points(s)

(4) Analyze the difference(s) to determine whether reasons for denying the inventive step can be established

(JPO Examination Guidelines, Part II, Chapter 2, 2.4)
Inventive Step

Examples of causes and motivations to deny Inventive Step

• Relation of technical fields
• Commonality of problems to be solved
• Commonality of operations or functions
• Suggestions in the cited prior art inventions

(JPO Examination Guidelines, Part II, Chapter 2, 2.5)
Inventive Step

Trend in Inventive Step assessment

Before yr. 2000
- Reasoning may be conducted from the viewpoint as to whether there is a motivation to arrive at the claimed invention (Previous JPO Examination Guidelines)
  - Reasoning is not possible if there is no motivation!

After yr. 2000
- Reasoning may be conducted from various and broad viewpoints (Current JPO Examination Guidelines)
  - Reasoning is possible even if there is no motivation!

After around yr. 2009
- For some cases, Inventive Step is assessed based on those similar to the Problem-solution approach and/or the Would- could approach in order to prevent hindsight
  - JPO Examination Guidelines have not yet been revised!

Relaxed
Strict
Relaxed a bit

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Inventive Step

IP High Court decision on January 28, 2009 [H20(2008) (Gyo-ke)10096]

• “It is indispensable to realize the characteristic points of the invention, i.e., the problem to be solved by the invention, precisely in order to determine whether it is easy to arrive at the invention…”

• “An *ex post facto* analysis and illogical thinking must be avoided in the assessment of the inventive step”

• “Speculations that one skilled in the art could have made an attempt to arrive at the invention are not sufficient in order to determine that it is easy to arrive at the invention. Suggestions that one skilled in the art would have made such an attempt to arrive at the characteristic points of the invention are necessary.”
Annex 1: Example 2-5 (Game machine)

[Claim 1]

A computerized card game machine, comprising:

means for assigning specific points of a score to a set of cards dealt, according to the complexity of the hand involved.

[Claim 2]

A computerized card game machine, comprising:

*means for memorizing* a scoring hand data table (i.e. a hand of cards dealt that scores points) in which a given set of cards is matched to specific scoring hand data, and a score data table in which the scoring hand data are matched to the score data;

means for *assigning corresponding scoring hand data* by retrieving said *scoring hand data table* based on a set of cards selected, *assigning corresponding score data* by retrieving the *score data table* on the basis of the applicable scoring hand data, and *outputting all of the scoring hand data and total points scored*. 
Annex 2: Example 2-4 (Points service method)

[Claim 1]

A service method for offering service points depending on an amount of commodity purchased in telephone shopping, comprising the steps of:

notifying via telephone of an amount of service points offered and a name of a person to whom the said service points are offered;

acquiring the telephone number of the said person from a customer list storage means based on the name of the said person;

adding the said service points to the accumulated points of the said person stored in the said customer list storage means; and

notifying to the said person that the said service points have been given via telephone using the said telephone number of the said person.
Annex 2: Example 2-4 (Points service method)

[Claim 2]

A service method for offering service points depending on an amount of commodity purchased at a shop on the Internet, comprising the steps of:

notifying an amount of service points offered and a name of a person to whom the said service points are offered via the Internet;

acquiring the e-mail address of the said person from a customer list storage means based on the name of the said person;

adding the said service points to the accumulated points of the said person stored in the said customer list storage means; and

notifying to the said person that the said service points have been given via e-mail using the e-mail address of the said person.
Annex 2: Example 2-4 (Points service method)

[Claim 3]

A service method for offering service points depending on an amount of commodity purchased at a shop on the Internet, comprising the steps of:

notifying a server of an amount of service points offered and a name of the person to whom the said service points are offered via the Internet;

acquiring by the said server, the e-mail address of the said person from a customer list storage means based on the name of the said person;

adding by the said server, the said service points to the accumulated points of the said person stored in the said customer list storage means; and

notifying by the said server, to the said person that the said service points have been given, by e-mail using the said e-mail address of the said person.
Thank you for your attention!

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