Examination Guidelines in Life Sciences

Examination Standards Office,
Administrative Affairs Division,
Japan Patent Office

July, 2018

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

What is a Patentable Invention?

- It is necessary for an invention to satisfy the requirements regulated by Patent Act to obtain a patent.
- Major requirements regulated by Patent Act are as follows*1:

Eligibility in terms of Patent Act (Article 2 (1))*2

Industrial Applicability (Main Paragraph of Article 29(1))

Novelty (Article 29 (1))

Inventive Step (Article 29 (2))

Clarity (Article 36 (6) (ii))

Enablement Requirements (Article 36 (4) (i))

*1 Patent Act regulates requirements other than those described herein. For example, a patent is not granted when an application claiming the identical invention has previously been filed (Articles 39 and 29bis), and an invention which is contrary to public order and morality shall not be patented (Article 32).

*2 Reasons for refusal is notified due to violation of the main paragraph of Article 29 (1).

What is a Patentable Invention?

Eligibility in terms of Patent Act

A patentable invention is defined as a highly advanced creation of technical ideas utilizing a law of nature. (Patent Act Article 2(1))

Utilizing a Law of Nature

× Those contrary to a law of nature

× Arbitrary arrangements that do not utilize a law of nature

Method of Study

Human mental activity is NOT patentable.

Technical Ideas

× Personal skill

Those being acquired through personal experience and cannot be shared with others as a knowledge due to lack of objectivity.

A method of throwing a split-fingered fastball

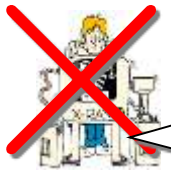
Personal skill is NOT patentable.

Creation

※"Creation" means to create a new thing.

× Mere discoveries of microorganisms in nature

○ Microorganisms which are isolated from their surroundings



Discovery of x-ray

Mere discovery of X-ray is NOT patentable.

Highly Advanced

※"Highly advanced" is considered mainly to identify the invention from a utility model under Utility Model Act, and thus it is not necessary to consider it to determine whether the application falls under "invention".

What is Patentable Invention?

Industrial Applicability	× Methods of surgery, therapy or diagnosis of humans (Medical devices or drug products themselves are considered to be industrially applicable)
Novelty	× Publicly known invention (an announcement, TV broadcast) × Publicly worked invention × Inventions described in publications (patent publications, research papers, books, Internet, etc.)
Inventive Step	× An invention which can easily be made by a person skilled in the art※ based on the inventions etc. described in publications. ※ A person skilled in the art: a person who has a general knowledge in the technical field for which an invention pertains.
Clarity	The statement of the claims for which the patent is sought should be clear.
Enablement Requirements	The detailed description of the invention should be described in a sufficiently clear and complete manner to carry out the claimed invention based on the matters described in the description and drawings.

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Filing Documents

Description

◎Explaining in detail the contents of the invention

- Title of the invention
- Detailed description of the invention
  - ・Background art
  - ・Prior art
  - ・Problems to be solved by the invention
  - ・Effects of the invention
  - ・Examples
  - ・・・
- Brief description of the drawings (where required)
- Sequence listing※ (where required)

etc.

Claims

・Claim 1 ・・・, ・Claim 2 ・・・, ・・・

Abstract

◎ Describing the points of the invention briefly

Drawings (where required)

◎ Drawing(s) useful for understanding the invention

※See the “Guidelines for Describing the Specification etc. including Base Sequences or Amino Acid Sequences”.
https://www.jpo.go.jp/tetuzuki/t_tokkyo/shinsa/enki_amino_guideline.htm (Japanese only)

Filing Documents

Description ◎Explaining in detail the contents of the invention

Title of the invention

Detailed description of the invention
- Background art
- Prior art
- Problems to be solved by the invention
- Effects of the invention
- Examples
- ・・・

Sequence listing ※ (where required)

etc.

- **Detailed description of the invention should be described in a sufficiently clear and complete manner to carry out the claimed invention.**

Claims

・Claim 1 ・・・, ・Claim 2 ・・・,

- **Technical scope in exercising the patent right**
- **Describing the invention for which the applicant is seeking for a patent**
- **Becoming a subject of the substantial examination**

Abstract ◎ Describing the points of the invention briefly

Drawings (where required) ◎ Drawing(s) useful for understanding the invention

※See the “Guidelines for Describing the Specification etc. including Base Sequences or Amino Acid Sequences”.
https://www.jpo.go.jp/tetuzuki/t_tokkyo/shinsa/enki_amino_guideline.htm (Japanese only)

How to Draft Filing Documents (Example)

Description

Title of the invention "A cup"

The detailed description of the invention

An example of a cup made of aluminum

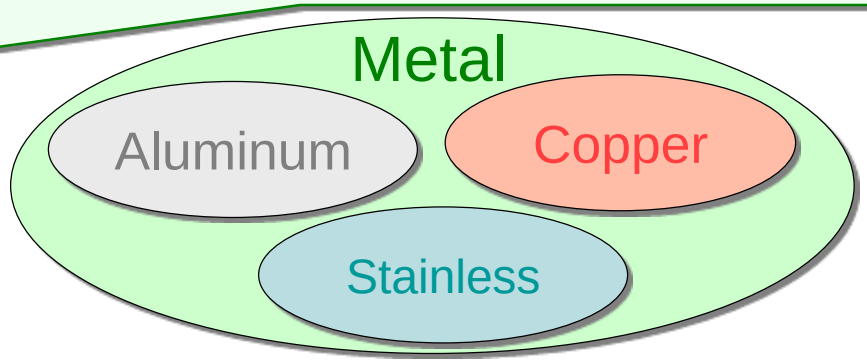
An example of a cup made of copper

Description of various examples of the invention

The Claims

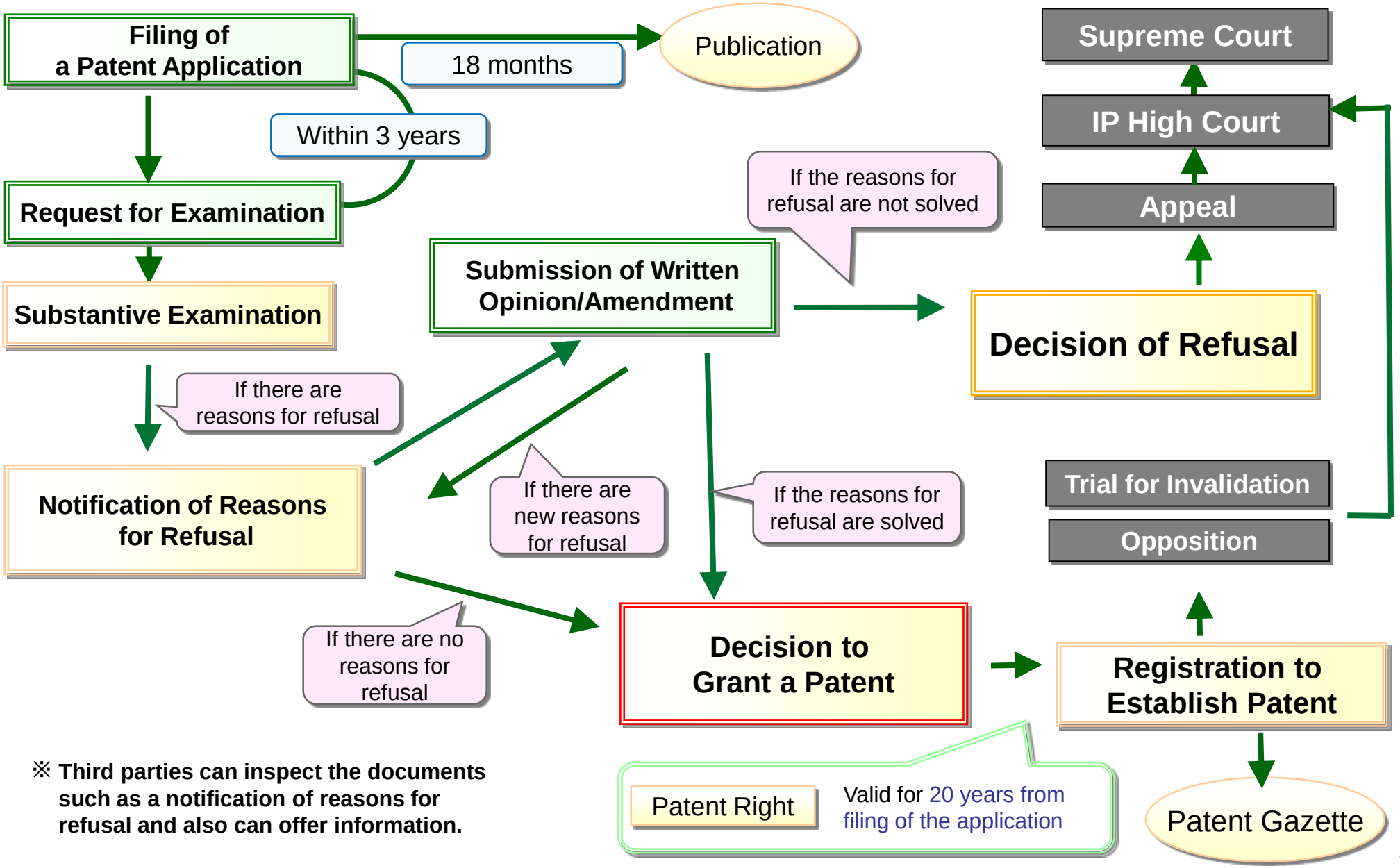
"A cup made of metal"

- If "a cup made of aluminum" is described, a patent right for a cup made of metal other than aluminum cannot be exercised.
- If "a cup made of copper" is described, a patent right for a cup made of metal other than copper cannot be exercised.
- If "a cup made of metal" is described, a patent right for a cup made of any kinds of metal can be exercised,
- However, if "a cup made of metal" is described and further "a cup made of stainless" is known, the invention is not considered to have novelty.
- In order to obtain a patent right with a broader scope of claim, it is necessary to describe various examples in "Detailed description of the invention".



1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Schematic Flow of Examination on Patent Applications



※ **Third parties can inspect the documents such as a notification of reasons for refusal and also can offer information.**

Schematic Flow after Registration of Establishment of Patent Right

- Carrying out of the Invention by the Patentee
- Transfer to Another Person
- Consent to Work the Invention (Licensing)
- Prosecution of Infringement Lawsuit

Request from a Third Party

- Patent Opposition
- Invalidation Trial
- IP High Court
- Supreme Court

Decision to Grant a Patent

Payment of Patent Fee

Registration of Establishment

Coming into Force of Patent Right

Patent Gazette

Patent Right

(Valid up to 20 Years from the Filing Date)

※There is a system for extending patent term for drug products and agricultural chemicals etc. (up to 5 years)

Accelerated Examination System

Patent Applications filed by an applicant or a licensee who has already commercialized the invention or plans to commercialize the invention within two years from the filing date of a request for accelerated examination (working-related application), internationally-filed patent applications, and patent applications filed by universities or SMEs, etc., can be examined more quickly than regular examination by making a request for accelerated examination.

- No fees are charged except for the fee for requesting examination.
- Applicants should submit a written explanation about the circumstances regarding the filing of an accelerated examination (describing the need for accelerated examination, disclosing the prior art, explaining comparison with the invention, etc.).
- If the applicant(s) consists of SME(s) / university(universities) only, the workload for prior art search can be reduced.

Prior art search is not always required, and in this case, just listing prior art references that the applicant(s) know suffices.
(However, prior art search is required when a large-sized enterprise is included in the applicants.)

The pendency of patent examination is normally about 9 months from submission of a request for examination.

The application is examined within about 2 months from the request for accelerated examination.

For More Details about Accelerated Examination and Accelerated Appeal Examination for Patent Applications, see <https://www.jpo.go.jp/torikumi_e/t_torikumi_e/outline_accelerated.htm>

Super Accelerated Examination System (Started as a Pilot Program from Oct. 2008)

Patent applications which satisfy both of the requirements (i) and (ii) can be examined more quickly than the accelerated examination system by a request for super accelerated examination.

(i) International patent applications filed by an applicant or a licensee who has already commercialized the invention or plans to commercialize the invention within two years from the filing date of a request for accelerated examination (working-related application).

(ii) Patent applications for which all the procedures have been made online from 4 weeks before the date of request.

- No fees are charged except for the fee for requesting examination.
- Applicants are required to submit a written explanation about the circumstances regarding the filing of an accelerated examination (describing the need for accelerated examination, disclosing the prior art, and explaining comparison with the invention concerned and the prior art, etc.).
- Applicants are required to conduct prior art search and explain comparison with the invention.

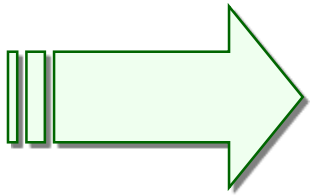
※ When there is a search result by a foreign patent Office, disclosing the prior art cited in the foreign Office's search result and explaining comparison with the invention are needed.

Pendency for examination: within 1 month (In principle, it is within 2 months for international applications which have entered the national phase).

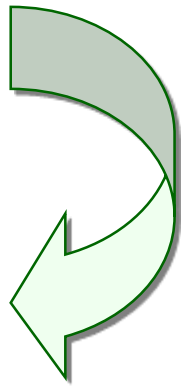
- Time limit for response from applicants or agents: within 30 days (within 2 months for residents abroad)
- Period from response to second examination：within 1 month

Green Accelerated Examination System (Started as a Pilot Program from Nov. 2009)

More Complicated and Serious Environmental Problems



Need to Promote Research and Develop Environment-friendly "Green Technologies"



Accelerated examination is applied to "Green-related Applications" in order to promptly protect the benefits resulting from research and development of "Green Technologies" and to promote further progress of the R&D activities!

Patent applications filed to obtain patent rights for the inventions having effects such as energy saving and CO_2 reduction (Green Inventions)

Similar way to the applications filed by an applicant or a licensee who has already commercialized the invention or plans to commercialize the invention within two years from the filing date of a request for accelerated examination (working-related application).

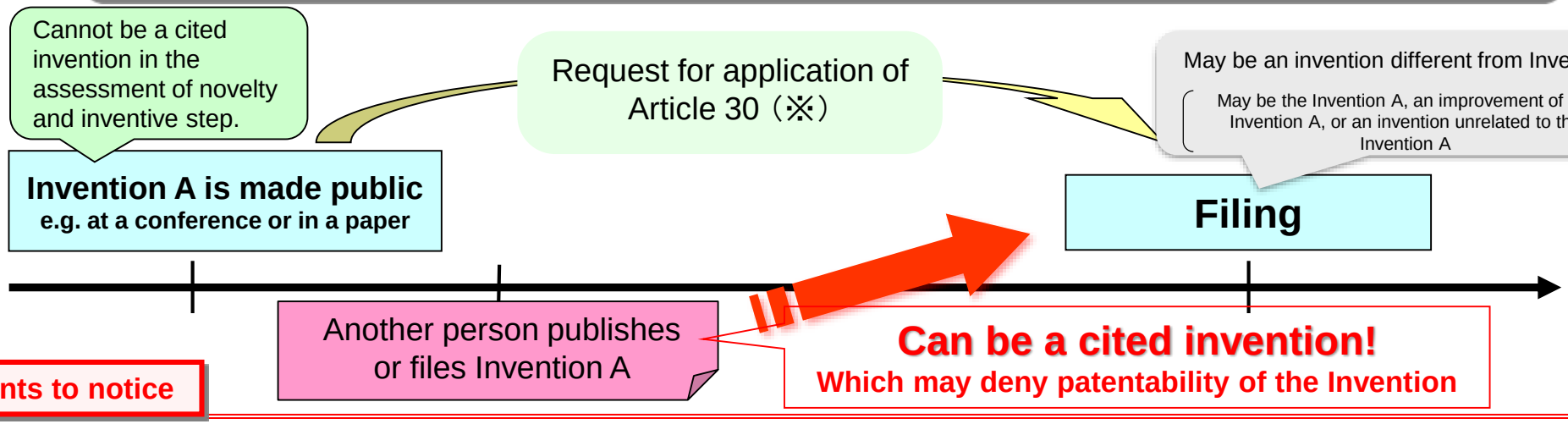
<Written Explanation about the Circumstances regarding the Filing of an Accelerated Examination>

- Reasonable explanation to consider the invention as Green Invention.
- Prior art search should be conducted so as to disclose the prior art and explain comparison with the invention.

Exceptions to Loss of Novelty of Invention

Exceptions to loss of novelty of invention is **just an emergency measure which can be applied only in case applicants etc. have carelessly disclosed inventions. Applying this exception is not desirable since this is just an exceptional means.** Make it a rule **not to disclose an invention at a conference etc. before filing the application of the invention.**

When the provision of exceptions to loss of novelty of invention is applied, that published invention is not considered as a cited invention in determination of novelty and inventive step of the invention of the application.



Points to notice

- **Filing date is not retroactive.**
  Patent may not be granted when a third party published or filed the invention before the inventor files the application.
- **Laws and regulations differ among countries/regions.**
  Even if an invention was patented in Japan, the invention may not always be patented in the other countries/regions.

※Refer to “Operational Guidelines for Applicants to Seek the Application of Exceptions to Loss of Novelty of Invention, corresponding to the Patent Act Article 30 revised in 2018.” <https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/e_pae_paa30.htm>

3. Procedures for Obtaining a Patent in Japan

Summary of Comparison among Countries/Regions in the provision of Exceptions to Loss of Novelty of Invention (as of Jun. 2018)

	Pendency (Months)	Reference Date	Subject	Requesting Procedure
JP **Patent Act Article 30**	**12**	**Filing date or National priority date**	(i) All public disclosure acts (any disclosure modes are included, except for those published in patent gazette etc.)	**Required** (1)To file a request for application at the time of filing (2)To submit a certificate at the time of filing or later
			(ii) Disclosure against the will of the applicant etc.	**Not Required** (proved through examination)
US **35 U.S.C. 102 (b)(1)**	**12**	**Effective Filing date (※1)**	(i) All public disclosure acts	**Not Required** (proved through examination)
EP **EPC Article 55**	**6**	**Filing Date**	(i) Display of the invention at an international exhibition which is official or officially recognized under the Convention relating to international exhibitions	**Required** (1)To file a request for application at the time of filing (2)To submit a certificate at the time of filing or later
			(ii) Evident abuse to the applicant etc.(※2)	**Not Required** (proved through examination)
CN **Patent Act Article 24 Rule11**	**6**	**Filing Date or Priority Date**	(i) Display at an international exhibition held or approved by Chinese Government (ii) Publication at academic or technical meetings held by the competent authority under the State Council or national academic organizations	**Required** (1)To file a request for application at the time of filing (2)To submit a certificate at the time of filing or later
			(iii) Leakage by a third party without any consent of the applicant	**Not Required** (proved through examination) ※(1) and (2) are required if the applicant knew the fact of (iii).
KR **Patent Act Article 30**	**12**	**Filing Date**	(i) All public disclosure acts (any disclosure modes are included, except for those published in patent gazette etc.)	**Required** (1)To file a request at the time of filing or later (2)To submit a certificate at the time of filing or later
			(ii) Disclosure against the will of the applicant etc.	**Not Required** (proved through examination)

※1 When priority is claimed based on the Paris Convention, it is the filing date of the earliest application as the basis of the priority of the claimed invention. In the case of a continuation or divisional application, etc., it is the filing date of the earliest application which shall be retroactive for the claimed invention. Otherwise, it is the actual filing date.
※2 Disclosure against the wish of the person having the right etc. (For more details, see the Guidelines for Examination in the European Patent Office, Part G, Chapter V "Non-prejudicial disclosures").

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Schematic Filing Procedures through the Paris Convention Route and the PCT Route

- The rights obtained at JPO do not mean the right protection at foreign countries/regions (the principle of territoriality).
- In order to seek for protection at a particular foreign country/region, obtaining a patent is required in that country/region.

Paris Convention Route

Basic Application
(Filed at Japan Patent Office, for example.)

PCT Route

File in Each Country/Region
within 12 Months

International Filing
within 12 Months

Receiving Office

File in the form and language defined by the laws and regulations of each country/region

International Search Report and Written Opinion

International Publication (18 months)

Demand for Preliminary Examination

International Phase

US　EP　CN

Submit a Translation to Each Designated Country
(Within 30 Months from Basic Application)

National Phase

US　EP　CN

Patent-granted according to the laws and regulations of each country/region

Granting Rights according to Laws and Regulations at Each Office

Advantages of PCT Application

You can obtain the same "filing date" in all member countries/regions by filing a single application.

The date of filing the PCT application (International filing date) is considered to be the filing date in all PCT member countries (152 states※).

※ As of April 2016

You can file an application in the official language of your own country.

You can file a PCT application in a language which the patent Office of each country accepts.
When you file a PCT application with the JPO, you can file it in Japanese or English.

You have 30 months from the filing date (priority date) before the entry into the national phase.

You can decide whether you wish to proceed further with your application in countries where you seek rights (whether to enter the national phase) within 30 months (with some exceptions) after the filing date (or the priority date). Accordingly, you have sufficient time to carefully consider whether to enter the national phase in each country by watching market trends and evaluating the technology, and to make preparations such as translations. (In the Paris Route, you have to make preparations such as translations within 12 months.)

You can receive the International Search Report and Written Opinion etc.

Before entering the national phase, you will receive the international search report and written opinion to know the examiner's view about the patentability.
However, they are not the notice of allowance or of reasons for refusal. (After entering the national phase, respective countries including Japan conduct their own examination procedures and may reach different determinations.)

For more details of PCT Application (particularly, International Search Report and International Preliminary Examination Report), see "Handbook for PCT International Search and Preliminary Examination" (PCT Handbook) (established in October 2015).
<https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pct_handbook_e.htm>

International Search Report (Excerpt)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	WO 2010/876543 A1 (XX CO., LTD.)	1-7
Y	2010.07.15, paragraphs [0020] to [0025], Fig. 7	9-10
A	& JP 2010-555555 A & US 2010/9876543 A1 & EP 9988776 A1	11-20
Y	JP 8-799999 A (XX INCOPORATED) 1996.06.25, paragraphs [0040] to [0055], Fig. 1 & CN 8999999 A & KR 10-0699999 B1	9-10
Y	JP 3333333 U (XX SANGYO CO., LTD.) 2014.01.16, paragraphs [0006] to [0016], Figs. 1-2 (Family: none)	10

☑ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:
"A" document defining the general state of the art which is not considered to be of particular relevance
"E" earlier application or patent but published on or after the international filing date
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
"O" document referring to an oral disclosure, use, exhibition or other means
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
25.04.2015	
Name and mailing address of the ISA/JP **Japan Patent Office** 3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan	Authorized officer SHINSAKI, Jun Telephone No +81-3-3581-1101 Ext. ****

9Z 9999

Form PCT/ISA/210 (second sheet) (January 2015)

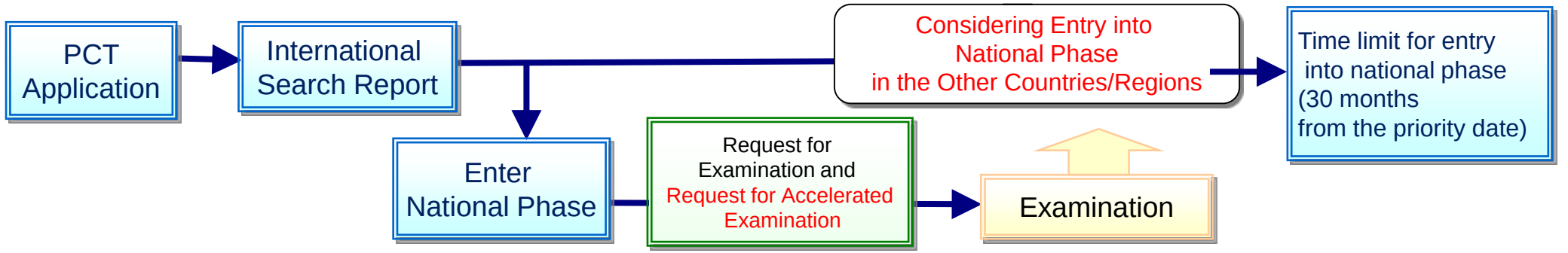
* The International search report is published together with the description etc. at the time of international publication.

4. Procedures for Obtaining a Patent Overseas

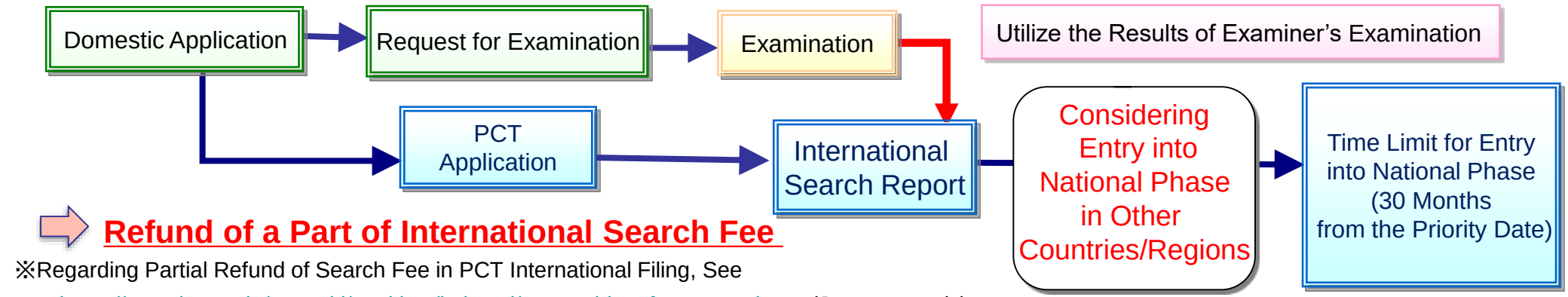
PCT Application and Accelerated Domestic Examination (Integration of International Search and Domestic Examination)

- By integrating PCT international search and domestic examination, the applicants can know the results of examination earlier, and can carefully plan the strategies regarding research and development, operations, intellectual properties, etc. for key technologies promising on foreign markets.
- It also helps the applicants properly determine whether or not they should enter the national phase at foreign Offices.

(1)Filing at JPO by PCT Route: A Case where Entering the National Phase Early at JPO and Requesting Accelerated Examination



(2)PCT Application Filing in the Other Countries/Regions while Maintaining Domestic Application Filing: Simultaneous Search and Examination on Domestic Application and PCT Application



Refund of a Part of International Search Fee

※Regarding Partial Refund of Search Fee in PCT International Filing, See <https://www.jpo.go.jp/tetuzuki/t_tokkyo/kokusai/researching_fee_return.htm> (Japanese only)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Examination Guidelines for Patent and Utility Model

Part III Chapter 1 Eligibility for Patent and Industrial Applicability

Examination Handbook for Patent and Utility Model

Annex B Chapter 2 Biological Inventions
Chapter 3 Medicinal Inventions

※ Also see the following:
Annex A Case Examples of “Examination Guidelines for Patent and Utility Model”
Annex D Court Precedents of “Examination Guidelines for Patent and Utility Model”

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Examination Practice

Patent Act (the main paragraph of Article 29 (1))

Any person who has made an invention which is industrially applicable may obtain a patent therefor …

Examination Guidelines (Part III, Chapter 1, 3. Determination on Industrial Applicability Requirements)

"Methods of surgery, therapy or diagnosis of humans" do not fall under the "industrially applicable invention". (not patentable subject matter)

Those that do not fall under "methods of surgery, therapy or diagnosis of humans" (patentable subject matter)

- Products such as medical devices or medicinal substances
- Methods of operating medical devices (excluding the cases where they include a process performed by a medical doctor, or a process of acting on a human body with the use of a device)
- Methods as below for collecting various information from a human body (excluding the cases where they include a process of determining medical conditions, etc. of humans for a medical purpose)
  - A method for collecting/analyzing samples or data from a human body

    ex.) a method for an influenza test by extracting oral mucous membranes with a cotton bud
  - A method for preliminary treatment for measuring structures or functions of various organs of humans

    ex.) a method for preventing uneven application of jelly for ultrasonography applied on the body
- Methods as below for processing samples that have been extracted from the human body:
  - A method not including the premise that the samples are to be returned to the same body for therapy
  - A method for manufacturing or analyzing drug products which are manufactured from samples extracted from the human body as raw material

5－2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans

Summary of Inventions relating to Methods of Surgery, Therapy or Diagnosis of Humans

特許庁 JAPAN PATENT OFFICE

○ Medicines | Vectors | Medical Materials | Medical Devices

Combinations of Physical and Biochemical Means

Invention of "Product"

○ Manufacturing Methods for Drug Products

Manufacturing Methods for Vectors

Manufacturing Methods for Medical Materials

Methods for Implanting Medical Material to Mice

Methods of Power Assist for Non-Medical Purposes

Methods for Inducing and Analyzing Cell Differentiation

Invention

× Methods for Administering Medicines to Humans

Methods for Introducing Genes to Humans using Vectors

Methods for Implanting Medical Materials to Humans

Methods of Therapy of Humans using Combinations

Methods of Power Assist for Medical Purposes (for rehabilitation, etc.)

Methods of Surgery, Therapy or Diagnosis of Humans using Medical Devices

Methods including a Process of Checking Medical Conditions etc. of Humans for a Medical Purpose

A Method Expressing Functions of a Medical Device itself as a Method

Not Including **a Process Performed by a Medical Doctor**

Not including **a Process effected on a Human Body by a Medical Device**

○ **Operation Method of Medical Devices**

A Method for Collecting Various Information from the Human Body by Measuring Structures and Functions of Various Organs of the Human Body

Not including a Process of Making a Determination for a Medical Purpose, as to Physical and Mental Conditions, such as the State of a Disease or Health, or as to a Prescription or Plan for Therapy or Surgery based thereon

Not including a Process falling under **a Method of Surgery or Therapy of Human**

○ **Methods for Collecting Various Information from the Human Body**

Comparison in Handling of Medical Practice-related Inventions among JP, US and EP

特許庁 JAPAN PATENT OFFICE

“Methods of Surgery, Therapy or Diagnosis of Humans”

JP ✕

Not Patentable Subject Matter

Main Paragraph of Patent Act Article 29(1)

“Any person who has made an invention which is industrially applicable may obtain a patent therefor except for the following inventions …”

Examination Guidelines

Types of “Industrially Inapplicable Inventions”:
Methods of surgery, therapy or diagnosis of humans”

US ○

Patentable Subject Matter

35 U.S.C. 101

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor …”

There is the provision of exemption of a medical practitioner's performance of a medical activity (i.e., the provision that does not permit an injunction or a claim for damage compensation based on a patent right). (35 U.S.C. 287(c)(1))

Not exempted: (i) the use of a patented machine, manufacture or composition of matter;
(ii) the practice of a patented use of a composition of matter; and
(iii) the practice of a process of a biotechnology patent (35 U.S.C. 287 (c)(2)(A))

EP ✕

Not Patentable Subject Matter

European Patent Convention (EPC) Article 53 (excerpt)
European Patents shall not be granted in respect of:
(c) Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods

Methods of Surgery, Therapy or Diagnosis of Humans

Patentable Subject Matter:
Those do not fall under the methods of surgery, therapy or diagnosis of humans.

- Medicines (including Combined Medicines)
- Methods for Manufacturing Medicines
- Vectors
- Methods for Producing Vectors
- Medical Materials (Combination of Tissue-derived Material and Scaffolding Material etc.)
- Methods for Implanting Medical Material to Mice
- Methods for Manufacturing Medical materials
- Combinations of Physical and Biochemical Means
- Methods for Inducing and Analyzing Cell Differentiation
- Methods of Power Assist (Non-medical purpose)
- Medical Devices (Pacemakers etc.)
- Methods of Operation of a Medical Device
- Methods for Collecting Information from a Human Body

Not Patentable Subject Matter:
Those do not fall under the methods of surgery, therapy or diagnosis of humans.

- Methods for Administering Medicines to Humans
- Methods for Introducing Genes to Humans using Vectors
- Methods for Implanting Medical Material in Humans
- Methods of Therapy of Humans using Combinations
- Methods of Power Assist for Medical Purposes (for Rehabilitation etc.)
- Methods of Surgery, Therapy or diagnosis of humans using medical devices
- Methods including a Process of Determining Physical Conditions of Humans for a Medical Purpose

Case not falling under “Methods of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

Methods for Manufacturing Drug Products

［Claim 1］

A method for manufacturing a cell preparation for cancer therapy by introducing genes with vector Z including both the DNA encoding protein X and the DNA encoding protein Y into a cell W extracted from a human body.

［Outline of the detailed description of the invention］

It was found that a cancer would be reduced as a result of suppression of angiogenesis particular to cancer tissues and simultaneous stimulation of immunity by the recombinant cell medicine for cancer therapy obtained by the claimed method.

The cells obtained from a donor who is a relative of the patient could be used. However, it is the most preferable to use cells from the patient himself or herself in view of compatibility.

［Explanation］

Methods for manufacturing drug products such as recombinant cell preparations from cells extracted from a human body as a raw material do not fall under "methods of surgery, therapy or diagnosis of humans," even if cells extracted from the patient are supposed to be used, as described in the detailed description of the invention.

(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 29-2)

Case falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Not Patentable Subject Matter

Methods for Administering Drug Products to Humans

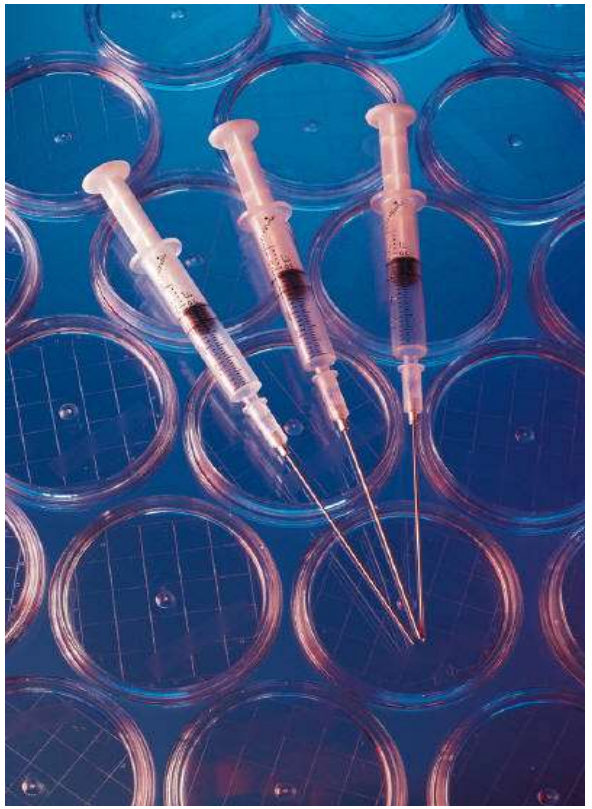
Methods for Introducing Genes into Humans with Vector

[Claim 1]

A method of reducing a cancer by administering a vector Z including both DNA encoding a protein X and DNA encoding a protein Y into a human body.

[Outline of the detailed description of the invention]

It was found that a cancer would be reduced as a result of suppression of angiogenesis particular to cancer tissues and simultaneous stimulation of immunity by administering the claimed recombinant vector into a human body.



[Explanation]

A method of reducing cancer by administration of a recombinant vector into a human body is considered as a method of therapy of humans. Therefore, the claimed method falls under "methods of surgery, therapy or diagnosis of humans."

(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 29-1)

Case not falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

Combination of Physical and Biochemical Means

[Claim 1]

A cancer treatment system comprising: a micro capsule X which contains an anti-cancer agent and releases the agent when disintegrated by a convergence supersonic wave, and an apparatus having means to obtain image data showing the position of the tumor, means to focus the convergence supersonic wave on the position of the tumor based on the image data, and means to irradiate the convergence supersonic wave onto the micro capsule X.

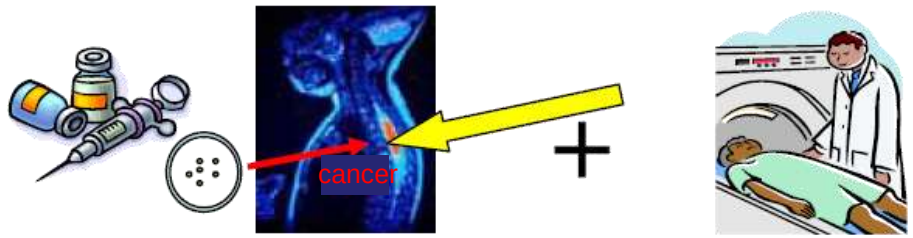
[Outline of the Detailed Description of the Invention]

The present invention relates to a system for effectively administering an anti-cancer agent to the tumor.

Since the convergence supersonic wave is focused onto the position of the tumor when the micro capsule X which contains an anti-cancer agent and has been injected into the blood vessel disintegrates inside the human body, only the micro capsule that has reached the tumor is disintegrated and thus the anti-cancer agent can be effectively administered to the tumor.

[Explanation]

The claimed treatment system is an invention of a combination of the micro capsule X, and the apparatus having the means to obtain image data, the means to focus the convergence supersonic wave on the position of the tumor, and means to irradiate supersonic waves; hence it is a product invention. Therefore, it is not considered to be “methods of surgery, therapy or diagnosis of humans.”



(See Examination Handbook Annex A “3. Eligibility for Patent and Industrial Applicability” Case 19-2)

Case falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Not Patentable Subject Matter

Methods of Therapy of Humans using Combinations

[Claim 1]

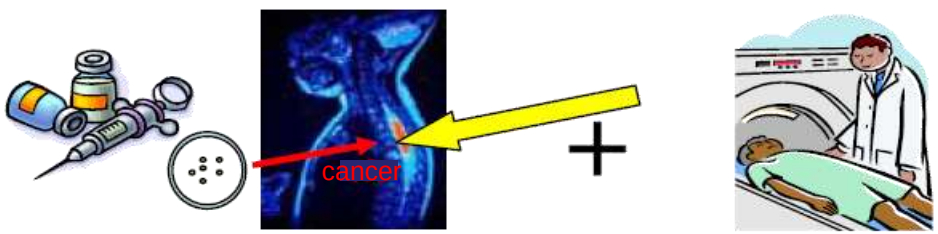
A method for treatment of cancer using; a micro capsule X which contains an anti-cancer agent and releases the agent when disintegrated by a convergence supersonic wave, and an apparatus having means to obtain image data showing the position of the tumor, means to focus the convergence supersonic wave on the position of the tumor based on the image data, and means to irradiate the convergence supersonic wave onto the micro capsule X.

[Outline of the detailed description of the invention]

This invention is directed to a method for treatment of cancer comprising injecting a micro capsule X with a anti-cancer agent inside into the blood vessel, destroying the micro capsule X in the body, and making the anticancer agent work efficiently on the tumor. Since the convergence supersonic wave is focused onto the position of the tumor, only the micro capsule that has reached the tumor is disintegrated and thus the anti-cancer agent can be effectively administered to the tumor.

[Explanation]

The claimed method is to make an anticancer agent work on the tumor for treatment. Thus the method is considered to be "methods of therapy of humans". Therefore it is not recognized as an industrially applicable invention.



(See Examination Handbook Annex A “3. Eligibility for Patent and Industrial Applicability” Case 19-1)

Case not falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

Medical Materials (a Combination of Tissue-derived Material and Scaffold Material)

[Claim 1]

An implant material for regenerating a cartilage consisting of biocompatible polymeric material Z and A-cells wherein the A-cells are embedded in gel formed of the biocompatible polymeric material Z, characterized in that the implant is transplanted to a joint of a human.

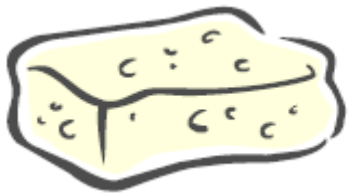
[Overview of the detailed description of the invention]

It was found that transplantation of a material wherein the A-cells are embedded in gel formed of the biocompatible polymeric material Z to a joint of a human has a remarkable cartilage regenerating effect.

[Explanation]

As the implant material for cartilage regeneration described in the claim itself is a product, the claimed invention does not fall under “methods of surgery, therapy or diagnosis of humans.”

＋



(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 22-2)

Case falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Not Patentable Subject Matter | Methods for Implanting Medical Materials in Humans | Methods of Therapy of Humans using Combinations

[Claim 1]

A method for regenerating cartilage wherein a material wherein the A-cells are embedded in gel formed of the biocompatible polymeric material Z is transplanted to a joint of a human.

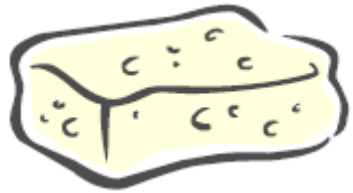
[Outline of the detailed description of the invention]

It was found that transplantation of a material wherein the A-cells are embedded in gel formed of the biocompatible polymeric material Z to a joint of a human has a remarkable cartilage regenerating effect.

[Explanation]

The claimed invention is a method for regenerating cartilage and thus a method of therapy of humans. Also the claimed invention is a method to transplant a medical material into the body and thus a method of surgery of humans. Therefore, the claimed invention is considered to be “methods of surgery, therapy or diagnosis of humans.”

＋



(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 22-1)

Case not falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

Methods of Inducing and Analyzing Cell Differentiation

[Claim 1]

A method of inducing differentiation of an human induced pluripotent stem cells to neural stem cells, wherein the human induced pluripotent stem cells are cultured in a serum-free medium under the presence of a X cell growth factor.

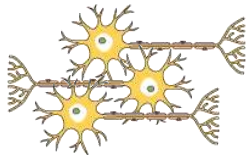
[Outline of the detailed description of the invention]

It was found that the differentiation of human induced pluripotent stem cells (hereinafter abbreviated as “iPS cells”) to neural stem cells was induced by culturing them in serum-free medium and in the presence of X cell growth factor. Moreover, taking immunological compatibility into consideration, it is preferable to use iPS cells derived from somatic cells of the same patient. The neural stem cells differentiated from human iPS cells can be used as a therapeutic agent for degenerative neurological disorder.

[Explanation]

Since the method of inducing differentiation to the neural stem cells outside the human body falls under "a method for manufacturing an intermediate product for a medicinal product or a medical material by utilizing raw materials collected from a human body," it does not fall under "methods of surgery, therapy or diagnosis of humans," even if the method is practiced on the presumption that the materials are to be returned to the same body.

iPS cells



Neural stem cells

(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 30-1)

Case not falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

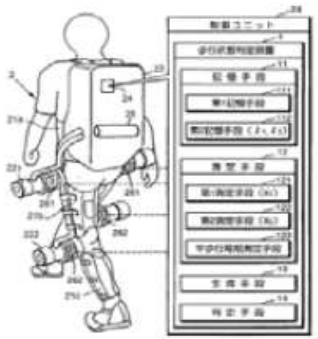
Power Assist Methods (Non-Medical Purpose)

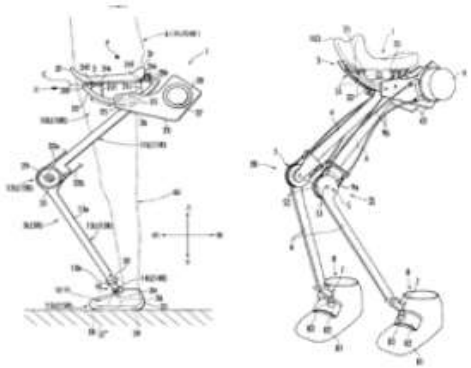
[Claim 1]

A power assisting method to assist movements of a worker by a power assisting equipment coupled to a worker to reduce his burden comprising, a step of placing a sensor attached to the power assisting equipment on skin of an arm or a leg of the worker, a step of measuring myogenic potential of the arm or leg of the worker with a sensor attached to the power assisting equipment, and a step of moving the arm or the leg of the worker by driving a motor attached to the power assisting equipment based on the measured myogenic potential.

[Outline of the Detailed Description of the Invention]

This invention relates to a method for controlling a power assisting equipment used to reduce a burden of a worker involved in hard work based on the myogenic potential of an arm or an leg of the worker and assisting movements of the worker. ("A worker" described in the claims is defined as a person involved in hard work in the detailed explanation of the invention. It is not supposed that the power assisting equipment of this invention assists movements of those who lost muscle strength and those who lost physical motor function for medical purposes.)





(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 31-3)

Case not falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

Power Assist Methods (Non-Medical Purpose)

[Claim 1]

A power assisting method to assist movements of a worker by a power assisting equipment coupled to a worker to reduce his burden comprising, a step of placing a sensor attached to the power assisting equipment on skin of an arm or a leg of the worker, a step of measuring myogenic potential of the arm or leg of the worker with a sensor attached to the power assisting equipment, and a step of moving the arm or the leg of the worker by driving a motor attached to the power assisting equipment based on the measured myogenic potential.

[Outline of the Detailed Description of the Invention]

This invention relates to a method for controlling a power assisting equipment used to reduce a burden of a worker involved in hard work based on the myogenic potential of an arm or an leg of the worker and assisting movements of the worker. ("A worker" described in the claims is defined as a person involved in hard work in the detailed explanation of the invention. It is not supposed that the power assisting equipment of this invention assists movements of those who lost muscle strength and those who lost physical motor function for medical purposes.)

[Explanation]

According to the detailed explanation of this invention, since “a worker” is defined as a person involved in hard work and it is not supposed that the power assisting equipment of this invention assists for the medical purpose movements of those who lost muscle strength and those who lost physical motor function, the power assisting method of this invention does not fall under “methods of surgery, therapy or diagnosis of humans.”

(See Examination Handbook Annex A “Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 31-3)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Relation to Methods of Surgery, Therapy or Diagnosis of Humans

Patentable Subject Matter:
Those do not fall under the methods of surgery, therapy or diagnosis of humans.

- Medicines (including Combined Medicines)
- Methods for Manufacturing Medicines
- Vectors
- Methods for Producing Vectors
- Medical Materials (Combination of Tissue-derived Material and Scaffolding Material etc.)
- Methods for Implanting Medical Material to Mice
- Methods for Manufacturing Medical materials
- Combinations of Physical and Biochemical Means
- Methods for Inducing and Analyzing Cell Differentiation
- Methods of Power Assist (Non-medical purpose)
- Medical Devices (Pacemakers etc.)
- Methods of Operation of a Medical Device
- Methods for Collecting Information from a Human Body

Not Patentable Subject Matter:
Those do not fall under the methods of surgery, therapy or diagnosis of humans.

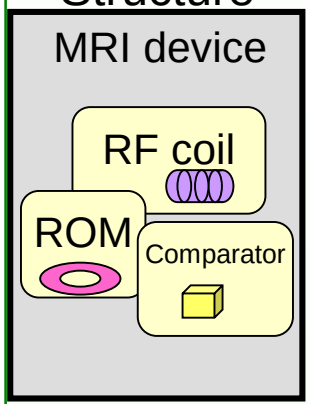
- Methods for Administering Medicines to Humans
- Methods for Introducing Genes to Humans using Vectors
- Methods for Implanting Medical Material in Humans
- Methods of Therapy of Humans using Combinations
- Methods of Power Assist for Medical Purposes (for Rehabilitation etc.)
- Methods of Surgery, Therapy or diagnosis of humans using medical devices
- Methods including a Process of Determining Physical Conditions of Humans for a Medical Purpose

Medical Device Inventions

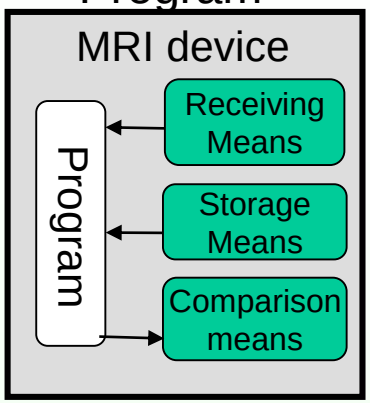
Patentable Subject Matter

Medical Device

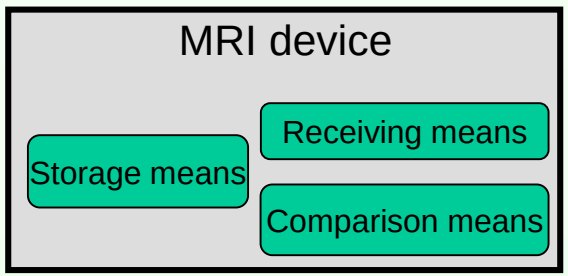
Structure



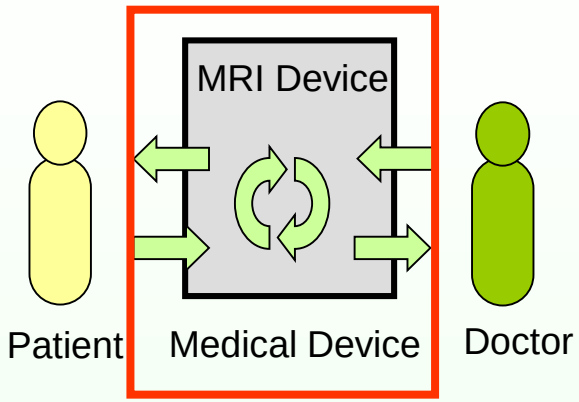
Program



Function



Methods of Operation of a Medical Device

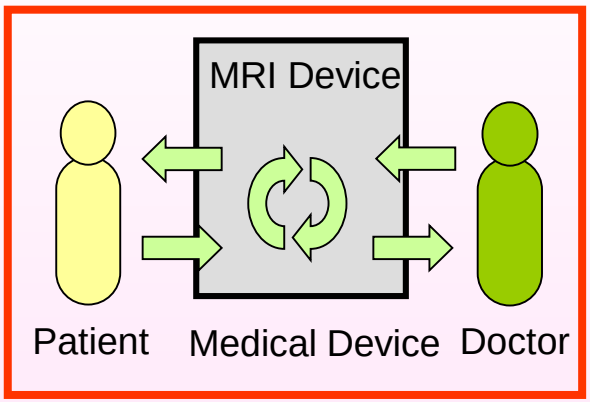


The function of the medical device itself is represented as a method.
It includes neither a process performed by a doctor nor a process of acting on a human body by a device.

Non-Patentable Subject Matter

(Methods of Surgery, Therapy or Diagnosis of Humans)

Methods of Surgery, Therapy or Diagnosis of Humans using Medical Devices.



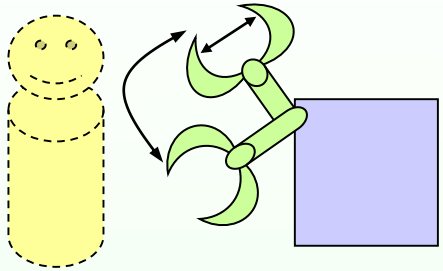
(See Examination Guidelines Part III, Chapter 1, “3.2.1 Types of methods not considered to be a "method of surgery, therapy or diagnosis of humans")

Methods of Operation of a Medical Device

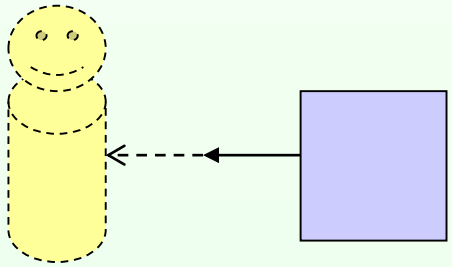
A method of operation of a medical device is an expression of a function of the medical device itself as a method.

○ Considered to be a Method of Operation of a Medical Device

Moving or Opening/Closing operation etc. of an Incising Means



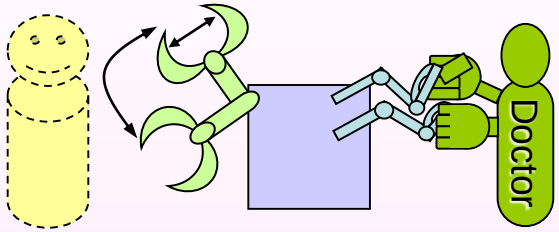
Transmission of Electromagnetic Waves etc.



× NOT Considered to be a Method of Operation of a Medical Device

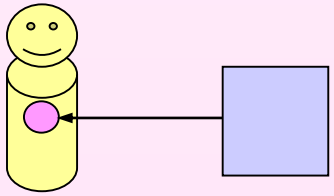
Methods including a Process performed by a Doctor

e.g.) a process in which a medical doctor operates a device to give treatment suited to the symptom of the patient.



Methods including a Process acting on a Human Body by a Medical Device

e.g.) a process of irradiating the human body with electromagnetic waves, or a process of incising or excising a particular part of the patient's body using equipment



(See Examination Guidelines Part III, Chapter 1, "3.2.1(2) Method for controlling the operation of a medical device")

Case falling under “Methods of Operation of a Medical Device”

Patentable Subject Matter

Methods of Operation of a Medical Device

[Claim 1]

A method for controlling the operation of a micro operation robot system provided with a micro operation robot and a remote operation device for remote-operating the robot with a manipulator, wherein the robot has at its head an optical observing means and an incising means and at its bottom a receiving means for receiving manipulator signals from the remote operation device, comprising the steps of; transmitting the signal of the manipulator by the transmitting device to the remote operation device, receiving the manipulator signal from the remote operation device by the receiving means of the robot, and controlling the operation of the incising means of the robot with the manipulator signal received.

[Outline of the Detailed Description of the Invention]

The capsule type micro operation robot of the present invention can, owing to very delicate constitution thereof, perform treatment of the affected part by remote control in an organ such as a blood vessel or the like, without excessively burdening the patient.

[Explanation]

Since the matter reading “controlling the operation of the incising means of the robot with the signal received” means that “the incising means” provided with the micro operation robot system is controlled with the manipulator signal received and does not mean so farther that the incising means incises the human body as a result of the operation; thus, the claimed method is judged not to include the step with an influence on the human body by the device.

It is thus recognized that the function of the medical device is represented as a method, and the method does not include the step with an action of a medical doctor or the step with an influence on the human body by the device. As a result, it is considered to be a method of operation of a medical device, and not considered to be “methods of surgery, therapy or diagnosis of humans.”

(See Examination Handbook Annex A “3. Eligibility for Patent and Industrial Applicability” Case 15-2)

Case not falling under “Methods of Operation of a Medical Device”

Not Patentable Subject Matter

Methods of Surgery, Therapy or Diagnosis of Humans using Medical Devices

[Claim 1]

A method for treating an affected part by using a micro operation robot having at its head optical observing means and incising means and having at its bottom receiving means for receiving manipulator signals from an extracorporeal remote operation device, comprising the steps of; operating a manipulator in order to give medical treatment to the affected part while viewing the monitor of the remote operation device, receiving a manipulator signal from the remote operation device by the receiving means, and incising the affected part of a patient by an incising means based on the signal received.

Acting on a Human Body by a Medical Device

Action by a Doctor

[Outline of the detailed description of the invention]

The capsule type micro operation robot of the present invention can, owing to very delicate constitution thereof, perform treatment such as incision, excision, or the like of the affected part by remote control in an organ such as a blood vessel or the like, without excessively burdening the patient.

[Explanation]

The matter reading “operating a manipulator in order to give medical treatment to the affected part while viewing a monitor of the remote operation device” includes the step with an action of a medical doctor to view a monitor and to operate a manipulator for treating the affected part. Furthermore, the matter reading “incising the affected part of a patient by incising means” depicts the step with an influence on the human body by the device.

Accordingly, the claimed method is not considered to be a method for controlling the operation of the medical device.

As a result, the method in this example is nothing but a method of surgery of humans since it corresponds to a method for operating a manipulator and incising the affected part for the treatment of the affected part. Accordingly, the claimed method includes a method of surgery of humans as part of the steps of the invention; thus, the method is considered to be “methods of surgery, therapy or diagnosis of humans”

(See Examination Handbook Annex A “3. Eligibility for Patent and Industrial Applicability” Case 15-1)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Relation to “Methods of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter:
Those do not fall under the methods of surgery, therapy or diagnosis of humans.

- Medicines (including Combined Medicines)
- Methods for Manufacturing Medicines
- Vectors
- Methods for Producing Vectors
- Medical Materials (Combination of Tissue-derived Material and Scaffolding Material etc.)
- Methods for Implanting Medical Material to Mice
- Methods for Manufacturing Medical materials
- Combinations of Physical and Biochemical Means
- Methods for Inducing and Analyzing Cell Differentiation
- Methods of Power Assist (Non-medical purpose)
- Medical Devices (Pacemakers etc.)
- Methods of Operation of a Medical Device
- Methods for Collecting Information from a Human Body

Not Patentable Subject Matter:
Those do not fall under the methods of surgery, therapy or diagnosis of humans.

- Methods for Administering Medicines to Humans
- Methods for Introducing Genes to Humans using Vectors
- Methods for Implanting Medical Material in Humans
- Methods of Therapy of Humans using Combinations
- Methods of Power Assist for Medical Purposes (for Rehabilitation etc.)
- Methods of Surgery, Therapy or diagnosis of humans using medical devices
- Methods including a Process of Determining Physical Conditions of Humans for a Medical Purpose

Methods for Collecting Various Types of Information from a Human Body

The methods (i) and (ii) shown below for collecting various types of information from the human body by measuring the structures and functions of organs in the human body do not correspond to a method of diagnosing the human unless the method includes a process as shown below.

- A process of making a determination for a medical purpose, as to physical or mental conditions, such as the state of a disease or health, or as to a prescription or plan for therapy or surgery based thereon

  e.g.) a process of determining an illness as a cerebral infarction by checking MRI images

- A process corresponding to a method of surgery or therapy of humans

(i) Methods for collecting samples or data from the human body, or methods for analyzing, e.g. comparing such samples or data with standards, including:

- a method for an influenza test by extracting oral mucous membranes with a cotton bud;
- a method for capturing an image of the lung by irradiating the chest with X-ray;
- a method for measuring the body temperature by inserting an electronic ear thermometer into the external ear canal; and
- a method of examining the susceptibility of the examinee to hypertension by determining the type of base on the nth line of the base sequence of the X gene of the examinee and comparing the base with a standard determining that when the base type is A the susceptibility is high, and when the type is G the susceptibility is low.

(ii) Preparatory treatment for measuring structures or functions of various organs of the human body, including:

- A method of preventing uneven application of jelly for ultrasonography that is applied o the body.

(Refer to Examination Guidelines Pat III, Chapter 1, “3.2.1(3) Method for gathering various kinds of information from the human body by measuring structures and functions of organs in the human body”)

Case not falling under “Methods of Surgery, Therapy or Diagnosis of Humans”

Patentable Subject Matter

Methods of Collecting Various Information from a Human Body

[Claim 1]

A method for imaging by controlling the respective parts of an X-ray CT scanner by control means, comprising; a step of exposing X-rays to the human body by controlling X-ray generating means, a step of detecting the X-rays permeated through the human body by controlling X-ray detecting means, and a step of performing reconstruction of the detected data and converting such detected data into picture data for display.

[Outline of the detailed description of the invention]

The present invention relates to a method for imaging by controlling an X-ray CT scanner for picking up an image of a human body, and a picture image thereof can be accurately displayed on account of the reconstruction of the detected data.

[Explanation]

The claimed invention does not include the steps of medical doctors judging for medical purposes the physical condition of a human body such as diseases and physical health, nor the steps of surgery or therapy of humans. Therefore, the claimed method is not considered to be “methods of surgery, therapy or diagnosis of humans.”

Since the matter reading “exposing X-rays to the human body” includes the step with an influence on the human body by the device, the claimed method is not considered to be a method for controlling the operation of the medical device.

(See Examination Handbook Annex A “3. Cases pertinent to Eligibility for Patent and Industrial Applicability” Case 24-1)

Case falling under “Method of Surgery, Therapy or Diagnosis of Humans”

Not Patentable Subject Matter

Methods of Surgery, Therapy or Diagnosis of Humans using Medical Device

[Claim 1]

A method for irradiating X-rays onto the human body by changing the tube voltage and the tube current of the X-ray generator each time the generator rotates one lap inside the gantry.

[Outline of the Detailed description of the Invention]

The present invention relates to a method for treatment of the human body by X-ray therapy while confirming the X-ray therapy process by monitoring the X-ray image of the affected area.

The device used in the present invention places the X-ray generator and the X-ray detector in opposite positions inside the gantry, and rotates one lap around the circumference of the gantry maintaining the opposite positions. The X-ray generator which is used for treatment of the human body and imaging procedures sets the appropriate tube voltage and tube current for treatment at the time of treatment and sets the appropriate tube voltage and tube current for image processing at the time of imaging. The X-ray device used in this invention has a control function for controlling the operation of the X-ray generator and the X-ray detector, and their rotation, detects the rotating position of the X-ray generator, and changes the tube voltage and tube current each time it rotates one lap around the circumference.

In the present invention the treatment and the imaging procedures are switched over each time the X-ray generator and the X-ray detector rotates one lap inside the gantry. At the time of treatment the X-ray will be irradiated to the affected area at the appropriate tube voltage and tube current value for treatment procedures while the X-ray generator is rotating one lap around the circumference. Just before the start of the next lap, the value of the tube voltage and tube current is changed to the appropriate value for imaging. During the next lap, the X-ray will be irradiated to the affected area at the appropriate tube voltage and tube current value for imaging, the X-ray that penetrate the affected area are detected by the X-ray detector, and image reconstruction is performed.

(See Examination Handbook Annex A “3. Eligibility for Patent and Industrial Applicability” Case18-1)

Case falling under “Methods of Surgery, Therapy or Diagnosis of Humans”

Not Patentable Subject Matter

Methods of Surgery, Therapy or Diagnosis of Humans using Medical Devices

[Claim 1]
A method for irradiating X-rays onto the human body by changing the tube voltage and the tube current of the X-ray generator each time the generator rotates one lap inside the gantry.

[Explanation]
Since the matter reading “irradiating X-rays onto the human body” includes the step with an influence on the human body by the device, the claimed method is not considered to be a method for controlling the operation of the medical device.
Additionally since the claimed method does not include the steps with an action of a medical doctor judging the condition of human diseases or the physical condition of a human body, it is not considered to be “methods of diagnosis of humans.”
According to the detailed description of this invention, by changing the tube voltage and tube current of the X-ray generator, the treatment and imaging is repeated alternately; thus the steps to irradiate X-rays onto the human body by changing the tube voltage and tube current of the X-ray generator include a step of therapy of humans.
Therefore, the claimed method is considered to be a “method of surgery, therapy or diagnosis of humans.”

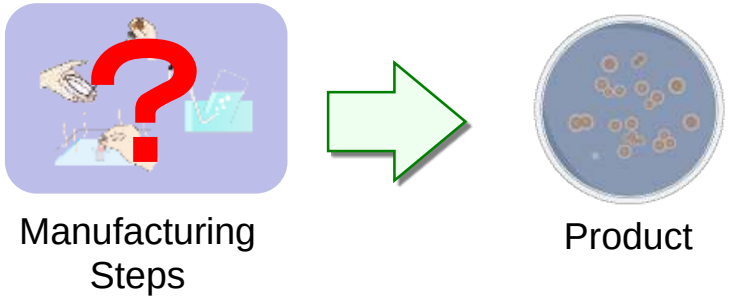
(See Examination Handbook Annex A “3. Eligibility for Patent and Industrial Applicability” Case 18-1)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Types of Inventions that are Considered to be Unclear

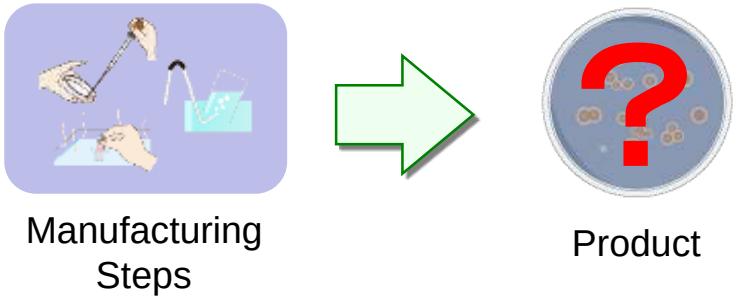
Types of the Inventions that are Considered to be Unclear where a Claim Includes an Expression for Specifying a Product by a Manufacturing Method thereof

1. Inventions are considered to be unclear when the person skilled in the art cannot understand the manufacturing method (starting material, manufacturing steps, etc.) based on the matter stated in the claim even by considering the description and drawings as well as the common technical knowledge at the time of filing.



The claim does not correspond to this type when the manufacturing method can be understood by considering the Description and Drawings as well as the common technical knowledge at the time of filling.

2. Inventions are considered to be unclear when the person skilled in the art cannot understand the characteristics of the product (structure, properties, etc.) even by considering the Description and Drawings as well as the common technical knowledge at the time of filling.



［Example］

The Description and Drawings only describe features not reflected to the product (high yield, high manufacturing efficiency, etc.), and hence the characteristic of the product (structure, properties, etc.) cannot be understood. (Refer to the next slide.)

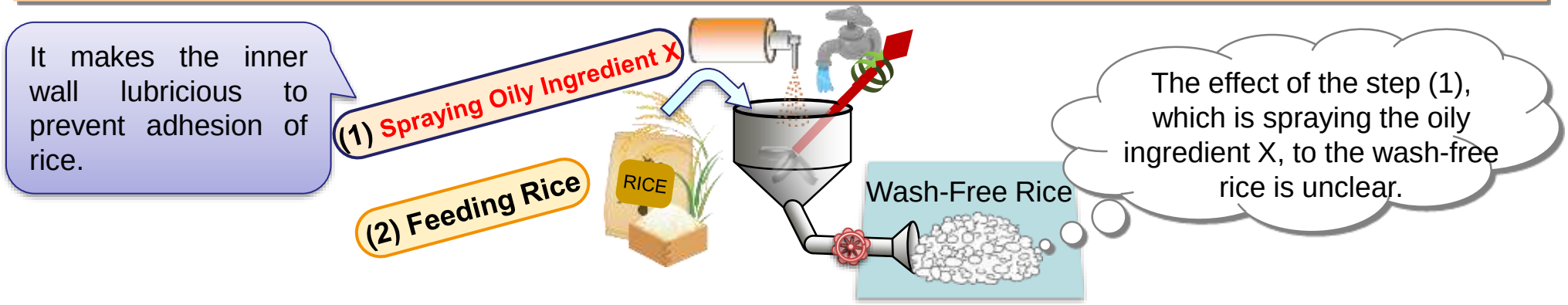
(See Examination Guidelines Part II, Chapter 2, Section 3 “4.3.1 Types of unclear inventions”)

Exemplary Case where an Invention is Considered to be Unclear because the Features of the Product cannot be Identified

The cases where the description and drawings only describe the features that are not reflected to the product and hence the features of the product cannot be identified

[Claim 1]
Wash-free rice manufactured by a wash-free rice manufacturing method comprising the steps of: receiving a feed of rice within a tank and removing bran by washing the rice in water; opening a drop valve situated at the bottom of the tank and dropping the bran-removed rice into a container provided down below; and drying the rice dropped into the container, wherein the manufacturing method further includes a step of spraying oily ingredient X onto the inner wall of the tank before feeding rice, and a step of blowing air into the tank immediately before opening the drop valve.

[Explanation]
The description states that the step of spraying oily ingredient X onto the inner wall of the tank before feeding rice makes the inner wall of the tank lubricious so as to prevent the rice from adhering to the wall, and that the step of blowing air into the tank immediately before opening the drop valve enables the rice on the inner wall of the tank to be dropped efficiently into the container provided down below.
Even when considering the statements of the description and drawings as well as the common general knowledge as of the filing, however, it is uncertain how the step of spraying oily ingredient X onto the inner wall of the rice washing tank could affect the wash-free rice to be obtained, and the characteristics of the claimed wash-free rice cannot be understood.



(See Examination Guidelines Part II, Chapter 2, Section 3 “4.3.1 Types of unclear inventions”)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

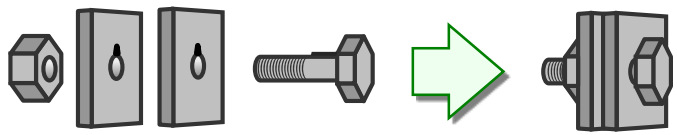
Basic Idea

"When a claim concerning an invention of a product describes a manufacturing method thereof", the invention of the claim is considered "clear" only when "impossible or impractical circumstances" exist.

cf. Judgment of the Second Petty Bench of the Supreme Court (June 5, 2015 (2012 (Ju) No. 1204, 2658) Case of suit against appeal decision)

The invention does not fall under this category when "what structure" or characteristic of the product the manufacturing method represents is clear, from the Description, Claim(s), and Drawing(s) and the common technical knowledge in that technical field at the time of filing.
(including the inventions fall under the types (1-1) and (1-2) on the next slide.)

An example that formally falls under Type (1-1) but is not considered as unclear: An apparatus having an anchorage formed by inserting a bolt provided with a convex portion into a hole provided with a concave portion so that the concave portion and the convex portion are engaged, and screwing a nut into an end portion of the bolt.



An example that formally falls under Type (1-2) but is not considered as unclear: A micro mechanical device comprising a frame member and a swing member capable of swinging in the frame member, wherein a gap between the members is formed through etching, and at least a part of the gap is filled with an elastic filler.

Applicants can explain or allege such circumstances in the description, written opinion, etc.

Circumstances where it is impossible or impractical to directly identify the product based on its structure or characteristics at the time of filing, such as when:

1. It was technically impossible to analyze the structure of the product or characteristics at the time of filing; or
2. It required an extravagant expenditure of money or time to carry out the work to identify the structure of the product or characteristics, considering the fact that the patent filing requires prompt action by its nature.

(See Examination Guidelines Part II, Chapter 2, Section 3 "4.3.2 The case where a claim concerning an invention of a product includes a manufacturing method for the product"; and Examination Handbook Part II 2203-2205)

Examples falling under / not Falling under "a Claim describing a Manufacturing Method of the Product"

✕ Type (1-1): Cases describing Time-Sequential Elements in Manufacturing

Falling under the Type of Claim **(Unclear)**

"A compound A sodium salt prepared by a process comprising the steps of:
a) forming an enriched organic solution of the compound A;
b) precipitating a compound A as its ammonium salt;
c) purifying the ammonium salt by recrystallization;
d) transposing the ammonium salt to sodium salt; and
e) isolating a compound A sodium salt."

Example of amendment:
A manufacturing method of a compound A sodium salt comprising the steps of:
a) forming an enriched organic solution of the compound A;
b) precipitating a compound A as its ammonium salt;
c) purifying the ammonium salt by recrystallization;
d) transposing the ammonium salt to sodium salt; and
e) isolating a compound A sodium salt."

✕ Type (1-2): Cases describing Technical Features or Conditions in Manufacturing

Falling under the Type of Claim **(Unclear)**

"A polymer C acquired by reacting a monomer A with a monomer B at 50°C."
"A fluorescent body formed by sintering under 1 to 1.5 atmospheric pressures."

Examples of amendment:
"A manufacturing method of a polymer C in which a monomer A is reacted with a monomer B at 50°C."
"A manufacturing method of a fluorescent body manufactured via a sintering step under 1 to 1.5 atmospheric pressures."

○ Type (2): Cases identifying the Structure or Feature only by Indicating a State

NOT Falling under the Type of Claim **(Clear)**

"A polymer with polymerized monomer A and monomer B"
"A PEGylated protein"
"A modified protein A after translation"
"A humanized antibody"
"A protein having an amino acid sequence represented by SEQ. No. X in which at least one amino acid is deleted, substituted or added."
"Isolated cell", "Extract", "Threshed rice", "Spirits", "Plating layer"

Particularly, terms of which concepts have been established as specifying the structure or characteristic of the matters.

(See Examination Guidelines Part II, Chapter 2, Section 3 "4.3.2 The case where a claim concerning an invention of a product includes a manufacturing method for the product"; and Examination Handbook Part II 2203-2205)

Examples falling under / not Falling under “Impossible/Impractical Circumstances”

Whether “impossible/impractical circumstances” exist is determined based on argument and verification provided by the applicant.

Common technical knowledge in the technical field of the invention is also considered.

The “impossible/impractical circumstances” are approved when there is no reasonable question about the argument and verification for the circumstances (when the examiner cannot state a specific doubt).

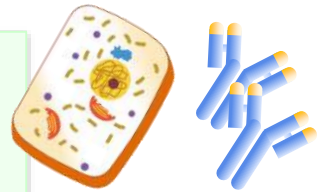
○ Type (i) Cases in which analyzing the structure of the products or characteristics was technically impossible at the time of filing.

Type (ii) Cases in which an extravagant expenditure of money or time was necessary to carry out the work to identify the product’s structure or characteristic while the filing for patent naturally requires prompt action.

Falling under the Type of Claim (Clear)

“Cells etc. created by a new genetic manipulation” (2012 (Ju) No. 1204, 2658)

“A monoclonal antibody prepared by a hybridoma cell A” (Reference Decision: Appeal 2014-17732)



× Type (iii) Cases in which the relations to the present invention are not described at all.

NOT Falling under the Type of Claim (Unclear)

A case making an argument that formulating “Claim(s)” is merely time consuming.

A case making an argument that the invention is easier to understand when it is described based on the manufacturing method.

(See Examination Guidelines Part II, Chapter 2, Section 3 “4.3.2 The case where a claim concerning an invention of a product includes a manufacturing method for the product”; and Examination Handbook Part II 2203-2205)

Process of Making a Determination

Does it fall under the “case where a claim concerning an invention of a product describes a method for manufacturing said product”? (※1)

YES → “Impossible/impractical circumstances” exist? (※2)

NO → No reasons for refusal

“A PEGylated protein”, “A modified protein A after translation”, “A humanized antibody”, “An isolated cell”, etc.

NO → Reasons for refusal based on violation of clarity requirements (Unclear)

YES → No reasons for refusal

“Cells etc. created by a new genetic manipulation”, “A monoclonal antibody prepared by a hybridoma cell A”, “Animal and plant obtained by a breeding method such as crossing”, etc.

Measures taken by the applicant (the applicant can take measures as shown below)

Argument and verification of “impossible/impractical circumstances” in a written opinion etc.

Amendments:
- Amendment to a manufacturing method invention
- Amendment to a product invention not including manufacturing method
- Deleting Claim(s)

An argument asserting that the invention does not fall under the “case where a claim concerning an invention of a product describes a method for manufacturing the product”.

There is a reasonable question	There is no reasonable question (※3)	Still falling under the “claim of a product describing its manufacturing method”	Not falling under the “claim of a product describing its manufacturing method”	The argument is NOT acceptable	The argument is acceptable
decision of refusal	Reasons for refusal solved	Decision of refusal	Reasons for refusal solved	Decision of refusal	Reasons for refusal solved

※1 The answer is “NO” when “what structure or characteristics of the matter the manufacturing method represents” is clear considering the description, claim(s) and drawing(s) and the common technical knowledge of that field at the time of filing.
※2 Circumstances that it is impossible or impractical to directly specify the structure or characteristics of the product at the time of filing.
※3 It is considered that there is no reasonable doubt in the case where the examiner found no specific doubt.

Exemplary Argument/Verification of “Impossible/Impractical Circumstances”

[Claim 1]

An oil-in-water type creamy emulsion composition for foods comprising water, an oil component, emulsifiers, a component A and a component B, and having a viscosity of X-Y mPa･s , wherein said emulsion composition includes an emulsifier X and an emulsifier Y with 10-20/30-40 weight ratio, and wherein an oil phase containing said emulsifiers, the component A and the component B is prepared in advance by mixing and stirring them and then the resulting product is added to a water phase to obtain said emulsion composition.

[Argument/verification regarding “impossible/impractical circumstances” in a written opinion]

The present invention prepares in advance an oil solution in which the prescribed emulsifiers, component A and component B are dispersed in the solution, and then the oil solution is added to a water phase for emulsion. The present invention provides an oil-in-water type creamy emulsion composition for foods having a good foam stability compared to one obtained by a conventional method in which a water phase dissolving an emulsion, a component A and a component B is added to an oil phase for emulsion (see the description of the present application, paragraphs X-X).

As described, compared to the prior art, the good foam stability achieved by the present invention is caused by the microscopic difference in a dispersed state of the components provided by the different manufacturing process. The microscopic difference in the dispersed state cannot be identified with general indexes such as the composition or viscosity.

Even if it is attempted to express the property of foam stability itself in a numerical range, the microscopic dispersed state in an oil-in-water type creamy emulsion composition for foods varies depending on the composition of the raw material, temperature, stirring speed and other manufacturing conditions. Then, if the microscopic dispersed state is different, the numerical value of foam stability naturally changes. Thus, manufacturing the product with raw materials constituting various compositions under various manufacturing conditions such as the temperature and the stirring speed and measuring the foam stability of each resulting product requires impractical numbers of experiments and drastically huge economic expenses. Furthermore, the result cannot be expressed in a claim comprehensively.

Therefore, it is utterly impractical to “specify the product directly with structure or property at the time of the filing of the application” in the case of the present invention.

(See Examination Guidelines Part II, Chapter 2, Section 3 “4.3.2 The case where a claim concerning an invention of a product includes a manufacturing method for the product”; and Examination Handbook Part II 2203-2205)

Exemplary Argument/Verification of “Impossible/Impractical Circumstances”

[Claim 1]
An antibody or an antigen-binding fragment thereof which is produced from a hybridoma deposited under accession No. FERM BP-11110 or No. FERM BP-11111.

[Argument/verification of “impossible/impractical circumstances” in a written opinion]
The “hybridoma” described in Claim 1 is a typical “hybridoma” obtained by the fusion between “lymphocytes obtained by immunization with a sweat antigen composition” and “myeloma cells” (as described in paragraphs A to B). Thus, it is apparent to a person skilled in the art from the common general knowledge that the “antibody” (a monoclonal antibody) produced from the specific “hybridoma” is only one antibody.
The hybridoma described in Claim 1 is one “deposited under accession No. FERM BP-11110 or No. FERM BP-11111” thereby, if the each hybridoma under those accession numbers is obtained from the depositary institution and produces an antibody, “an antibody” of Claim 1 can be obtained and used. In other words, even if Claim 1 does not describe the chemical structure (such as the amino acid sequence) of the “antibody” but specifies the antibody as an “’antibody’ produced from a hybridoma”, it is always produced only one antibody (the monoclonal antibody), and therefore it is recognized that such “antibody” can be produced and used.
On the other hand, when an attempt is made to further specify the chemical structure of the “’antibody’ produced from the hybridoma”, it is considered that identification of the chemical structure of the antibody takes substantial amount of time, effort and cost because the “antibody” is not a low molecular weight compound, but a high molecular weight protein having a three dimensional structure.
Therefore, it can be said that it is “impractical” to take substantial amount of time, effort and cost for only the purpose of identification of the chemical structure of the “antibody” … under the common general knowledge as described above. Further, it can be said that it is also impractical in view of the first-to-file system because the filing date of the application might be delayed for that reason. In addition, in the field of biotechnology to which the invention pertaining to the present application belongs, the technology thereof has rapidly developed and the global competitiveness has become intense. It is therefore quite important to file a patent application promptly, so that the circumstances being “impractical” exist still more.
Then, it is recognized that the description of Claim 1 falls under the case of “impossible or impractical circumstances”.

(See Examination Handbook Annex D “2. Court precedents relating to requirements for description” Classification (24)-7)

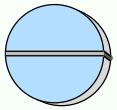
1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Patentable Categories of Medicinal Inventions

Patentable Categories (Invention of a Product)

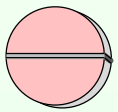
New Medicinal Use

Applied to a New Disease
Medicines for Asthma,
Antihypertensives,
Anti-allergic Agents, etc.



An Agent for
Disease Y

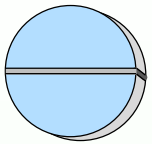
Applied to a Specific Disease with New Dosage or Administration
－Dosage or Administration－
Time, Method, Dose, and Site, etc. of Administration



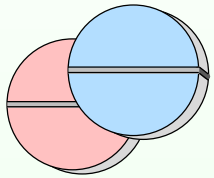
An Agent for
Disease Z
X μg/kg (Body Weight)
Y time(s) a day

Single Agents, Combined Agents etc.

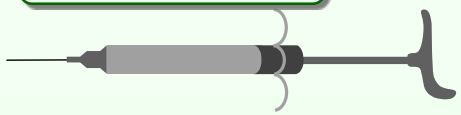
Single Agents



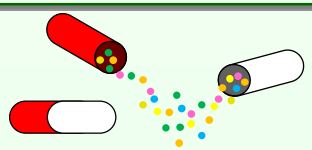
Combined Agents



Injections

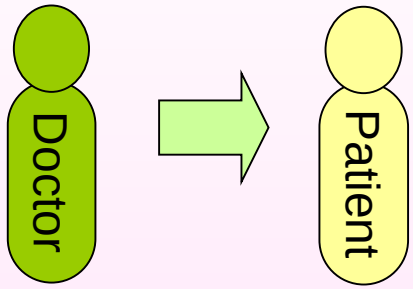


Oral agents



Unpatentable Categories (Methods of Surgery, Therapy or Diagnosis of Humans)

Medicine Administration Method etc.



(See Examination Handbook Annex B Chapter 3 “Medicinal Inventions”)

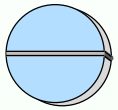
Patentable Categories of Medicinal Inventions

Patentable categories (Invention of a product)

New Medicinal Use

Applied to a New Disease

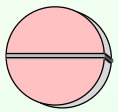
Medicines for Asthma, Antihypertensives, Anti-allergic Agents, etc



An Agent for Disease Y

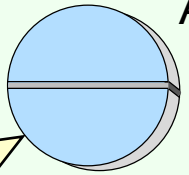
Applied to a Specific Disease with a New Dosage or Administration

－Dosage or Administration－
Time, Method, Dose, and Site, etc. of administration



An Agent for Disease Z

△ μg/kg (body weight)
▲ time(s) a day

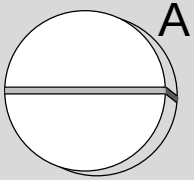


An Agent for Disease Y

Involves novelty even if the composition is the same as that of the prior art.

Medicine of the Present Invention
(Applied to disease Y different from disease Z)

Involves Novelty

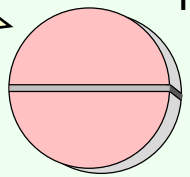


A medicine for disease Z

○ μg/kg (body weight)
● time(s) a day

Medicine of Prior Art

Involves Novelty



Medicine for disease Z

△ μg/kg (body weight)
▲ time(s) a day

Involves novelty even if the composition and target disease are the same as those of the prior art.

Medicine of the Present Invention
(Dosage and administration differ from those of the prior art)

(See Examination Handbook Annex B Chapter 3 “Medicinal inventions”)

Definition of “Medicinal Inventions”

A medicinal invention is “an invention of a product” which intends to provide a new medicinal use(※1) of a material(※2) based on the discovery of an unknown attribute of the material.

(※1) “Material” here means a component used as an active ingredient, including a compound, a cell, a tissue, and a chemical substance (or a group of chemical substances) whose chemical structure is not specified, such as an extract from a natural product, and a combination thereof.

(※2) “Medicinal use" here means (i) an application to a specific disease; or (ii) an application to a specific disease in which dosage or administration, such as a dosing time, a dosing procedure, a dosing amount or an administration site, etc., is specified.

(See Examination Handbook Annex B Chapter 3 “Medicinal inventions”)

Comparison of Expressions in terms of Medicinal Inventions among JP, EP and US

JP, EP

Protected as Product Invention

- When an already-known substance is specified in terms of a medicinal use, it is protected (novelty is allowed) as a “product invention”.
- Not patentable and not protected as a “method invention”.

○ An anti-cancer medicine containing an active ingredient A

Patentable

× A method of treating cancer by administering a medicine containing an active ingredient A

Unpatentable

US

Protected as Method Invention

- Even if an already-known substance is specified in terms of a medicinal use, it is considered as an identical substance with the already-known substance and not protected (novelty is not allowed) as a “product invention”.
- Protected as a “method invention” instead.

× An anti-cancer medicine containing an active ingredient A

Considered to Lack Novelty

○ A method of treating cancer by administering a medicine containing an active ingredient A

Patentable

Clarity of Invention

The scope of the claimed invention should be clear.

A medicinal invention can be described in a claim as an "invention of a product" as shown below:

Example 1:	A medicine for disease Z containing an active ingredient A.
Example 2:	A medicinal composition for disease Y containing an active ingredient B.
Example 3:	A medicine for disease W containing active ingredients C and D in combination.
Example 4:	A kit for disease V comprising an injection agent including an active ingredient E and an oral agent including an active ingredient F.

(See Examination Handbook Annex B, Chapter 3 “1.2.2 Clarity Requirement”)

Enablement Requirements

Carrying out of an invention of a product means that the product can be produced and used. Embodiments of the invention shall be described in such a manner that the product can be produced and used.

Generally, medicinal invention belongs to a technical field where it is relatively difficult to understand how to make and use a product on the basis of its structure or name. Hence, one or more representative examples are normally required. In addition, the description of results of pharmacological study is usually required for supporting the medicinal use.

All of the following should be made sufficiently clear as the results of pharmacological study: (i) which compound was applied to (ii) what pharmacological study system, (iii) what results were obtained, and (iv) what relevance the pharmacological study system has with the medicinal use of the claimed medicinal invention.

In principle, the results of pharmacological study should be described with numerical data, and clinical studies, animal experiments, and *in-vitro* studies can be employed as the pharmacological study system.

(See Examination Handbook Annex B, Chapter 3 “1.1.1 Enablement Requirement”)

Case Example where the Enablement Requirements are not Satisfied

[Claim 1]
An antiemetic drug containing ingredient A as an active ingredient.

[Outline of the detailed description of the invention]
The present invention relates to a new use of the ingredient A (the ingredient A itself is publicly known). The detailed description of the invention describes the effective dose of ingredient A, the mode of administration, and the method of formulation.
(However, it does not contain any statement of the pharmacological test method or results. Furthermore, the use of ingredient A in an antiemetic drug cannot be presumed from the common general knowledge as of the filing.)

[Explanation]
The detailed description of the invention does not contain any statement of the pharmacological test method or results which show the use of ingredient A as an antiemetic drug. Furthermore, as the use of ingredient A in an antiemetic drug cannot be presumed from the common general knowledge as of the filing, the statement of the detailed description of the invention cannot be deemed to be informative enough to use an antiemetic drug containing ingredient A as an active ingredient.
Thus, the detailed description of the invention is not stated clearly or sufficiently as to enable a person skilled in the art to work the invention of claim 1, which relates to an antiemetic drug containing ingredient A as an active ingredient.

(See Tokyo High Court decision dated October 30, 1998 (Hei 8 (Gyo-Ke), No. 201))

[Measures to be taken by the applicant]
The reasons for refusal cannot be overcome even when the applicant submits a certificate of experimental results describing the pharmacological test method and results and argues that the drug functions as an antiemetic drug.

(See Examination Handbook Annex A “Description Requirements” Case 8)

Support Requirements

The claimed invention should not depart from the scope of the invention described in the description.

It is determined whether the statement in the claims satisfies the support requirement by comparing the claimed invention and the invention stated in the description.

In making this comparison, the examiner examines the substantial correspondence between the claimed invention and the invention described in the description, regardless of the consistency of expression.

The substantial correspondence is accessed by the examiner by examining whether or not the claimed invention exceeds “the extent of disclosure in the description to which a person skilled in the art would recognize that the problem to be solved by the invention would be actually solved”.

When it is determined that the claimed invention exceeds “the extent of disclosure in the description,” the claimed invention and the invention disclosed in the description cannot be said as substantially corresponding to each other, and thus the claims are considered as not satisfying the support requirement.

(See Examination Handbook Annex B, Chapter 3 “1.2.1 Support Requirement”)

Case Example where the Support Requirements are not Satisfied

[Claim 1]
An antiemetic drug containing ingredient A as an active ingredient.

[Outline of the detailed description of the invention]
The present invention relates to a new use of the ingredient A (the ingredient A itself is publicly known). The detailed description of the invention describes the effective dose of ingredient A, the mode of administration, and the method of formulation.
(However, it does not contain any statement of the pharmacological test method or results. Furthermore, the use of ingredient A in an antiemetic drug cannot be presumed from the common general knowledge as of the filing.)

[Explanation]
Claim 1 describes an invention relating to an antiemetic drug containing ingredient A as an active ingredient, whereas in light of the statement of the detailed description of the invention, as well as the common general knowledge as of the filing, which are mentioned above, the detailed description of the invention cannot be regarded as disclosing the invention in such a way that a person skilled in the art could recognize that the problem to be solved by the invention of claim 1, which is providing an antiemetic drug containing ingredient A as an active ingredient, would be actually solved.
Thus, the invention of Claim 1 is not stated in the detailed description of the invention.

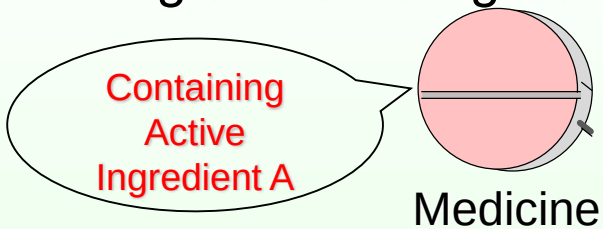
[Measures to be taken by the applicant]
The reasons for refusal cannot be overcome even when the applicant submits a certificate of experimental results describing the pharmacological test method and results and argues that the drug functions as an antiemetic drug.

(See Examination Handbook Annex A “Description Requirements” Case 8)

Novelty / Inventive Step

Present Invention

"A medicine for **Disease Z** containing an active ingredient A"



Cited Invention

"A Medicine for **Disease W** containing an Active Ingredient A"

[Novelty]

- The present invention has novelty because its medicinal use differs from that of the cited invention.

[Inventive step]

- Even when the "medicine for **Disease W** containing the active ingredient A" is publicly known, the present invention involves an inventive step as long as no prior art document provides motivation to apply the active ingredient A to the therapy of disease Z.
- When it is known that the active ingredient A has the function of inhibiting activity of protein P and that the disease Z can be cured by inhibiting the activity of the protein P, the present invention does not involve an inventive step.

Case Example having Novelty / Inventive Step (applied to a Specific Disease)

[Claim 1]

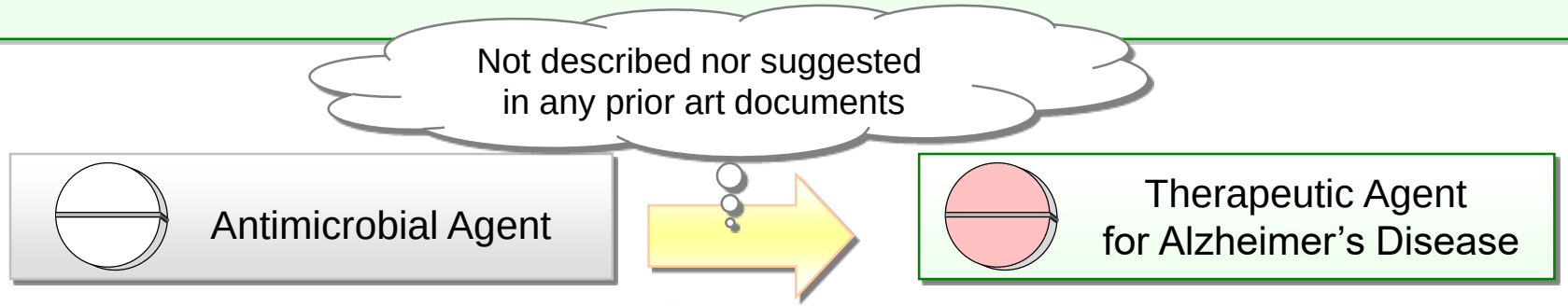
A therapeutic agent for Alzheimer's disease, comprising a compound A as an active ingredient.

[Outline of the detailed description of the invention]

In this invention, the compound A that was known as an active ingredient in an antimicrobial agent has been found to reversibly inhibit acetylcholine esterase to suppress the degradation of acetylcholine. In the working example, the results of pharmacological study are described to show that the compound A has a remarkable inhibitory activity on acetylcholine esterase and that the compound A reduced symptoms of Alzheimer's disease.

[Results of the prior art search]

Although the compound A is already known as an active ingredient in an antimicrobial agent, no therapeutic agent for Alzheimer's disease having the compound A as an active ingredient therein is described in any prior art document. In addition, neither the existence of a structural similarity between the compound A and a compound having an inhibitory activity on acetylcholine esterase, nor the relevance of the mechanism of action of the compound A in an antimicrobial agent with the treatment of Alzheimer's disease have been revealed or suggested in any prior art document.



(See Examination Handbook Annex B Chapter 3 "3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease" Case 1)

Case Example having Novelty / Inventive Step (applied to a Specific Disease)

[Claim 1]
A therapeutic agent for Alzheimer's disease, comprising a compound A as an active ingredient.
[Outline of the detailed description of the invention]
In this invention, the compound A that was known as an active ingredient in an antimicrobial agent has been found to reversibly inhibit acetylcholine esterase to suppress the degradation of acetylcholine.
In the working example, the results of pharmacological study are described to show that the compound A has a remarkable inhibitory activity on acetylcholine esterase and that the compound A reduced symptoms of Alzheimer's disease.

[Explanation]
It is evident that the medicinal use of the compound A (to treat Alzheimer's disease) is different from the medicinal use conventionally known (antimicrobial), and therefore, the medicinal invention of Claim 1 is a novel invention.
Moreover, there is no prior art document that provides a motivation to apply the compound A to treat Alzheimer's disease, such as a structural similarity between the compound A and a compound having an inhibitory activity on acetylcholine esterase, or a relevance of the mechanism of action of the compound A in an antimicrobial agent with the treatment of Alzheimer's disease, and therefore, the medicinal invention of Claim 1 involves an inventive step.

(See Examination Handbook Annex B Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 1)

Case Example having Novelty / Inventive Step (applied to a Specific Disease)

[Claim 1]

A graft material to treat myocardial infarction comprising a cell sheet made of cells A.

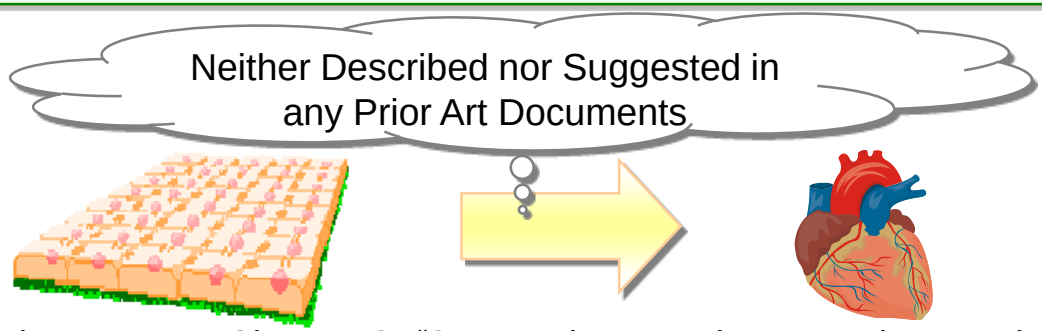
[Outline of the detailed description of the invention]

In this invention, it has been found that the cardiac function is recovered by implanting a cell sheet made of cells A to a site of myocardial infarction.

In the working example, the results of pharmacological study are described to show that the cardiac function is recovered and symptoms of myocardial infarction are reduced by implanting such cell sheet to the site of myocardial infarction in rats of a myocardial infarction model.

[Results of the prior art search]

It is publicly known that the cells A are used to make a cell sheet, which is used as a graft material. However, no prior art document describes or suggests the implantation of such cell sheet to the site of myocardial infarction or the reduction of symptoms of myocardial infarction by such implantation. Moreover, it is not possible to predict the recovery of the cardiac function or the reduction of symptoms of myocardial infarction by implanting the cells A from the state of the art as of the filing.



(See Examination Handbook, Annex B, Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 2)

Case Example having Novelty / Inventive Step (applied to a Specific Disease)

[Claim 1]
A graft material to treat myocardial infarction comprising a cell sheet made of cells A.

[Outline of the detailed description of the invention]
In this invention, it has been found that the cardiac function is recovered by implanting a cell sheet made of cells A to a site of myocardial infarction.

In the working example, the results of pharmacological study are described to show that the cardiac function is recovered and symptoms of myocardial infarction are reduced by implanting such cell sheet to the site of myocardial infarction in rats of a myocardial infarction model.

[Explanation]
The medicinal use of the cell sheet made of the cells A (to treat myocardial infarction) is different from the medicinal use conventionally known, and therefore, the medicinal invention of Claim 1 is a novel invention.
Moreover, there is no prior art document publicly known that provides a motivation to apply the cell sheet made of the cells A to treat myocardial infarction, such as the relevance of the cells A with the recovery of the cardiac function, and therefore, the medicinal invention of Claim 1 involves an inventive step.

[Remarks]
When, however, the claimed invention is directed to cells with a limited use, such as "cells A to treat myocardial infarction", those cells are interpreted as the cells themselves, not having a limited use, because such limited use, in general, merely indicates the utility of the cells.
Therefore, in this case, "the cells A to treat myocardial infarction" and the publicly known "cells A" that do not have a limited use shall not be recognized as different cells.

(See Examination Handbook Annex B, Chapter 3, “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 2)

Case Example having Novelty / Inventive Step (applied to a Specific Disease with Specific Dosage / Administration)

[Claim 1]

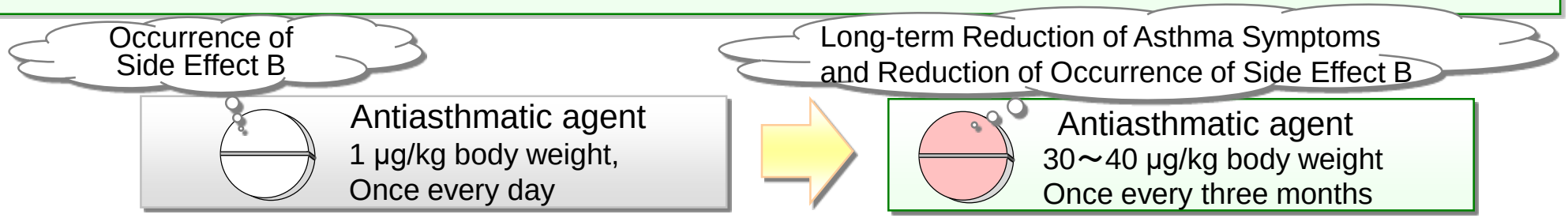
An antiasthmatic agent comprising the compound A characterized in that the compound A is administered in an amount of 30 to 40 μg/kg of body weight orally once every three months to a human.

[Outline of the detailed description of the invention]

It has been known that the symptoms of asthma are reduced by administering the compound A in an amount of 1 μg/kg of body weight per day to an asthmatic patient orally every day. However, the reduction of the symptoms was provided only while the compound A was administered, and once the administration was discontinued, the symptoms recurred, and thus, the continuous daily administration of the compound A was required. Moreover, it was suggested that when the compound A was administered in an amount of 1 μg/kg of body weight per day orally every day, the side effect B frequently occurred.

In this invention, it has been found that, by administering the compound A in an amount of 30 to 40 μg/kg of body weight orally once every three months to an asthmatic patient, the symptoms of asthma are reduced for a long period of time, and also the occurrence rate of the side effect B is lower than that previously seen.

In the working example, the results of pharmacological study were described: when a single dose of the compound A was orally administered to each of the groups of asthmatic patients (body weight: 30 kg to 90 kg), in amount of 30 μg/kg of body weight, 35 μg/kg of body weight, and 40 μg/kg of body weight, respectively, the symptoms of asthma were reduced at least for three months in all treatment groups; no apparent difference in efficacy by body weight was noted; and moreover, few occurrences of the side effect B were noted in all treatment groups in this study, the frequency of which was significantly lower than the frequency of the side effect B developed when the compound A was conventionally administered in an amount of 1 μg/kg of body weight per day orally every day.



(See Examination Handbook, Annex B, Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 3)

Case Example having Novelty / Inventive Step (applied to a Specific Disease with Specific Dosage / Administration)

[Claim 1]
An antiasthmatic agent comprising the compound A characterized in that the compound A is administered in an amount of 30 to 40 μg/kg of body weight orally once every three months to a human.
[Outline of the detailed description of the invention] ….

[Results of the prior art search]
It is publicly known that the symptoms of asthma are reduced by administering the compound A in an amount of 1 μg/kg of body weight to an asthmatic patient orally every day and that the side effect B frequently occurs by such administration. However, no prior art document describes or suggests the administration of the compound A in an amount of 30 to 40 μg/kg of body weight orally once every three months.
Moreover, it is not possible to predict from the state of the art as of the filing that the symptoms of asthma would be reduced for at least three months by the oral single administration of the compound A in an amount of 30 to 40 μg/kg of body weight and that the occurrence rate of the side effect B would be lowered compared to the prior art.

[Explanation]
In terms of dosage or administration of the compound A in the treatment of asthma, the dosage or administration of the claimed invention is different from the dosage or administration conventionally known, and therefore, the medicinal invention of Claim 1 is a novel invention.
Moreover, the reduction of the symptoms of asthma for at least three months and also the occurrence rate of the side effect B significantly lower than that developed by the daily oral administration of the compound A in an amount of 1 μg/kg of body weight per day are afforded by the single administration of the compound A in an amount of 30 to 40 μg/kg of body weight to an asthmatic patient, and are remarkable effects surpassing the extent predictable from the state of the art, and therefore, the medicinal invention of Claim 1 involves an inventive step.

(See Examination Handbook Annex B Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 3)

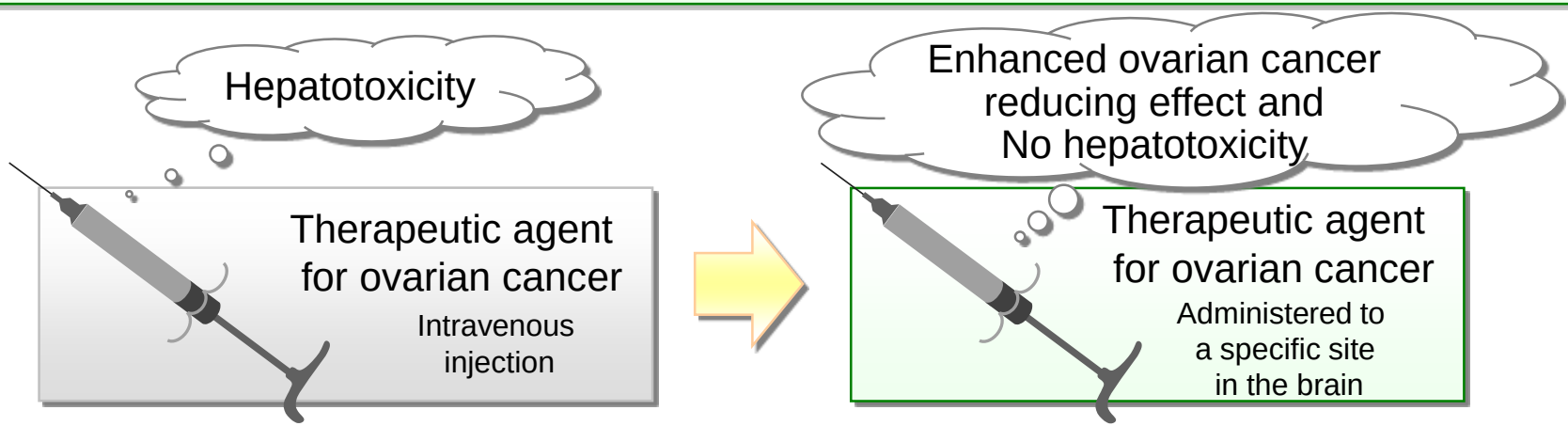
Case Example having Novelty / Inventive Step (applied to a Specific Disease with Specific Dosage / Administration)

[Claim 1]

A therapeutic agent for ovarian cancer comprising the compound A as an active ingredient characterized in that the compound A is administered in an amount of 100 to 120 μg/kg of body weight per administration to the specific site Z in the brain of a human.

[Outline of the detailed description of the invention]

The compound A has been known to have an effect of growth suppression on ovarian cancer when administered intravenously to a human, but has also been known to have hepatotoxicity as a side effect. In this invention, it has been found that the blood concentration of the hormone Y secreted from the pituitary gland changes by the administration of the compound A to the specific site Z in the brain of a human, and as a result, the ovarian cancer significantly reduces in size compared to the treatment by the conventional intravenous administration. In the working example, the results of pharmacological study are described to show that the blood concentration of the hormone Y secreted from the pituitary gland changes by the administration of the compound A to the specific site Z in the brain of a human, and as result, the ovarian cancer further reduces in size compared to the treatment by the conventional intravenous administration. Other results of pharmacological study are also described to show that when administered to the specific site Z in the brain, the compound A does not move to the liver, and thus has no hepatotoxicity.



(See Examination Handbook, Annex B, Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 4)

Case Example having Novelty / Inventive Step (applied to a Specific Disease with Specific Dosage / Administration)

[Claim 1]
A therapeutic agent for ovarian cancer comprising the compound A as an active ingredient characterized in that the compound A is administered in an amount of 100 to 120 μg/kg of body weight per administration to the specific site Z in the brain of a human.

[Outline of the detailed description of the invention]
・・・

[Results of the prior art search]
It is publicly known that the compound A has an effect of growth suppression on ovarian cancer when administered intravenously to a human and has a side effect of hepatotoxicity. However, no prior art document describes or suggests that the compound A intravenously administered moves into the brain through the blood-brain barrier and that the ovarian cancer further reduces in size by the administration of the compound A to the specific site Z in the brain in a human compared to the intravenous administration.
Moreover, it is not possible to predict that the reduction in size of the ovarian cancer would be provided without a side effect of hepatotoxicity by the administration of the compound A to the specific site Z in the brain in a human from the state of the art as of the filing.

[Explanation]
In terms of dosage or administration of the compound A in the treatment of ovarian cancer, the dosage or administration of the claimed invention (the administration to the specific site Z in the brain) is different from the dosage or administration conventionally known (intravenous administration), and therefore, the medicinal invention of Claim 1 is a novel invention.
Moreover, no development of the side effect of hepatotoxicity and also the further reduction in size of the ovarian cancer compared to the treatment by the intravenous administration are afforded by the administration of the compound A to the specific site Z in the brain, and are remarkable effects surpassing the extent predictable from the state of the art, and therefore, the medicinal invention of Claim 1 involves an inventive step.

(See Examination Handbook, Annex B, Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 4)

Case Example without Inventive Step (applied to a Specific Disease with Specific Dosage / Administration)

[Claim 1]

An antitussive agent comprising the compound A characterized in that the compound A is administered in an amount of 400 to 450 μg/kg of body weight per administration orally once a day to a human.

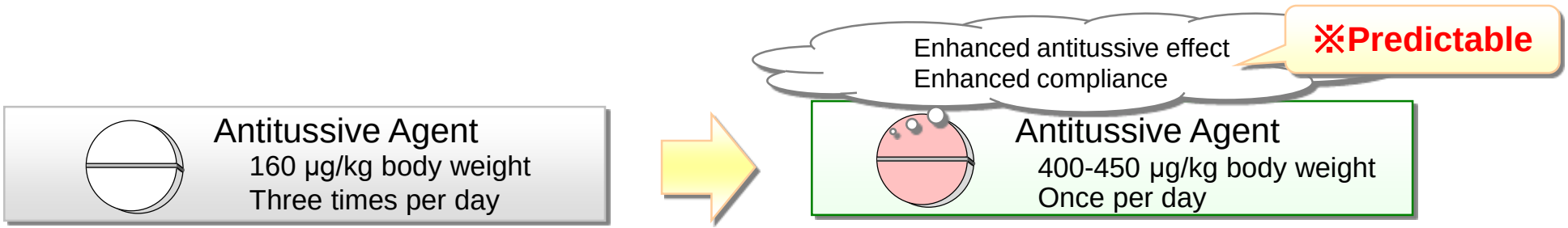
[Overview of the description]

It was known that an antitussive effect was provided by administering the compound A in an amount of 160 μg/kg of body weight per administration orally three times a day to a human. In contrast, in this invention, it has been found that the administration of the compound A in an amount of 400 to 450 μg/kg of body weight per administration orally once a day to a human provides an antitussive effect better than that previously provided.

In the working example, the results of pharmacological study are described to show that the antitussive effect is increased by the administration of the compound A in an amount of 400 μg/kg of body weight per administration orally once a day to a patient compared to the administration of the compound A in an amount of 160 μg/kg of body weight per administration orally three times a day. It is described that compliance is also improved because of the decreased frequency of administration per day.

[Results of the prior art search]

It is publicly known that an antitussive effect is provided by administering the compound A in an amount of 160 μg/kg of body weight per administration orally three times a day. Moreover, the level of the increase in antitussive effect and compliance described in the description of the claimed invention falls within the extent predictable from the state of the art as of the filing.



(See Examination Handbook, Annex B, Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 5)

Case Example without Inventive Step (applied to a Specific Disease with Specific Dosage / Administration)

特許庁 JAPAN PATENT OFFICE

[Claim 1]
An antitussive agent comprising the compound A characterized in that the compound A is administered in an amount of 400 to 450 μg/kg of body weight per administration orally once a day to a human.

[Overview of reasons for refusal]
It is publicly known that an antitussive agent, the active ingredient of which is the compound A, is orally administered. In general, making dosage or administration of a drug preferred in order to solve a problem well known to a person skilled in the art, such as to increase a drug effect or to improve compliance, is an exercise of ordinary creativity of a person skilled in the art, and thus, the determination of the preferred dosage or administration of the compound A can be readily done with experiments by a person skilled in the art.
Moreover, a person skilled in the art would commonly predict that a drug effect or compliance can be increased by making dosage or administration preferred, and in the claimed invention, the level of the increase thereof cannot be recognized to be remarkable surpassing the extent predictable from the state of the art as of the filing.

[Explanation]
In general, the reasons for refusal above cannot be overcome.

[Notes]
To what level the effect is "remarkably surpassing the extent predictable from the state of the art as of the filing" shall be determined on a case-by-case basis in consideration of what is disclosed in the description of the claimed invention, the results of prior art search, the common general knowledge as of the filing, and the like.

(See Examination Handbook Annex B Chapter 3 “3.1.1 A therapeutic agent characterized by its medicinal use in which the drug is applied to a specific disease” Case 5)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Genetic Engineering-related Inventions

Examples of Genetic Engineering related Inventions

- Nucleic acids such as Genes
- Proteins
- Antibodies
- Fused Cells
- Dedifferentiated Cells
- Transformants
- Microorganisms
- Animals and Plants

Clarity of Invention

The scope of claimed Invention must be clear.

Genetic engineering related inventions can be described in various forms of expression (effects, functions, characteristics, etc.)

Examples

1. Specified with a base sequence
   (Example) A polynucleotide whose DNA sequence is represented as ATGTATCGG…..TGCCT.

2. Specified with an amino acid sequence of an encoded protein.
   (Example) A polynucleotide which encodes the protein consisting of an amino acid sequence represented as Met-Asp- … Lys-Glu.

3. Specified with a combination of terms such as “deletion, substitution, or addition” and “hybridize”, with functions of the gene in a generic form.
   (Example) A polynucleotide encoding a protein of (i) or (ii) below:
   (i) a protein whose amino acid sequence is represented by Net-Asp- … Lys-Glu;
   (ii) a protein derived from the protein of (i) by deletion, substitution or addition of one or more amino acids in the amino acid sequence defined in (i) and having the activity of enzyme A.

   (Example) A polynucleotide selected from the group consisting of:
   (i) A polynucleotide whose DNA sequence is represented as ATGTATCGG … TGCCT;
   (ii) A polynucleotide which hybridizes under stringent conditions to the polynucleotide whose DNA sequence is complementary to that of the DNA sequence defined in (i), and encodes the protein having the activity of enzyme B.

   (note) The “stringent conditions” are described in the detailed description of the invention.

(See Examination Handbook, Annex B, Chapter 2 “2.1 (1) Invention relating to Nucleic acids and Polypeptides”)

Enablement Requirements

The detailed description of the invention must be described clearly and sufficiently in such a manner that a person skilled in the art can implement the claimed invention based on the description and drawings as well as the common technical knowledge at the time of filing.

(1) Invention of a product

The detailed description of the invention must be described in such a manner that the product can be produced and used.

(2) Invention of a process

The detailed description of the invention must be described in such a manner that the process can be used.

(3) Invention of a process for producing a product

The detailed description of the invention must be described in such a manner that the product can be produced by using the process.

(See Examination Handbook, Annex B, Chapter 2 “1.1 Enablement Requirement”)

Enablement Requirements

“in such a manner that the product can be produced”

- In order to show that a gene can be produced in an invention relating to the gene, a production process may be described, such as the origin or source, a condition of treatment, a process of collecting or purifying, and a means for identifying.
- If genes are claimed in a generic form in the claim, in a case where 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 obtain those genes, then such a description is not described in such a manner that enables a person skilled in the art to produce the product.

[Example not satisfying the enablement requirement]

A polynucleotide selected from (i) or (ii) below:
(i) a polynucleotide whose DNA sequence is represented as ATGTATCGG.....TGCCT;
(ii) a polynucleotide whose DNA sequence has more than X% of sequence identity to that of (i) and which encodes the protein having the activity of enzyme B.
(Note) A protein encoded by the polynucleotide of (i) has the activity of enzyme B.
X% represents extremely low identity.

If "polynucleotide whose DNA sequence having more than X% of sequence identity to that of (i) and which encodes the protein having the activity of enzyme B" includes many polynucleotides which encode the protein not having the activity of enzyme B, trials and errors, and/or complicated and sophisticated experimentation beyond the extent to which a person skilled in the art should be reasonably expected are generally needed to select the polynucleotides which encode the protein having the activity of enzyme B from said polynucleotides.

(See Examination Handbook, Annex B, Chapter 2 “1.1(1) Inventions relating to Nucleic acids and Polypeptides”)

Enablement Requirements

“The product can be used”

- In order to show how an invention relating to a gene can be used, it may be described that the gene has a specific function (the "specific function" here means a "function from which a specific use with technical meanings can be assumed").
- If genes are claimed in a generic form and the function is not specified in the claim, the genes claimed in a generic form contain the ones which do not have said function and the part of said genes cannot be used. In this case, the description is not described in such a manner that enables a person skilled in the art to use the product.

[Example not satisfying the Enablement Requirement]

A polynucleotide of (i) or (ii) below:
(i) a polynucleotide whose DNA sequence is represented as ATGTATCGG.....TGCCT;
(ii) a polynucleotide whose DNA sequence identity has more than X% of identity to that of (i).
(Note) A protein encoded by the polynucleotide of (i) has the activity of enzyme B.

Since the polynucleotide of (ii) is not specified by its function, the polynucleotide includes a polynucleotide encoding a protein not having the activity of enzyme B. Since the polynucleotide does not have the specific function, the description is not described in such a manner that enables a person skilled in the art to use the product.

(See Examination Handbook, Annex B, Chapter 2 “1.1(1) Invention relating to Nucleic acids and Polypeptides”)

Case Example where the Enablement Requirements are not Satisfied

[Claim 1]
A polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 5.

[Outline of the detailed description of the invention]
A polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 5 is cDNA of 3000 bp obtained from the human liver cDNA library, and encodes a polypeptide consisting of 1000 amino acid residues represented by SEQ ID NO: 6.
As a result of homology search of the DNA sequence represented by SEQ ID NO: 5 and the amino acid sequence represented by SEQ ID NO: 6 using DNA and amino acid sequence databases published before filing the application, there is found no other sequence having 30% or more sequence identity. On the other hand, the amino acid sequence represented by SEQ ID NO: 6 is proved to have a potential site of glycosylation in the polypeptide.

Therefore, the polynucleotide of the invention claimed in Claim 1 is assumed to encode a new glycoprotein, whose specific function is unknown, that may be used for developing a new drug.

[Result of the prior art search]
There is no other DNA and amino acid sequence having 30% or more sequence identity.

Sequence 5

```
atg ctc ttc aaa caa gcc att ctt
gtc gct act act ctc gcc acc ctt
        ⋮
```

Sequence 6

```
Met Leu Phe Lys Gln Ala Ile Leu
Val Ala Thr Thr Leu Ala Thr Leu
        ⋮
```

(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirement of Unity of Invention, Description Requirements, and Requirements for Patentability” Case 7)

Case Example where the Enablement Requirements are not Satisfied

[Claim 1]
A polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 5.

[Outline of the reasons for refusal]

Since there are various kinds of function of glycoprotein, even though the polynucleotide encodes a glycoprotein, a specific function of the glycoprotein is unknown.

While the fact that proteins having high sequence identity probably have similar functions to each other was the common general knowledge at the time of filing, there was no publicly known protein, prior to filing the application, having high sequence identity with the polypeptide encoded by “the polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 5.”

Then, the specific function of the protein encoded by “the polynucleotide” cannot be expected.

Since the specific function of the polynucleotide is unknown, how to use the polynucleotide is also unknown.

Therefore, the description cannot be regarded as stating the invention clearly and sufficiently so as to enable a person skilled in the art to carry out the invention claimed in Claim 1.

[Measures of the applicant]
Generally, the reason for refusal stated above cannot be overcome.

(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements, and Requirements for Patentability” Case 7)

Novelty

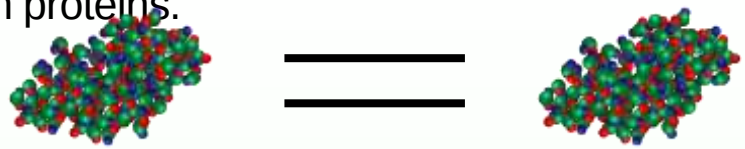
If it is impossible to distinguish a “product” of the invention concerned from known products, it is usually* considered that the invention lacks novelty, even if the “product” of the invention is specified in a different expression from known products.

※ Inventions such as use inventions (Examination Guidelines, Part III, Chapter 2, Section 4, 3.1.2) and medicinal inventions (Examination Handbook, Annex B, Chapter 3) may involve novelty even if they are not distinguishable from known “products”.

[Examples of Determination of Novelty]

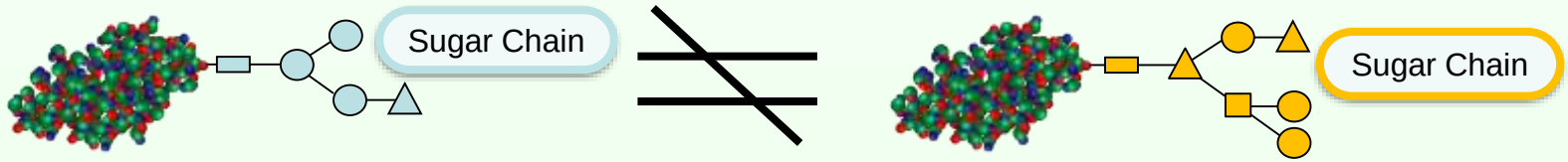
Proteins

✕ In the case of an invention relating to a recombinant protein, the invention lacks novelty when the protein as a product is not distinguishable from known proteins, even if its manufacturing method differs from those of known proteins.



Protein developed with microorganism A　＝　Protein developed with microorganism B

○ In the case of an invention of a recombinant protein of which manufacturing method is specified, the invention has novelty if the manufacturing method differs from those of known proteins (e.g. using different microorganisms, animals or plants) and hence its sugar chains, for example, differ from those of known proteins, even if its amino acid sequence is undistinguishable from those of known proteins.



Protein developed with microorganism A　≠　Protein developed with microorganism B

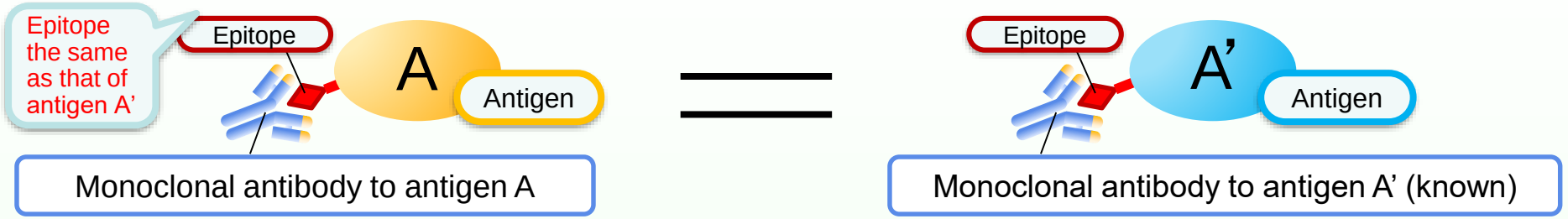
(See Examination Handbook, Annex B, Chapter 2 “5.2 Novelty”)

Novelty

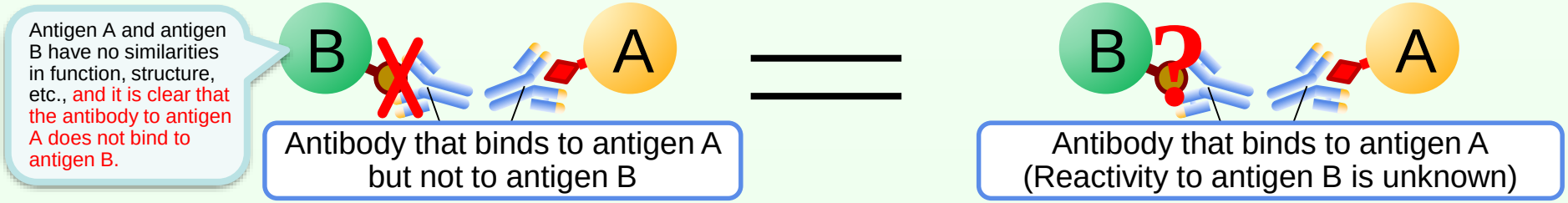
[Other Examples relating to Determination of Novelty]

Antibodies

If an antigen A has novelty, an invention of an antibody to the antigen A has novelty in general. However, if a monoclonal antibody to publicly known antigen A' is publicly known and the antigen A has the same epitope as that of antigen A' because the antigen A is partially modified from the publicly known antigen A', a monoclonal antibody to the antigen A' also binds to the antigen A. In such a case, an invention of "a monoclonal antibody to the antigen A" cannot be distinguished from the publicly known monoclonal antibody as a product. Therefore, the invention does not have novelty.



An invention relating to an antibody which binds not to an antigen B but to an antigen A is not considered that the cross-reactivity represents a definition of the specific product, if an antibody to the antigen A is publicly known and there is no particular technical significance to specify the antibody described by the cross-reactivity (e.g. when it is evident that the antibody to the publicly known antigen A does not bind to the antigen B because the antigen B has no similarity to the antigen A in terms of function, structure, etc.). Therefore, the invention does not have novelty, since the invention cannot be distinguished from the publicly known antibody as a product in general.



(See Examination Handbook, Annex B, Chapter 2 “5.2 Novelty”)

Case Example that Lacks Novelty

[Claim 1]

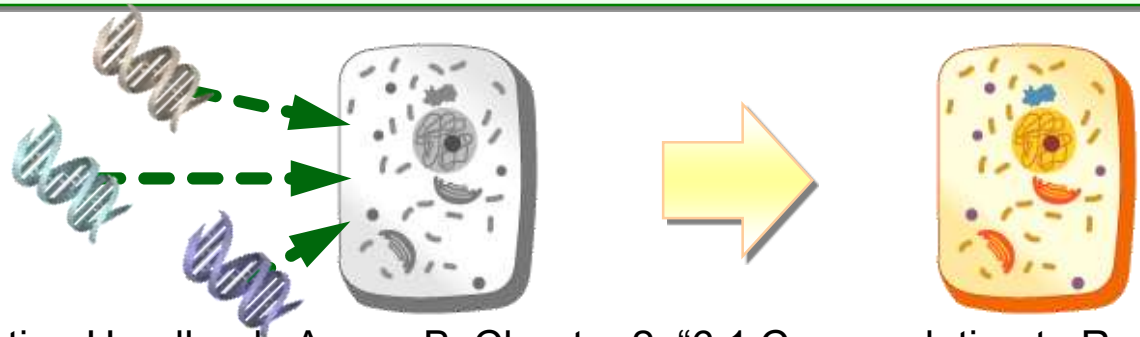
A pluripotent stem cell X produced by a method comprising introducing genes a, b and c into a gastric epithelium cell.

[Outline of the detailed description of the invention]

Modified cells in gene expression were produced by introducing the genes a, b and c into gastric epithelial cells, differentiated cells taken from mature tissue. The produced cells exhibited gene expression characteristic to undifferentiated cells and were those which can differentiate into endodermal, mesodermal and ectodermal cells upon induction of differentiation. The efficiency of dedifferentiation was high.

[Result of the prior art search]

A document 1 discloses that a cell having characteristics of the pluripotent stem cell was produced by introducing the genes a, b and c into a dermal fibroblast, a differentiated cell taken from mature tissue. Similarly, documents 2 and 3 disclose that cells having characteristics of the pluripotent stem cell were produced by introducing the genes a, b and c into a bone marrow-derived cell and a hepatocyte, both derived from mature tissue.



(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 26)

Case Example that Lacks Novelty

[Claim 1]
A pluripotent stem cell X produced by a method comprising introducing genes a, b and c into a gastric epithelium cell.

[Outline of the reasons for refusal]
Since the pluripotent stem cell X of the present application cannot be distinguished from the pluripotent stem cells produced in the cited documents 1-3, the invention according to claim 2 is not novel in view of the cited documents 1-3.

[Measures to be taken by the applicant]
The aforementioned reason for refusal regarding novelty shall not be usually overcome unless it is demonstrated that the pluripotent stem cell X of the application is definitely distinguished by objective indicator(s) from the pluripotent stem cells obtained by the methods described in the cited documents 1-3.

[Supplemental explanation]
As of "objective indicator(s)" mentioned above, indicators that can change depending on preservation or culture conditions of the pluripotent stem cell (for example, expression of a specific gene) are not adequate. Such an objective indicator has to be constantly capable of being detected, measured, or observed as a characteristic of the cell (for example, a cell surface marker, the difference in the recombination of a TCR-related gene between iPS cells derived from the T cell and iPS cells derived from the fibroblast). If such an indicator that can be constantly detected, measured, or observed is present, even when it is not indicated in the description, it might be demonstrated by using the indicator that the pluripotent stem cell X of the patent application is different from the pluripotent stem cell described in the cited documents 1-3.

(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 26)

Inventive Step

[Examples of Determination of Inventive Step]

Nucleic Acids such as Genes

○ If a protein A has novelty and inventive step, an invention of a gene encoding the protein A involves an inventive step.

× If the amino acid sequence of a protein A is publicly known, an invention of a gene encoding the protein A does not involve an inventive step.※

× If a protein A is publicly known but the amino acid sequence is not publicly known, an invention of a gene encoding the protein A does not involve an inventive step when a person skilled in the art could determine the amino acid sequence of the protein A easily at the time of filing※

※ In either case, the invention involves an inventive step when (i) the gene of the invention is described by a specific nucleotide sequence and (ii) has an advantageous effect that a person skilled in the art cannot expect in comparison with other genes having a different nucleotide sequence encoding the protein A.

Proteins

× If a protein is publicly known, an invention of a mutant of the protein which has the same property and function as that of the protein, does not involve an inventive step.

※ However, the mutant of the protein of the invention involves an inventive step if the invention has an advantageous effect that a person skilled in the art cannot expect, as compared with known proteins.

Antibodies

× If an antigen A is publicly known and it is evident that the antigen A has immunogenicity (for example, the antigen A is a polypeptide with a large molecular weight), an invention of “an antibody to the antigen A” does not involve an inventive step.

※ However, the invention involves an inventive step if the antibody of the invention is further specified by another characteristic etc. and has an advantageous effect that a person skilled in the art cannot expect.

(See Examination Handbook, Annex B, Chapter 2 “5.3 Inventive step”)

Case Example that Lacks Inventive Step

[Claim 1]

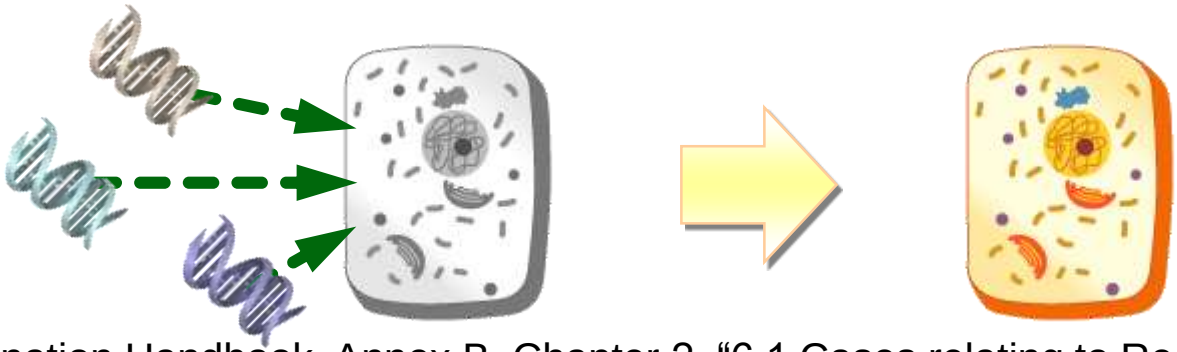
A method for producing a pluripotent stem cell X, comprising introducing genes a, b and c into a gastric epithelium cell.

[Outline of the detailed description of the invention]

Modified cells in gene expression were produced by introducing the genes a, b and c into gastric epithelial cells, differentiated cells taken from mature tissue. The produced cells exhibited gene expression characteristic to undifferentiated cells and were those which can differentiate into endodermal, mesodermal and ectodermal cells upon induction of differentiation. The efficiency of dedifferentiation was high.

[Result of the prior art search]

Document 1 discloses that a cell having characteristics of the pluripotent stem cell was produced by introducing the genes a, b and c into a dermal fibroblast, a differentiated cell taken from mature tissue.
Similarly, documents 2 and 3 disclose that cells having characteristics of the pluripotent stem cell were produced by introducing the genes a, b and c into a bone marrow-derived cell and a hepatocyte, both derived from mature tissue.



(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 26)

Case Example that Lacks Inventive Step

[Claim 1]
A method for producing a pluripotent stem cell X, comprising introducing genes a, b and c into a gastric epithelium cell.

[Outline of the reasons for refusal]
It is a well-known problem to improve a method for producing a useful pluripotent stem cell. Moreover, a method for producing a pluripotent stem cell by introducing the genes a, b and c into a differentiated cell to dedifferentiate it is a well-known technique as disclosed in the documents 1-3.
Therefore, it is an idea a person skilled in the art would conceive easily to apply the aforementioned method disclosed in the cited documents 1-3, which has been performed with various cells belonging to different histological lines, such as a dermal fibroblast, a bone marrow-derived cell, and a hepatocyte, to a gastric epithelial cell, another cell derived from mature tissue, in order to produce the pluripotent stem cell X. Furthermore, unexpectedly advantageous effects over the cited documents 1-3 and the well-known technique cannot be acknowledged for the invention according to claim 1.

[Measures taken by the applicant]
If there is some modifications necessary to successfully apply the method disclosed in the documents 1-3 to the gastric epithelial cell, the reason for refusal may be overcome by making an amendment to include such modifications in the claim and asserting in a written opinion or the like that a person skilled in the art could not conceive the modifications easily.
Alternatively, the reason for refusal may be overcome by asserting based on a certificate of experimental results, etc. in a written opinion or the like that the dedifferentiation efficiency by the method according to claim 1 is markedly higher than that of the method described in the documents 1-3 and the efficiency is an effect that exceeds the scope that can be predicted from the descriptions of the documents 1-3 and the common general knowledge.

(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 26)

Case Example that Lacks Inventive Step

[Claim 1]
A polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 11.

[Outline of the detailed description of the invention]
A polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 11 is cDNA of 2700 bp obtained from the human liver cDNA library, and encodes a polypeptide consisting of an amino acid sequence of 900 amino acids represented by SEQ ID NO: 12.
As a result of homology search of DNA sequence represented by SEQ ID NO: 11 and the amino acid sequence represented by SEQ ID NO: 12 using DNA and amino acid sequence databases published prior to filing the application, the DNA sequence has 80% of sequence identity to the DNA sequence encoding rat factor XX1 described in document A and the amino acid sequence has 85% of sequence identity to the amino acid sequence of rat factor XX1 described in document A.
Therefore, the polynucleotide of the invention claimed in Claim 1 is assumed to encode human factor XX1 and to be useful.

[Results of prior art search]
There is no other DNA and amino acid sequence having 80% or more sequence identity.
It is well-known that mammalians such as human have factor XX1.

Sequence 11

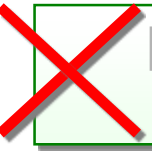
```
atg ctc ttc aaa caa gcc att ctt
gtc gct act act ctc gcc acc ctt
        ⋮
```

Sequence 12

```
Met Leu Phe Lys Gln Ala Ile Leu
Val Ala Thr Thr Leu Ala Thr Leu
        ⋮
```

(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 10)

Case Example that Lacks Inventive Step



[Claim 1]
A polynucleotide consisting of the DNA sequence represented by SEQ ID NO: 11.

[Overview of the reasons for refusal]
It was a well-known problem to obtain a polynucleotide encoding one protein prior to filing the application.
On the basis of the common general knowledge that a polynucleotide encoding one mammal protein and a polynucleotide encoding a homolog protein from another mammal have high sequence identity to each other in general, it was a well-known technique to obtain the polynucleotide encoding the homolog protein by PCR method, etc. using a part of the polynucleotide encoding the known mammal protein as a PCR primer.
Therefore, a person skilled in the art would easily conceive the idea of using a PCR primer prepared on the basis of the DNA sequence of the polynucleotide encoding rat factor XX1 described in document A, and obtaining the polynucleotide encoding human factor XX1 from a human cDNA library so as to obtain human factor XX1. It is also considered that the polynucleotide of the invention claimed in Claim 1 does not have any advantageous effect which cannot be expected from the document A and well-known art.

[Measures to be taken by the applicant]
The reason for refusal stated above may be overcome if the applicant proves in a written opinion that there was specific difficulty to obtain the polynucleotide of the invention claimed in Claim 1 in view of the state of the art at the time of filing.

(See Examination Handbook, Annex B, Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 10)

Sequence Listing Code Data

Guidelines to Submit Code Data (Text Data) of Gene Sequence Listings in Recording Media (Japanese Only)
<https://www.jpo.go.jp/tetuzuki/t_tokkyo/shutsugan/idensi_txt_de-ta.htm>

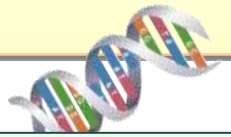
特許庁 JAPAN PATENT OFFICE

Submitting Sequence Listings in the form of Code Data

※ Sequence listings submitted in an electronic medium are NOT considered to form a part of the description.

Applicants are invited to submit electronic media recording code data of sequence listings, in order to file applications including nucleotide or amino acid sequence listings.
However, the submittal is not required in the case where the sequence listings are described in the form of code data in the description and the application is electronically filed.

"Sequences" required to be Submitted in the form of Code Data



- ○ Unbranched, straight-chain or cyclic sequences of ten or more "nucleotides"※.
- ○ Unbranched, straight-chain or cyclic sequences of four or more "amino acids"※.

However, the sequences below are excluded from this definition.

- × Sequences of three or fewer specifically defined nucleotides or amino acids (e.g. nna ngn nnn nnn n)
- × Sequences comprising nucleotides or amino acids other than those listed in Tables 1 to 4 of Appendix 2

※ Nucleotides: Only the nucleotides that can be represented using the symbols set forth in Table 1 or Table 2 in Appendix 2 of the Guidelines.

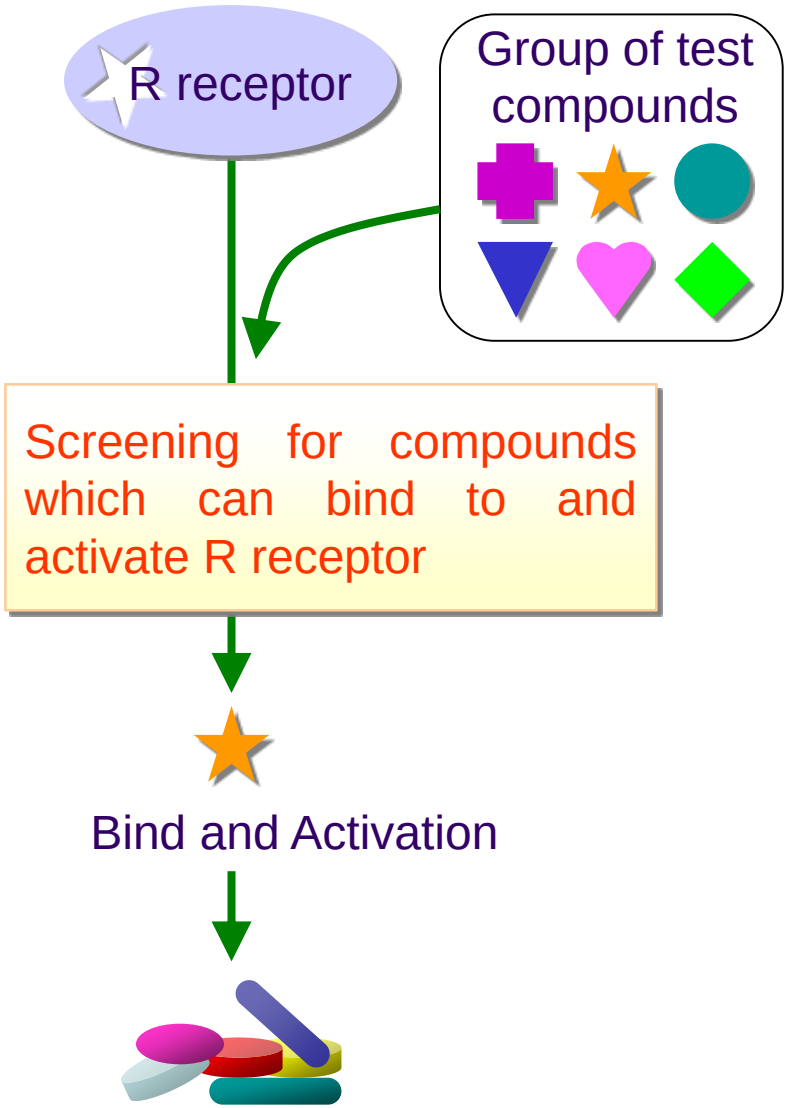
※ Amino acids: L-amino acids listed in Table 3 in Appendix 2 of the Guidelines.

- Including L-amino acids representable in combination with abnormal linkages, disulfide bridge, non-peptidyl bonds, etc.
- Not including D-amino acids (not defined)

Guidelines for Preparation of Descriptions etc. including Nucleotide or Amino Acid Sequences (conforming to Administrative Instructions under the PCT, Annex C and WIPO Standards ST. 25)
<https://www.jpo.go.jp/tetuzuki/t_tokkyo/shinsa/pdf/enki_amino_guideline/hairetsu_guideline.pdf> (Japanese only)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Enablement Requirements



Exemplary Claims

[Claim 1]
A method of screening comprising steps of contacting a test compound with R receptor and seeing whether the test compound activate the R receptor.

[Claim 2]
The compound having activity of activating R receptor obtained by the screening method according to Claim 1.

[Claim 3]
An anti-obesity agent containing, as an active ingredient, the compound having activity of activating R receptor according to Claim 1.

Enablement Requirements

[Outline of detailed description of the invention]

The description specifically describes a series of steps including a screening step for producing a compound having activity of activating R receptor. However, the relation between the function of activating R receptor and the structural feature of the compound is not known.

Examples describes that specific compounds Z, Y and Z whose chemical structures were identified were actually produced through the steps above and that it was confirmed that these compounds actually have the function of activating the R receptor. However, the description mention nothing about structural features and producing methods of compounds having the function of activating the R receptor other than the compounds X, Y and Z.

[Outline of the reasons of refusal based on violation of enablement requirements]

The relation between the structural features of the compounds corresponding to the invention of Claim 2 and the function of activating the R receptor is not described in the description of the invention, and the relation cannot be said to be obvious from the common technical knowledge at the time of filing. Accordingly, it is not understandable how to produce and use compounds whose structural features are not identified and which have the function of activating the R receptor.

Further, even if a specific compound is obtained by the method of Claim 1, actually carrying out screening is required to know whether other compounds than the obtained compound has the function of activating the R receptor. However, screening unidentified compounds at random requires a person ordinarily skilled in the art to excessively repeat try and error.

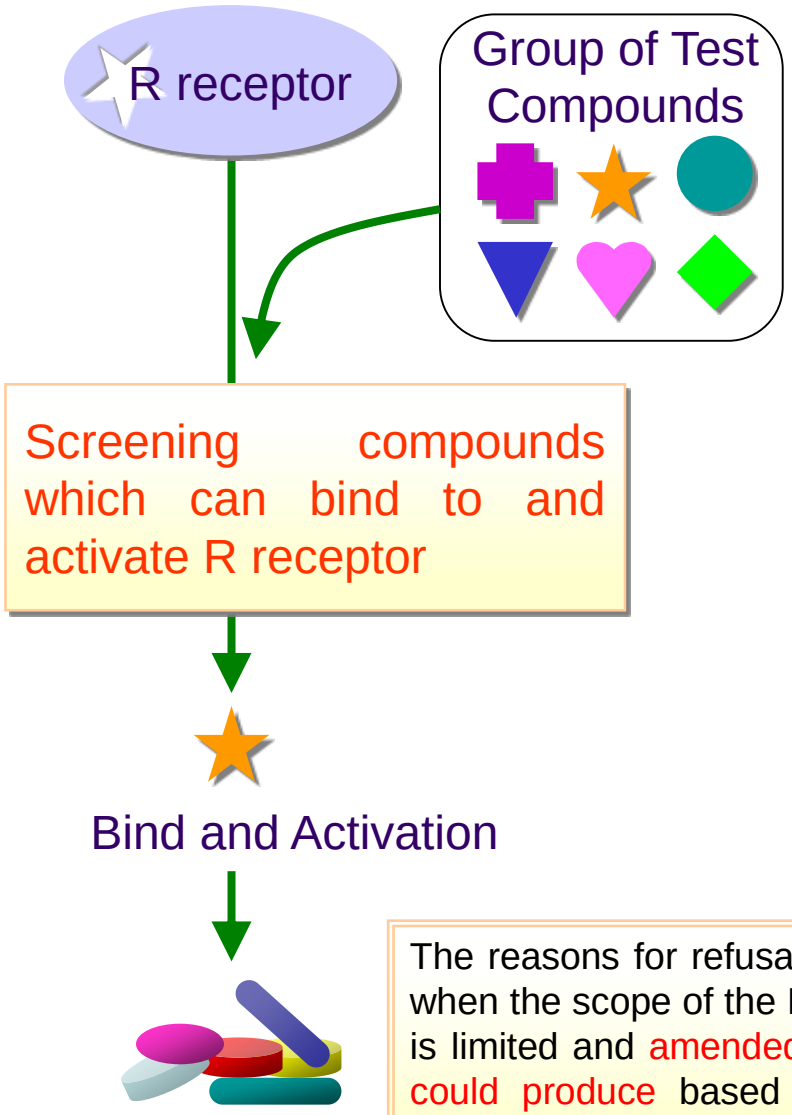
Then, the person ordinarily skilled in the art cannot know what compounds other than the compounds X, Y and Z have the activity to the R receptor, and so, to carry out the invention of Claim 2, the person ordinarily skilled in the art has to actually produce and screen countless compounds and repeat trial and error over the extent they are expected.

In this way, regarding the invention of Claim 2, the description of the invention does not meet enablement requirements.

The same applies to the invention of Claim 3 which contains the compound of Claim 2 as an active ingredient.

(See Examination Handbook Annex A “Description Requirements” Case 2)

Enablement Requirements



Exemplary Claims

[Claim 1]
A method of screening comprising steps of contacting a test compound with R receptor and seeing whether the test compound activate the R receptor.

[Claim 2]
The compound having activity of activating R receptor obtained by the screening method according to Claim 1.

[Claim 3]
An anti-obesity agent containing, as an active ingredient, the compound having activity of activating R receptor according to Claim 1.

The reasons for refusal regarding the violation of enablement requirements are overcome when the scope of the R receptor activating compounds of the inventions of Claims 2 and 3 is limited and amended into only compounds which the person ordinarily skilled in the art could produce based on the description of the invention and the common technical knowledge at the time of filing.

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Protein 3D Structure Information and Development of Genome-based Medicines

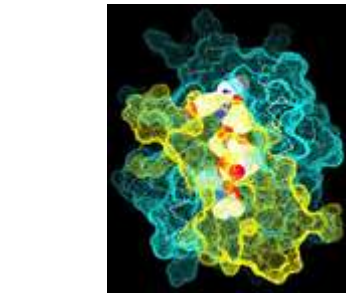
Genome → **cDNA** → **Protein (Primary Structure)**

-GAAYFLQHK-

→ **Crystal**

→ **Analyze 3D Structure with X ray**

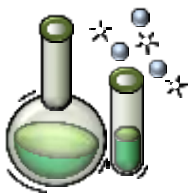
→ **3D structure Information**



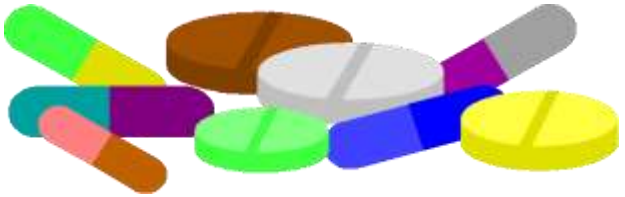
→ **Design Candidate Molecules for Medicine *in silico***

(agonist/antagonist)

→ **Compose Medicine Candidate Molecules and Measure Activity *in vitro, in vivo***

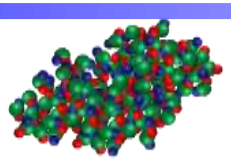


→ **Medicine**

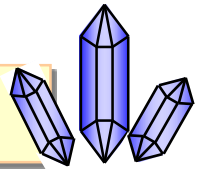


Eligibility for Patent

Protein



Crystal of Protein



Analyze 3D Structure of Protein

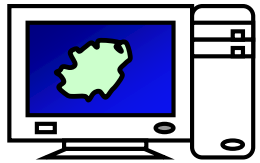
Protein 3D Structure Data

ATOM	147	C	VAL	A	25	30.447	15.105	58.363	1.00	12.34	A1	C
ATOM	148	O	VAL	A	25	29.520	15.059	59.174	1.00	15.65	A1	O
ATOM	149	CB A	VAL	A	25	30.385	17.437	57.230	0.28	13.88	A1	C
ATOM	150	CB B	VAL	A	25	30.166	17.399	57.373	0.72	15.41	A1	C
. . . .	. .	. . . . .	. . .	.	. .	. . . .	. . . .	. . . .	. . . .	. .	. .	. .

A Compound obtained by a Computer Screening Method using Protein 3D Structure Data

A Computer Screening Method using Protein 3D Structure Data

A Computer Model of a Protein



?

A Recording Medium in which Protein 3D Structure Data is Recorded

?

?

Eligibility for Patent

[Claim 1]
Three-dimensional structural data about a protein P comprising an atomic coordinate of a protein P represented by FIG. 1.

[Claim 2]
A computer model of a protein P produced by an atomic coordinate stated in FIG. 1.

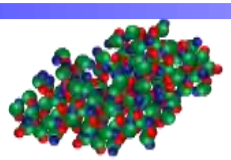
[Claim 3]
A recording medium in which three-dimensional structural data about a protein P recording an atomic coordinate of a protein represented by FIG. 1 is recorded.

[Outline of the reason for refusal regarding eligibility for patent]
Mere presentation of information (the feature resides solely in the content of the information, and the main object is to present information), such as presentation per se, means for presentation or a method of presentation, in which a technical feature does not reside, is not considered as a statutory “invention” (“creation of a technical ideal utilizing a law of nature”).
All of the protein three-dimensional structural data of Claim 1, the computer model of a protein of Claim 2, and the recording medium in which protein three-dimensional structural data is recorded have the characteristic only for the content of information to be presented, and are to mainly present the information. Furthermore, it cannot be said that the presentation of information (presentation per se, means for presentation, a method of presentation and the like) has a technical feature. Accordingly, all of what are described in Claims 1 to 3 are mere presentation of information, and are not the “creation of technical idea utilizing a law of nature”.

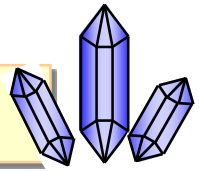
(See Examination Handbook, Annex B, Chapter 2 “6-1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 33)

Eligibility for Patent

Protein



Crystal of protein



Analyze 3D structure of protein

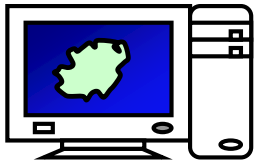
Protein 3D Structure Data

```
ATOM   147  C    VAL A  25      30.447  15.105  58.363  1.00 12.34      A1   C
ATOM   148  O    VAL A  25      29.520  15.059  59.174  1.00 15.65      A1   O
ATOM   149  CB AVAL A  25      30.385  17.437  57.230  0.28 13.88      A1   C
ATOM   150  CB BVAL A  25      30.166  17.399  57.373  0.72 15.41      A1   C
. . . .    . .  . . . . . . . . . . . .  . . . .  . . . .  . . . .  . . . .  . .  . .  . .
```

A compound obtained by a computer screening method using protein 3d structure data

A computer screening method using protein 3D structure data

A computer model of a protein

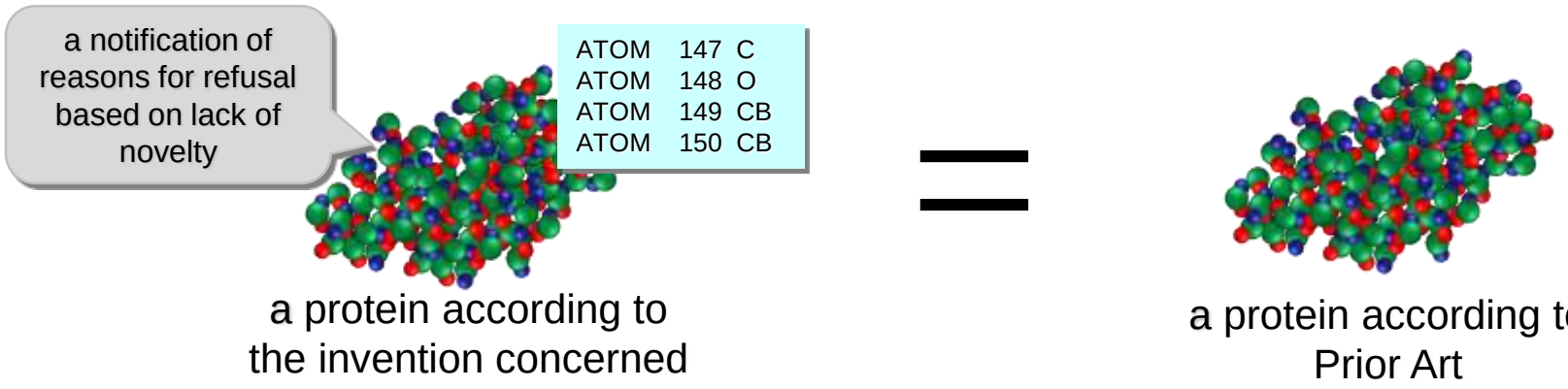


A recording medium in which protein 3D structure data is recorded

Novelty

Protein identified with 3D structure

As to the inventions related to the proteins defined by the structure coordinates, a notification of reasons for refusal should be issued based on lack of novelty, as long as the examiner is convinced that the protein according to the invention concerned and the protein according to Prior Art are the same (e.g., the protein according to the invention concerned is derived from the same organism, has the same specific function, and a similar molecular weight with that according to Prior Art), even if there is no Prior Art found that discloses the same Protein 3D structure with that of the invention concerned.



a protein according to the invention concerned

a protein according to Prior Art

The reason for refusal can be solved in this case, if the applicant presents a sufficient basis to determine that a protein according to the invention concerned is different from a protein according to Prior Art.

(See Examination Guidelines Part III, Chapter 2, Section 3 “5.2 Procedure of Examination pertaining to Determination on Novelty”)

Case having Novelty / Inventive Step and satisfying Enablement Requirements

[Claim 1]

Crystal of a protein P, having unit lattice constants of a=4.0 nm, b=7.8 nm and c=11.0 nm.

[Overview of the description]

The amino acid sequence of the protein P was publicly known. It has been also publicly known that the administration of the protein P decreases the blood pressure. The present inventors succeeded in newly manufacturing a stable crystal of the protein P. The method of manufacturing the crystal is stated in the description and the experimental data. While the protein P in the crystal form is inactive, to regain its activity again by dissolving the crystal into a solution is also proved by the experimental data. It is also proved by the experimental data that the routine prior art used for the crystallization of a protein cannot be applied to the protein P, and it is obvious that there has been technical difficulties in manufacturing the claimed crystal of the protein P.

[Result of prior art search]

No prior art disclosing or suggesting a crystal of the protein P or its related protein was found. In addition, there was no prior art relating to a method of crystallizing the protein P.

[There is no reason for refusal found]

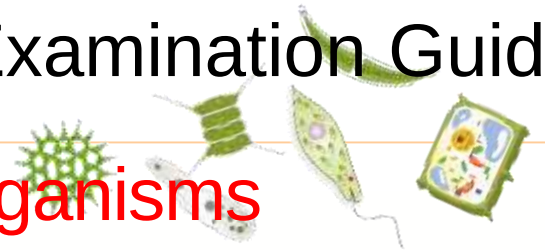
The invention of the crystal of the protein P has novelty since a crystal of a protein can be distinguished and be different from a protein which is not crystallized in terms of its shape and structure. The prior art does not teach the crystal of the protein P or the method of manufacturing the crystal of the protein P stated in the Claim. Further, the crystallization of the protein P was not successfully achieved by the publicly known method used for crystallizing a protein. Therefore, the invention according to the above-mentioned crystal involves an inventive step.

(See Examination Handbook Appendix B Chapter 2 “6.1 Cases relating to Requirements of Unity of Invention, Description Requirements and Requirements for Patentability” Case 35)

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Biological Inventions

Definition in Examination Guidelines



- **Microorganisms**
  - fungi, bacteria, unicellular algae, viruses and protozoans
  - animal or plant cells (including stem cells, dedifferentiated cells and differentiated cells) and tissue cultures
  - fused cells (including hybridomas) obtained by genetic engineering, dedifferentiated cells and transformants

  etc.

- **Microorganism-related inventions**
  - microorganisms themselves
  - inventions using microorganisms

  etc.

The inventions include those based on the discovery of use of publicly known microorganisms

(See Examination Handbook Appendix B Chapter 2 “Biological Inventions”)

Eligibility for Patent and Industrial Applicability

Those which do not fall under "Industrially Applicable Invention"

- **Those do not fall under “invention”**

  ex.) **Merely discovered microorganisms existing in nature**

  It is mere a discovery and not a creation, and thus does not fall under “invention.”

  However, an invention of a microorganism which is isolated from nature artificially involves creativity, and thus falls under “invention.”

- **Those which do not fall under "Industrially Applicable Invention"**

  ex.) **Biological materials of which applicability is not stated in the description, claims, or drawings, and usability of which can not be inferred.**

  They are considered to be a commercially inapplicable invention, and do not fall under "Industrially Applicable Invention."

(See Examination Handbook Appendix B Chapter 2 “5.1 Eligibility for Patent and Industrial Applicability”)

Deposit of Microorganisms

As to an invention related to microorganisms※, if the description is not stated in such a manner that enables a person skilled in the art to produce the microorganisms, it is necessary to deposit the microorganisms with a depositary institution designated by the JPO.

(Regulations under the Patent Law Article 27 bis. (1))

※This is applied also in the cases of the inventions related to genes, vectors, recombinant proteins, monoclonal antibodies, animals and plants, etc.

- Institution designated by Commissioner of JPO

  Also be International Depositary Authority

  National Institute of Technology and Evaluation (NITE) <http://www.nite.go.jp/nbrc/patent/index.html >
  - NITE Patent Microorganism Depositary (NPMD)
  - NITE-International Patent Organism Depositary (NITE-IPOD)

- Authority (designated by Commissioner of JPO) in a non-contracting state under the Budapest Treaty

  Taiwan: Food Industry Research and Development Institute (FIRDI)

- International Deposit Authority under the Budapest Treaty

If any microorganism requiring deposition is not deposited, it results in violation of enablement requirements.

（See Examination Handbook Appendix B Chapter 2 “1.1.4 Deposit and Furnishing of Biological Material”）

Deposit of Microorganisms

Biological Inventions

microorganisms

2. Stating the Deposit Number in the Originally Attached Description (Copy of the Receipt of an Original Deposit is not Required)

Description

FERM AP-XXX

3. Filing

JPO

1. Application of Patent Depositary

Depositary Institution

If Receipt of Deposit is not issued, the case is treated as the case where the deposition had not been made.

Receipt

FERM AP-XXX

Testing the Viability and Finding the Microorganism to be Viable

Receipt of Deposit

FERM P-XXX

Copy of the Receipt

FERM P-XXX

4. Submitting Copy of the Receipt of Deposit

It is not necessary to amend an accession number into a deposit number in the description.

Deposit should be maintained during the time period when the patent right is valid.

Microorganisms excluded from Obligation to be Deposited

- **Microorganisms which cannot be deposited by a depositary institution designated by the JPO Commissioner for technical reasons or the like**

  In such a case, furnishing of the microorganisms should be guaranteed by the applicant.
  (Such microorganisms should preferably be deposited with a reliable culture collection.)

  An animal cell, which is not accepted for deposit due to mycoplasma contamination, is NOT excluded from obligation of deposition.

- **Microorganisms easily available for a person skilled in the art**
  - Commercially available microorganisms, such as baker's yeast
  - Microorganisms in a case where it has been evident, prior to filing, that the microorganisms have been stored at a reliable culture collection and are freely furnished from a catalog or the like issued by the culture collection
  - Microorganisms which can be produced by a person skilled in the art on the basis of the description

※ It is technically possible to avoid mycoplasma contamination, in general. Therefore, an animal cell is not excluded from obligation of deposition even if deposition is rejected due to mycoplasma contamination, except for a case beyond the control of the depositor.

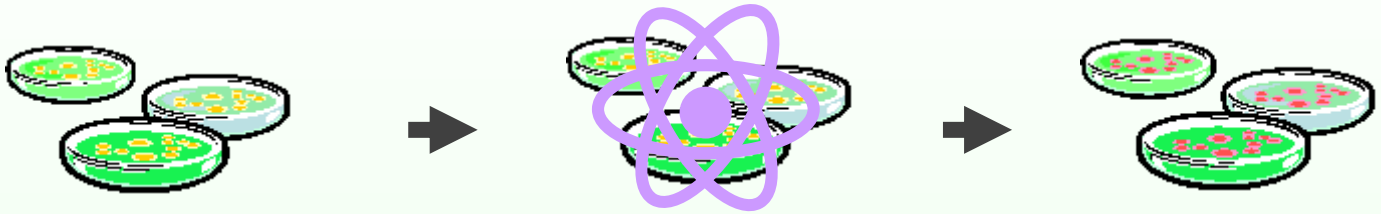
(See Examination Handbook Appendix B Chapter 2 “1.1.4 Deposit and Furnishing of Biological Material”)

Microorganisms excluded from Obligation to be Deposited

Examples of Microorganisms Easily Available for a Person Skilled in the Art

[Claim 1]
A transformed cell X to which a gene A has been induced.

[Overview of the description]
A gene A is induced into a commercially available animal cell Z through a known genetic engineering process in order to obtain a transformed cell X.



commercially available animal cell Z → genetic engineering process → transformed cell X

[Overview of the description]
A person skilled in the art can purchase a commercially available animal cell Z and a transformed cell X, based on the disclosure in the description. Therefore, deposit is not required.

(See Examination Handbook Appendix B Chapter 2 “1.1.4 Deposit and Furnishing of Biological Material”)

Cases where Deposit of Microorganisms is Required

[Claim 1]
A Bacillus subtilis T-169 strain, having dioxin decomposing ability.

[Overview of the description]
Saline mud at Toyama Bay was collected as a sample, and the Bacillus subtilis T-169 strain was isolated from the sample by a well-known method for a person skilled in the art. The taxonomical property of the Bacillus subtilis T-169 strain was analyzed in detail and the difference with the publicly known bacteria strain among the same species was examined. As a result, it was found that the Bacillus subtilis T-169 strain is a new bacteria strain. In addition, it was revealed upon performing experiments that the Bacillus subtilis T-169 strain can decompose dioxin with high efficacy.

[Explanation relating to determination of necessity for deposit of microorganisms, etc.]
Usually, the types and amounts of microorganisms present in soil and sea water may vary, even when the soil and sea water are obtained from the specific region.
Accordingly, even where a new microorganism is isolated using a sample collected from the soil, sea water, and the like in the specific region, it is difficult to obtain the new microorganism with reproducibility, as long as there is no reasonable basis that the new microorganism is present in the sample which is re-collected from the soil, sea water and the like.
In this case, the description does not provide a reasonable basis that the Bacillus subtilis T-169 strain is present in the sample which is re-collected from the saline mud at Toyama Bay.
Hence, since the Bacillus subtilis T-169 strain cannot be obtained with reproducibility when a person skilled in the art performs an additional test, the Bacillus subtilis T-169 strain is not a microorganism which can be manufactured by a person skilled in the art based on the statement in the description.
Therefore, it is necessary to deposit the Bacillus subtilis T-169 strain, since the Bacillus subtilis T-169 strain is not a microorganism which is easily available for a person skilled in the art.

(See Examination Handbook Appendix B Chapter 2 “6.2 Cases relating to Determination of Necessity for Deposit of Microorganisms, etc.” Case 40)

Cases where Deposition of Microorganisms is not Required

［Claim 1］
DNA encoding argininosuccinic acid synthase derived from coryneform bacterium strain K-336 and containing a nucleotide sequence represented by SEQ ID No. 1.

［Overview of the description ］
The taxonomical property of the coryneform bacterium strain K-336 producing L-arginine which was isolated from the soil based on chemical tolerance was analyzed in detail to examine any variation with native similar species. As the result, it was revealed that the coryneform bacterium strain K-336 is a new species.
It was publicly known prior to the filing the present application that the group of genes including ArgA gene and ArgH gene is esponsible for L-arginine biosynthesis pathway in the coryneform bacterium. The inventors first isolated and purified ArgG gene containing the nucleotide sequence represented by SEQ ID No. 1 from the coryneform bacterium strain K-336, and expressed ArgG gene by well-known gene engineering approaches and they have confirmed that a protein encoded by ArgG gene is argininosuccinic acid synthase.

[Explanation relating to determination of necessity for deposit of microorganisms, etc.]
In this case, the invention according to Claim 1 relates to DNA, not the coryneform bacterium strain K-336. In addition, the nucleotide sequence of the DNA is specifically represented in the description. Accordingly, a person skilled in the art can obtain the DNA through the artificial synthesizing method, etc. based on this nucleotide sequence.
Therefore, it is not necessary to deposit the coryneform bacterium strain K-336.

(See Examination Handbook Appendix B Chapter 2 “6.2 Cases relating to Determination of Necessity for Deposit of Microorganisms, etc.” Case 41)

Furnishing of Sample of Microorganism

A person who intends to test or perform research on an invention involving microorganisms deposited under the provisions of the preceding Article, may be furnished with a sample of the microorganism in the following cases.

(Regulations under the Patent Law Article 27-ter. (1))

- Where the registration of the establishment of the patent right regarding an invention involving the microorganism has been made.
- Where documents describing the contents of the invention involving the microorganism are submitted and a warning is received.
- Where a sample is necessary to prepare an argument (including the cases for comparison to the applicant's invention etc.)

A person who intends to test or perform research

request for furnishment

furnishment

depository institution

A person who entrusted to be furnished with a sample of the microorganism should not allow a third party to use the sample.

(See Examination Handbook Appendix B Chapter 2 "1.1.4 Deposit and Furnishing of Biological Material")

1. Patentable Invention
2. Claims and Description, etc.
3. Procedures for Obtaining a Patent in Japan
4. Procedures for Obtaining a Patent Overseas (Application using PCT)
5. Examination Guidelines in Life Sciences
5-1. Major Examination Guidelines associated with Life Sciences
5-2. Inventions of Methods of Surgery, Therapy or Diagnosis of Humans
5-2-1. Medical Device Inventions
5-2-2. Methods for Collecting Various Types of Information from a Human Body
5-3. Invention where there is a Description to Identify a Product by a Method of Manufacturing the Product
5-3-1. Types of Inventions that are Considered to be Unclear
5-3-2. Cases where a Claim concerning an Invention of a Product Describes a Method for Manufacturing the Product
5-4. Medicinal Inventions
5-5. Invention relating to Genetic Engineering
5-6. Invention relating to Screening Method
5-7. Invention relating to Protein 3D Structure
5-8. Invention relating to Microorganisms
5-9. Use Invention of Foods

Cases that Include an Expression specifying a Product by Its Use (Limitation of Use)

General concept of a “product with limitation of use”

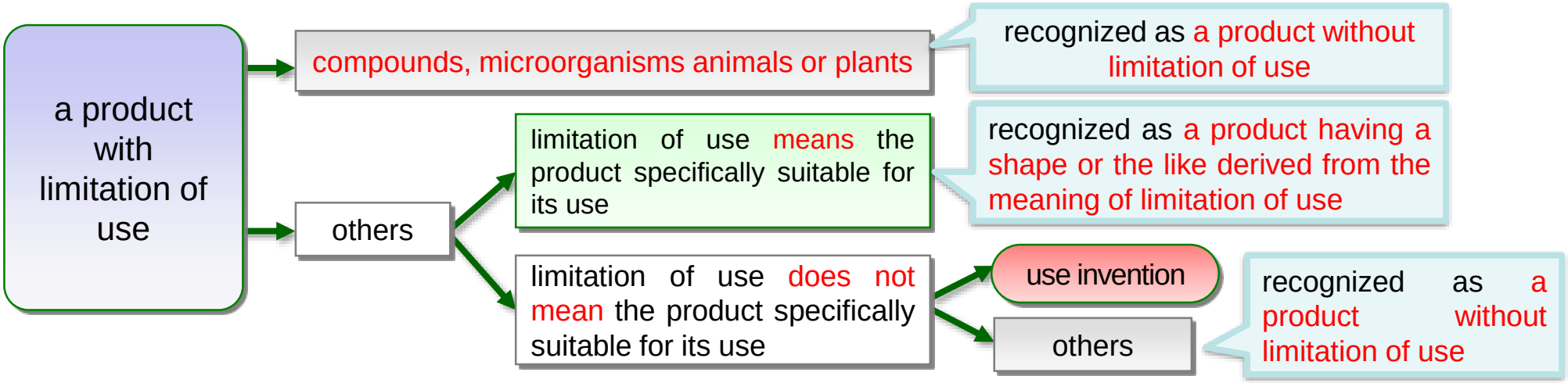
- If a product with limitation of use means a product specifically suitable for its use, the examiner recognizes that the product has a shape, structure or composition, etc. derived from the meaning of limitation of use.

(Example) a crane hook with a shape of ... ≠ fishing hook (fishhook) with a shape of …

Means a crane having a structure specifically suitable for its use from the aspect of the size, intensity, or the like.

- If a product with limitation of use does not mean a product specifically suitable for the use, except for the cases of use invention, the examiner recognizes the product as that without limitation of use.

  If the product with limitation of use is compounds, microorganisms animals or plants themselves, the examiner recognizes the product as that without limitation of use.



(See Examination Guidelines Part III, Chapter 2, Section 4,
“3. Expression Specifying the Product by its Use Application (Limitation of Use)”)

Use Invention

Definition of “Use Invention"

The invention based on (i) discovering an unknown attribute of a product and (ii) finding out that the product is suitable for a novel use because of such an attribute.

The concept of use invention is generally applied to the technical fields where it is relatively difficult to know how to use a product based on the structure or name of the product (e.g., a technical field for the use as a composition including chemical substances) .

Example of Use Invention

a composition for the use as anti-fouling ship bottoms comprising a component A

(a composition for preventing sticking of shells to ship bottoms)

Determined to be different from each other in spite of the same composition

a composition for the use as undercoating for electrodeposition comprising a component A

(a composition that is already known)

The invention based on (i) discovering an unknown attribute of a component A (that prevents sticking of shells to ship bottoms) and (ii) finding out that the product is suitable for a novel use (anti-fouling ship bottoms) because of such an attribute.

(See Examination Guidelines Part III, Chapter 2, Section 4,
“3.1.2 Cases where an invention of a product with limitation of use application should be interpreted as a use invention”)

Use Invention of Foods (Effective in Examination from April 1, 2016)

The concept of use invention had not been applied to foods.

Under the premise that an unknown use which differentiates from known foods cannot be provided, even if an unknown attribute of known foods is discovered (use application of foods ⇒ eating)

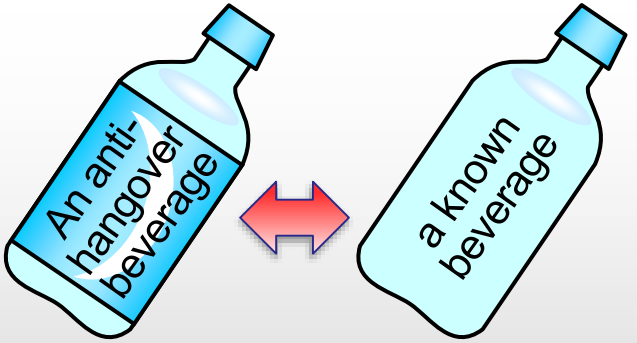
Growing health consciousness has activated research and development related to the functionalities of foods.

Questionnaire surveys on enterprises, case studies on court decision, deliberation at expert committees were conducted.

A large number of positive opinions were given on the concept of use invention of foods

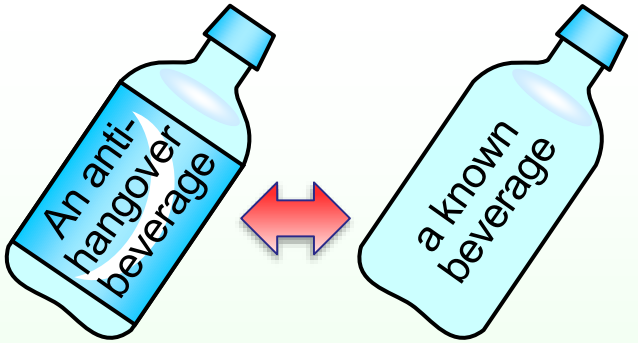
Use inventions of foods were made patentable for promoting protection and use of inventions related to functionalities of foods.

Animals or plants are, even with limitation of use, considered to be the animals or plants themselves without limitation of use (because such limitation of use only presents the usefulness of the animals or plants).



If a product has the same composition with that of another known product, they are considered to be the same.

(NOT a Use Invention)



Even if a product has the same composition with that of another known product, they are considered to be different.

(a Use Invention)

(See Examination Guidelines Part III, Chapter 2, Section 4, “3.1.2(1) Cases where claimed invention is considered to be a use invention”)

Case Example relating to Novelty (Inventions that Lack/Have Novelty)

Title of invention：Food Composition for preventing periodontal disease

[Claim 1] A food composition for preventing periodontal disease comprising an ingredient A as an active ingredient.
[Claim 2] A beverage composition for preventing periodontal disease comprising an ingredient A as an active ingredient.
[Claim 3] An agent for preventing periodontal disease comprising an ingredient A as an active ingredient.
[Claim 4] Grapefruit juice for preventing periodontal disease comprising an ingredient A as an active ingredient.
[Claim 5] Grapefruit for preventing periodontal disease comprising an ingredient A as an active ingredient.
[Claim 6] A food product for preventing periodontal disease comprising an ingredient A as an active ingredient.

The conditions (i) and (ii) required for use inventions are satisfied.

The invention based on (i) discovering an unknown attribute of an ingredient A (an antimicrobial effect against a pathogen causing periodontal disease) and (ii) finding out that the product is suitable for a novel use (periodontal disease prevention) because of such an attribute.

[Overview of the description]
The inventor found that the ingredient A contained in grapefruit juice and grapefruit has an antimicrobial effect against porphyromonas gingivalis which is a pathogen causing periodontal disease. Foods containing the ingredient include grapefruit, grapefruit beverages, and grapefruit jelly. (In an example, an antimicrobial effect of the ingredient A contained in grapefruit juice and grapefruit against porphyromonas gingivalis was observed).

Prior art: An ingredient A as an ingredient that decreases LDL cholesterol in blood

[Overview of the description]
The ingredient A as an ingredient that decreases LDL cholesterol in blood was isolated from grapefruit, and a chemical structure thereof was specified. Hyperlipidemia can be prevented by dairy intake of the composition for decreasing the LDL cholesterol in which the ingredient A as an active ingredient is contained, such as a food composition for decreasing LDL cholesterol and a beverage composition for decreasing LDL cholesterol, or an agent for decreasing LDL cholesterol in which the ingredient A as an active ingredient is contained. (In an example, decrease of LDL cholesterol was observed by the intake of a supplement containing the ingredient A or juice, produced by squeezing grapefruit, which contains the ingredient A.)

(See Examination Handbook Appendix A “Cases pertinent to Novelty” Case 30)

Case Example relating to Novelty (Inventions that Lack/Have Novelty)

Title of invention: Food composition for preventing periodontal disease

- ○ **[Claim 1]** A food composition for preventing periodontal disease comprising an ingredient A as an active ingredient.
- ○ **[Claim 2]** A beverage composition for preventing periodontal disease comprising an ingredient A as an active ingredient.
- ○ **[Claim 3]** An agent for preventing periodontal disease comprising an ingredient A as an active ingredient.
- ○ **[Claim 4]** Grapefruit juice for preventing periodontal disease comprising an ingredient A as an active ingredient.
- ✕ **[Claim 5]** Grapefruit for preventing periodontal disease comprising an ingredient A as an active ingredient.
- ✕ **[Claim 6]** A food product for preventing periodontal disease comprising an ingredient A as an active ingredient.

[Overview of the description]

The inventor found that the ingredient A contained in grapefruit juice and grapefruit has an antimicrobial effect against porphyromonas gingivalis which is a pathogen causing periodontal disease. Such foods include grapefruit, grapefruit beverages, and grapefruit jelly. (In an example, an antimicrobial effect of the ingredient A contained in grapefruit juice and grapefruit against porphyromonas gingivalis was observed).

The invention based on (i) discovering an unknown attribute of an ingredient A (an antimicrobial effect against a pathogen causing periodontal disease) and (ii) finding out that the product is suitable for a novel use application (periodontal disease prevention) because of such an attribute.

The conditions (i) and (ii) required for use inventions are satisfied.

[Explanation]

- **Claims 1-4** ⇒ ○ **Novelty is found**

  The inventions in Claims 1-4 are recognized as invention including the limitation of use "for preventing periodontal disease," because it is interpreted that they do not include grapefruit as a plant.

- **Claim 5** ⇒ ✕ **Novelty is NOT found**

  The limitation of use "for preventing periodontal disease" in Claim 5 merely indicates the usefulness of grapefruit as a plant. Therefore, the invention in Claim 5 is interpreted as grapefruit without limitation of use.

- **Claim 6** ⇒ ✕ **Novelty is NOT found**

  The description states that foods containing an ingredient A "include grapefruit, … ." The description states that the ingredient A is contained in grapefruit, and the statement is recognized as a common general technical knowledge. Taking this into consideration, it is interpreted that "a food product … comprising an ingredient A as an active ingredient" includes grapefruit, and thus the limitation of use "for preventing periodontal disease" indicates mere the usefulness of grapefruit as a plant. Therefore, the invention according to Claim 6 is interpreted as a food product including grapefruit without limitation of use.

(See Examination Handbook Appendix A "Cases pertinent to Novelty" Case 30)

Case Example relating to Novelty (Inventions that Lack/Have Novelty)

[Supplemental explanation]

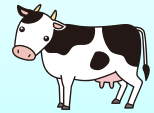
In a case where a claim of invention related to foods includes limitation of use, the limitation of use is recognized to have a meaning for specifying the invention according to the claim. However, when the limitation of use is provided to animals or plants themselves, since such limitation of use merely indicates the usefulness of the animals or plants themselves, the invention is interpreted as the animals or plants without limitation of use.

[Examples]

The inventions that are recognized to have no limitation of use

banana for … **fresh tea leaves for …** **mackerel for …** **beef for …**



The inventions that are recognized to have limitation of use

banana juice for … **tea beverage for …** **fish sausage for …** **milk for …**



[Points to be noted]

i) The description “agent for …” is used in various fields and does not usually mean animals or plants themselves. Similarly, in the field of foods, it can be determined that such description means supplements or food additives but does not include animals or plants themselves.

ii) The description “composition for …” or “food composition for …” usually means something obtained by mixing an ingredient suitable for a certain kind of use through a certain technical means, and it can be determined that such description does not include animals or plants themselves.

iii) The description “a food product for …” is interpreted as a food product without limitation of use in the case where it is determined that such description includes animals or plants themselves based on the statement in the description and a common general technical knowledge as of filing the application.

(See Examination Handbook Appendix A “Cases pertinent to Novelty” Case 30)

Case Example relating to Novelty (Invention that Lacks Novelty)

Title of invention: Food composition for improving bloodstream

[Claim 1]
A food composition for improving bloodstream comprising an ingredient A as an active ingredient.

[Overview of the description]
In the morning fasting, seven test subjects were gathered and kept quiet for one hour and, in this condition, blood flow of the index finger of the right hand of each of the test subjects was measured (blood flow before intake). Then, the seven test subjects were caused to take 30 g of biscuits containing the ingredient A by 5%. One hour after the intake, the blood flow of each of the seven test subjects was measured again (blood flow after intake). For the sake of comparison, the same test subjects were caused to take biscuits which do not contain the ingredient A in another day, and blood flow of each of the test subjects was measured before and after the intake. In the comparison, blood flow became 1.3 times when the test subjects were caused to take the biscuits containing the ingredient A.

Prior Art: Food composition for decreasing blood viscosity

[Claim 1]
A food composition for decreasing blood viscosity comprising an ingredient A as an active ingredient.

[Overview of the description]
A food composition containing the ingredient A as an active ingredient has an effect of decreasing viscosity of blood. 10 test subjects were caused to take 20 g of sausage which contains the ingredient A by 3%. Two hours after the intake, viscosity of blood was measured by using a blood viscosity measurement device. For the sake of comparison, another 10 test subjects were caused to take 20 g of sausage which does not contain the ingredient A. Two hours after the intake, the viscosity of blood was measured by using the blood viscosity measurement device. There was no difference in viscosity in the groups of the test subjects before the intake. However, after the intake of the sausage, the blood viscosity significantly decreased in the group who took the sausage that contains the ingredient A.

[Explanation]

- **Claim 1** → **Novelty is NOT found**

The limitation of use of the invention according to Claim 1 differs in terms of expression from the limitation of use of the invention disclosed in the prior art. It is, however, a common general technical knowledge as of filing the present application that the decrease of blood viscosity naturally achieves the bloodstream improvement.

In view of this, “a food composition for improving bloodstream comprising an ingredient A as an active ingredient” is a matter substantially equivalent to what is disclosed in Prior Art. Therefore, the invention of Claim 1 lacks novelty.

(See Examination Handbook Appendix A “Cases pertinent to Novelty” Case 33)

Case Example relating to Novelty (Invention that Lacks Novelty)

Title of Invention: Chlorella vulgaris for born-strengthening

✕ **[Claim 1]**
Chlorella vulgaris for born-strengthening.

[Overview of the description]
It was confirmed that an intake of chlorella vulgaris achieves born-strengthening. (An example is described showing the fact that an extract from chlorella vulgaris was added to a culture medium, cultured, and then a facilitated proliferative effect on osteoblastic cells was observed, as well as the fact that the bone density of osteoporosis patients who took chlorella vulgaris was observed.)

Title of invention: Chlorella vulgaris for intestinal regulation

[Overview of the description]
It was confirmed that an intake of chlorella vulgaris shows an intestinal regulation effect (an example is described showing the fact that the examinees who suffered from chronic constipation took chlorella vulgaris and then the constipation relieved.)

[Explanation] ⇨ ✕ **Novelty is NOT found**

- **Claim 1**

  Since the limitation of use application “for born-strengthening” indicates mere usefulness of chlorella vulgaris as a microorganism, the invention according to Claim 1 is simply interpreted as chlorella vulgaris. Therefore, there is no difference between the invention according to Claim 1 and the invention disclosed in Prior Art.

[Measures to be taken by an applicant]
If the applicant amends Claim 1 into “a food composition for born-strengthening comprising chlorella vulgaris,” Claim 1 is recognized as invention including the limitation of use. This solves the reason for refusal relating to lack of novelty.

(See Examination Handbook Appendix A “Cases pertinent to Novelty” Case 32)

Case Example relating to Inventive Step (Invention that Lacks Inventive Step)

Title of Invention: Sugar beet sherbet for removing bad breath

[Claim 1]
Sugar beet sherbet for removing bad breath.

[Overview of the description]
In the meeting, etc. after the meal including smelling materials such as garlic, bad breath is a concern. The purpose of the invention is that in order to eliminate this concern, a person takes sugar beet sherbet as a dessert after the meal to remove the bad breath, i.e., to remove unpleasant smell. It is known that sugar beet has an effect of removing bad breath, and sugar beet sherbet is also known. However, it is not known to use the sugar beet sherbet for removing bad breath (an example is described showing the fact that the sugar beet sherbet had a better effect of suppressing unpleasant smell caused by trimethylamine than that of the green tea sherbet).

Prior Art 1 (Primary Citation)

Prior Art 1 discloses that a person eats green tea sherbet as a dessert for removing bad breath.
(The invention according to Claim 1 differs from the invention disclosed in Prior Art 1 only in the tea ingredient "green tea," instead of "sugar beet.")

Prior Art 2 (Secondary Citation)

Prior Art 2 discloses that the intake of sugar beet shows a stronger effect of suppressing bad breath than that of green tea.

[Overview of reasons for refusal]

- **Claim 1** → ✗ **Novelty is NOT found**

The invention disclosed in Prior Art 1 and the invention disclosed in Prior Art 2 belong to the same technical field "food which contains tea ingredient for removing bad breath" **(relation of technical fields)**. The inventions in Prior Art 1 and 2 are common in "enabling removal of bad breath by an intake of food" **(similarity of problems to be solved)**. Further, the "green tea" in Prior Art 1 and the "sugar beet" in Prior Art 2 are common to each other in the effect and function of removal of bad breath **(similarity of operations or functions)**. Still further, Prior Art 2 discloses that the intake of sugar beet achieves a stronger effect of suppressing the bad breath, compared to green tea. This disclosure suggests replacement of the green tea in Prior Art 1 with the sugar beet so as to enhance the effect of suppressing bad breath **(suggestions shown in the content of prior art)**. Therefore, in the green tea sherbet of Prior Art 1, a person skilled in the art could have easily arrived at changing the tea ingredient from green tea to sugar beet for the purpose of enhancing the effect of suppressing bad breath. The effect of the invention, in which the sugar beet sherbet has a better effect of suppressing the bad breath than the green tea sherbet, can be expected by a person skilled in the art based on Prior Art 2 **(consideration of advantageous effects)**.

(See Examination Handbook Appendix A "Cases pertinent to Inventive Step" Case 21)

Case Example relating to Inventive Step (Invention that Lacks Inventive Step)

Title of invention: Beverage containing ginger juice for improving shadows under the eyes

[Claim 1]
Beverage containing ginger juice for improving shadows under the eyes.

[Overview of the description]
It is popular that poor health due to bad blood circulation is improved by causing a person to take an ingredient having an effect of increasing blood circulation. The present invention aims at improving shadows under the eyes by a simple means such as an intake of beverage. (An example is described showing that shadows under the eyes of examinees were suppressed by taking beverage which contains ginger juice.)

Prior Art 1 (Primary Citation)

The prior art 1 discloses that blood circulation is improved and shadows under the eyes are suppressed by taking beverage containing gingerol. (The invention according to Claim 1 differs from the invention in Prior Art 1 only in that an ingredient for suppressing shadows under the eyes is “gingerol” instead of “ginger juice”).

Prior Art 2 (Secondary Citation)

The prior art 2 discloses that ginger juice contains gingerol.

[Overview of reasons for refusal]

- **Claim 1** → **Novelty is NOT found**

The inventions disclosed in Prior Art 1 and 2 belong to the same technical field “foods containing gingerol”. Prior Art 1 discloses that an intake of beverage containing gingerol improves blood circulation and suppresses shadows under the eyes. This suggests mixing of ginger juice containing gingerol in Prior Art 2 with beverage for the purpose of suppressing shadows under the eyes **(suggestions shown in the content of prior art)**. Therefore, in Prior Art 1, a person skilled in the art could have easily arrived at employing ginger juice as an ingredient containing gingerol for the purpose of suppressing shadows under the eyes.

(See Examination Handbook Appendix A “Cases pertinent to Inventive Step” Case 22)

Case Example relating to Inventive Step (Invention that Lacks Inventive Step)

Title of invention: Squid ink spaghetti for excreting metal ions

[Claim 1]
Squid ink spaghetti for excreting metal ions.
[Overview of the description]
Ions of metals, e.g., ions of barium, lead, aluminum, etc., are stored in the body through daily meals, which adversely affects nerves and muscles. It is known that various kinds of chelating agents are used for excreting metal ions from the body. It is, however, not known that squid ink spaghetti is used for excreting metal ions from the body. The present invention aims at effectively excreting the stored metal ions from the body, by taking squid ink spaghetti (an example is described showing the excreting function of metal ions by giving squid ink spaghetti to mice.)

Prior Art 1 (Primary Citation)

Prior Art 1 discloses that the intake of a food composition composed of eumelanin as a main ingredient enables excreting of ions of metals such as ions of barium, lead, aluminum from the body. Prior Art 1 also discloses an example of a food composition, in which a supplement contains eumelanin as an active ingredient. (Prior Art 1 differs from the invention as in Claim 1 only at the point that it does not include a limitation of food composition “squid ink spaghetti.”)

Prior Art 2 (Secondary Citation)

Prior Art 2 discloses that a main ingredient of pigment of the squid ink in the squid ink spaghetti is eumelanin.

[Overview of the reasons for refusal]

- **Claim 1** → **Novelty is NOT present**

The inventions disclosed in Prior Art 1 and 2 belong to the same technical field “a food composition containing eumelanin” **(relation of technical fields)**. Prior Art 1, which discloses that an intake of a food composition composed of eumelanin as a main ingredient enables excreting of ions of metals such as ions of barium, lead, aluminum from the body, suggests application of squid ink spaghetti containing eumelanin as a main ingredient, which is disclosed in Prior Art 2, to the use of excreting of the ions of metals **(suggestions shown in the content of prior art)**. Therefore, a person skilled in the art could have easily arrived at using the squid ink spaghetti as the food composition containing eumelanin as a main ingredient in Prior Art 1.

(See Examination Handbook Appendix A “Cases pertinent to Inventive Step” Case 23)

5－9. Use Invention of Foods

Case Example relating to Description Requirements (Case Example where neither the Enablement Requirements nor Support Requirements are Satisfied)

Title of invention: Supplement for lowering blood sugar level

✕ **[Claim 1]**
A supplement for lowering a blood sugar level comprising an ingredient X_1 or X_2 as an active ingredient.

✕ **[Overview of the description]**
A purpose of the present invention is to achieve lowering of a blood sugar level by taking a supplement before or after meals. In a working example, a dietary supplement in the form of a tablet composed mainly of an ingredient X_1 or X_2 was produced. An excipient such as a microcrystalline cellulose or a maltodextrin and the ingredient X_1 or X_2 are subjected to dry-blending and, subsequently, are compressed. It is suitable to blend the ingredient X_1 or X_2 by a ratio of 20%. It is, however, also possible to blend the excipient and the ingredient X_1 or X_2 by a ratio of 50:50 to 90:10. Also, a powdered colorant can be added thereto, as required. The ingredient X_2 is an ester of the ingredient X_1. The detailed explanation of the invention includes a description of "a supplement containing the ingredient X_1 or X_2 has an effect of lowering a blood sugar level". However, the detailed explanation of the invention does not include a description of the common general technical knowledge or description of specific test result which shows that the ingredient X_1 or X_2 shows the effect of lowering a blood sugar level.

[Overview of the reasons for refusal]
The description does not include any explanation on a specific test which shows that the ingredient X_1 or X_2 has the effect of lowering a blood sugar level. Further, it is not foreseeable that the ingredient X_1 or X_2 has the effect of lowering a blood sugar level even in the light of the common general technical knowledge.

(Enablement requirements)
It is not possible to consider that a detailed explanation of the invention is disclosed to the extent that "a supplement for lowering a blood sugar level which comprises an ingredient X_1 or X_2 as an active ingredient" can be used. In view of this, the detailed explanation of the invention is not stated clearly or sufficiently as to enable a person skilled in the art to work the invention of claim 1. Therefore, the description does not satisfy enablement requirements.

(Support requirements)
Considering the description of the detailed explanation of the invention and a common general technical knowledge as of filing the application, it is not possible to consider that the detailed explanation of the invention is disclosed to the extent that the disclosure enables a person skilled in the art to recognize a solution of the problem of the invention, i.e., a solution of providing a supplement for lowering a blood sugar level which contains the ingredient A as an active ingredient. However, Claim 1 recites the supplement for lowering a blood sugar level which contains the ingredient X_1 or X_2 as an active ingredient.

[Measures to be taken by the applicant]
Even when the applicant submits the Certificate of Experimental Results which includes the specific test result relating to the effect of lowering a blood sugar level of the supplement and argues that the invention according to Claim 1 can work as a supplement for lowering a blood sugar level, the reasons for refusal can not be overcome.

(See Examination Handbook Appendix A "Cases pertinent to Description Requirements" Case 45)

References

Examination Guidelines for Patent and Utility Model
https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm

Examination Handbook for Patent and Utility Model
https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/handbook_sinsa_e.htm

Procedures for Seeking the Application of Exceptions to Lack of Novelty of Invention
https://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/e_pae_paa30.htm

Handbook for PCT International Search and Preliminary Examination
http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/pct_handbook_e.htm

Major Judicial Precedents of Biological Inventions
http://www.jpo.go.jp/shiryou_e/s_sonota_e/gizyutu_hanketu_e.htm

Patent Application Technical Trends Survey (Japanese only)
https://www.jpo.go.jp/shiryou/gidou-houkoku.htm

Guidance on the Deposit of a Microorganism (Japanese only)
https://www.jpo.go.jp/seido/tokkyo/tetuzuki/shutugan/biseibutu/index.html

Guidelines for the Preparation of Specifications which Contain Nucleotide and/or Amino Acid Sequences (Japanese only)
https://www.jpo.go.jp/tetuzuki/t_tokkyo/shinsa/enki_amino_guideline.htm

Contact

Examination Standards Office,
Administrative Affairs Division,
Japan Patent Office

E-mail : PA2A10@jpo.go.jp