Examination Guideline for Medicinal Inventions under the Japanese Patent Law

This presentation was prepared based on Part VII: EXAMINATION GUIDELINES FOR INVENTIONS IN SPECIFIC FIELDS,
Chapter 3 “Medicinal Inventions” available at JPO website.

Sera, Toyama, Matsukura & Kawaguchi

Examples of Claims

A medicinal inventions can be described in a claim as “an invention of a product“ as follows:

- Example 1: A medicament for treating disease Z comprising an active ingredient A (Novel pharmaceutical use of known compound A is protected by this type of claim.)
- Example 2: A pharmaceutical composition for treating disease Y comprising an active ingredient B
- Example 3: A medicament for treating disease W comprising active ingredients C and D in combination
- Example 4: A kit for treating disease V comprising an injection agent comprising an active ingredient E, an oral agent comprising an active ingredient F, and an agent comprising an auxiliary ingredient G.

Claims

- ○ A medicament for treating disease B comprising compound A
- ○ USE of compound A in manufacturing a medicament for treating disease B
- ○ Method of producing a medicament for treating disease B, comprising formulating compound A
- X Method of treatment for treating disease B, comprising administering compound A

Novelty

(i) In the case that the medicinal use of a compound is conceived from a known working mechanism of the compound, novelty is not acknowledged.

- (Cited invention) Bronchodilator
  → (Claimed invention) Asthma preparation
- (Cited invention) Vasodilator
  → (Claimed invention) Hypotensive agent
- (Cited invention) Coronary vessel dilator
  → (Claimed invention) Therapeutic agent for Angina
- (Cited invention) Histamine liberation inhibitor
  → (Claimed invention) Anti-allergy drug
- (Cited invention) Histamine H-2 receptor inhibitor
  → (Claimed invention) Therapeutic agent for Gastric ulcer

Novelty

(ii) In the case that the medicinal use of a compound inevitably results from closely related pharmacological effect of the compound, novelty is not acknowledged.

- (Cited invention) Cardiotonic agent

  → (Claimed invention) Diuretic agent

- (Cited invention) Anti-inflammation agent

  → (Claimed invention) Painkiller

Novelty

(iii) When the medicinal use disclosed in the cited invention is expressed in a more specific concept than the medicinal use of the claimed medicinal invention, the novelty of the claimed invention is denied.

- (Cited invention) Antipsychotic agent comprising compound A

→ (Claimed invention) Agent acting on central nervous system comprising compound A

(iv) the medicinal use of the claimed medicinal invention is only expressed as a newly found working mechanism in place of the medicinal use of the cited invention and both uses cannot be substantially distinguished from each other, the novelty of the claimed medicinal invention is denied.

- (Cited invention) Antibacterial agent comprising compound A

→ (Claimed invention) Bacterial cell membrane formation inhibitor comprising compound A

Inventive step

- (1) Even if the medicinal use of the claimed medicinal invention differs from the medicinal use of the cited invention, when the relevance of the working mechanism between both has been derived from the state of the art as of the filing, the inventive step of the claimed medicinal invention is usually denied.

- (2) Merely conversion of a medicine for animals other than human beings to a medicine for human beings usually does not involve an inventive step.

Inventive step

- (3) Medicine formulated by combining two or more medicinal components in order to solve a problem well known to a person skilled in the art such as the increase in a medicinal effect, or the reduction of a side effect, optimization of the combination of two or more medicinal components is among exercise of ordinary creativity of a person skilled in the art. When the difference between the claimed medicinal invention and the cited invention falls only on these points, the inventive step of the claimed medicinal invention is usually denied.
- However, in the case where there is another ground for inferring the inventive step such that an advantageous effect compared with the cited invention cannot be foreseen by a person skilled in the art from the state of the art, the claimed medicinal invention is considered to involve an inventive step.

Example 1 ~ A medicinal drug performing remarkable effect by combination of active ingredients

- Claim:
- An antidiabetic composition containing a compound A and a compound B at a ratio by weight 5:1 to 4:1.

- **[Explanation]**
- As the result of the pharmacological test shows a remarkable effect of reducing the side effects that cannot be foreseen by a person skilled in the art from the state of the art as of the filing by combining the compound A and the compound B at the specific ratio, the invention involves an inventive step.

Inventive step

- (4) Medicine characterized in the medicinal use of an application to a specific disease with a specific dosage and administration
- In order to solve a problem well known to a person skilled in the art such as the increase of a medicinal effect, the reduction of a side effect or the improvement in drug compliance, the optimization of dosage and administration of a medicine is among exercise of ordinary creativity of a person skilled in the art. Accordingly, the inventive step is usually denied, even if the claimed medicinal invention is novel compared with the cited invention in that applied disease does not differ but dosage and administration differ from each other.

- However, in the case where there is another ground for inferring the inventive step such that an advantageous effect compared with the cited invention cannot be foreseen by a person skilled in the art from the state of the art, the claimed medicinal invention is considered to involve an inventive step.

Example 2 ~ Medicine performing remarkable effect by an application to a specific disease in which dosage and administration is specified

- Claim A therapeutic agent for asthma containing compound A wherein 30~40 μg/kg of compound A is orally administered to humans once per 3 months.

- [Explanation]
- Regarding dosage and administration of compound A for asthma treatment, dosage and administration of this invention is different from the already known dosage and administration. Therefore, the medicinal invention of claim 1 is novel.
- Furthermore, by a single administration of 30~40μg/kg of compound A, the symptom of asthma is reduced for about 3 months and the incidence of side effect B significantly decreases compared to the case of the daily oral administration of 1μg/kg/day of compound A.
- As they are remarkable effects which cannot be foreseen from the state of the art as of the filing, the medicinal invention of the claim involves an inventive step.

Example 3 ~ Medicine performing remarkable effect by an application to a specific disease in which dosage and administration is specified

- Claim: A therapeutic agent for ovary cancer containing compound A as an active ingredient wherein 100~120μg/kg of compound A is administered to the particular site Z in human brain.
- **[Explanation]**
- Regarding dosage and administration of compound A for ovary cancer treatment, dosage and administration (administration to the particular site Z in the human brain) of this invention is different from the known dosage and administration (intravenous administration). Therefore, the medicinal invention of the claim is novel.
- Furthermore, as it is a remarkable effect which cannot be foreseen from the state of art as of the filing that compound A does not cause a side effect by administration to the particular site Z in the brain, the claimed invention has inventive step.

Selection invention

- A selection invention involves an inventive step, when it shows an advantageous effect, not disclosed in a cited reference, qualitatively different or qualitatively the same but quantitatively prominent in comparison with that of an invention with a generic concept in a cited invention, neither of the effect being foreseen by a person skilled in the art from the state of the art.

- [Example]
- It was publicly known that a chemical compound expressed with generic formula has the property of insecticide. While a specific compound is included in the generic formula, but was not specifically publicly known with respect to the property of insecticide, the claimed invention selected the specific compound as an effective component in the insecticide, on the basis of the discovery that the toxicity to humans of the specific compound is remarkably less than the other compounds in the generic formula. And, there is no other evidence which suggests such an effect. Thus, the claimed invention could not form a selection invention.

Selection invention defined with Numerical Value

- When a claimed invention is defined by specific numerical values, i.e., an invention with numerical limitation, the determination of inventive step comes under the following criteria.

- (i) Optimizing by experiment a numerical range is normally considered as an exercise of ordinary creativity of a person skilled in the art, and hence its inventive step is denied in general.
- (ii) However, a claimed invention involves an inventive step, when within a limited numerical range it has an advantageous effect, not disclosed in cited references, and qualitatively different or qualitatively the same but quantitatively prominent in comparison with that of a cited invention, neither of the effects also being foreseen by a person skilled in the art from the state of the art.
- The remarkable effect should be recognized in any part of a limited numerical range.
- A remarkable difference in effect is required between inside and outside the limited numerical range where a claimed invention differ from the cited invention only in the presence of the numerical limitation, and has the closely similar problem to be solved.

Selection Invention~ chiral compound

- Japanese IP court H18-10498, H15-62
- In both cases, inventive step of a chiral compound was disputed over prior arts which disclose the corresponding racemic compound, and it was decided that inventive step was not acknowledged on the reason that a skilled person had a motivation to isolate a chiral compound and its effect was within the range of expectation.

Description Requirements

(i) A pharmacological composition for healing nausea including compound A as an effective component is claimed, whereas the detailed description (specification) of the invention does not include a pharmacological test or data demonstrating the effectiveness of compound A against nausea.

(ii) The application will be rejected on the reason that a skilled person cannot recognize that the compound A actually has nausea-healing effect from the disclosure of the description.

(iii) Generally, pharmacological data demonstrating the effectiveness of the claimed compound should be presented in the original description and generally, such data are not considered by the Examiner even if they are presented in response to the Office Action.

(iv) Refer to Tokyo High Court Decision 1996, gyo-ke 201

Description Requirements

- Claim 1: A compound having R-receptor activating function.

  Claim 2: The compound of claim 1, wherein said compound is obtained by contacting a compound, measuring R-receptor activity and selecting a compound that enhances the R-receptor activity.

  Claim 3: The compound of claim 1, wherein said compound is selected from the group consisting of compounds X, Y and Z.

  Claim 4: A pharmaceutical composition comprising the compound of any one of claims 1-3.

  Claim 5: The pharmaceutical composition of claim 4, wherein said composition is for treatment of cancer.

- In the description, only compounds X, Y and Z are disclosed as “a compound having R-receptor activating function”, which was obtained as a result of drug screening.
- Usually, claim 1 is rejected on the reason that “a compound having R-receptor activating function” is indefinite and a skilled person cannot obtain claimed compounds other than X, Y and Z without undue experimentation.
- Claim 3 which limits the compound to X, Y and Z is allowed.
- Even if the applicant presents data which shows other compounds at the response to the Office Action, the rejection is usually maintained by the Examiner without considering such data.

Recitation of amino acid and nucleotide sequences

① A gene may be described by specifying its nucleotide sequence (SEQ ID NO:1).
A DNA (polynucleotide) comprising the nucleotide sequence of SEQ ID NO:1

② A protein may be described by specifying its amino acid sequence (SEQ ID NO:2).
A protein comprising the amino acid sequence of SEQ ID NO: 2.

③ A protein may be described by the term “substitution, deletion or addition" with the function of the protein.
A protein comprising the amino acid sequence of SEQ ID NO: 2 whereby one to five amino acids are substituted, deleted and/or added, and has an activity to catalyze the reaction X.

④ A protein may be described by the term “% identity" with the function of the protein.
A protein comprising the amino acid sequence at least 90% identical to SEQ ID NO: 2, and has an activity to catalyze the reaction X.

⑤ A gene may be described by specifying the term “hybridize under stringent conditions” with the function of the protein encoded by the gene.
A gene which hybridizes a complement of SEQ ID NO: 1 under stringent conditions, and encodes a protein having an activity to catalyze the reaction X.

“ Cell-based Medicine” characterized in a medicinal use of the cells specified by manufacturing process

- Claim 1: An anticancer agent comprising the cells as an active ingredient obtained by the following process consisting of the steps of;
- (1) culturing W-cells obtained from a human body in medium A containing 0.1~0.2 weight % of protein X for 5 to 10 hours and collecting them, and
- (2) disseminating the collected cells in the step (1) on an extracellular matrix Y, culturing them in medium B containing 0.1~0.2 weight % of protein Z for 24 to 48 hours, and collecting them.

- Claim 2: A method of manufacturing an anticancer agent consisting of the steps of;
- (1) culturing W cells obtained from a human body in medium A containing 0.1~0.2 weight % of protein X for 5 to 10 hours and collecting them,
- (2) disseminating the collected cells in the step (1) on an extracellular matrix Y, culturing them in medium B containing 0.1~0.2 weight % of protein Z for 24 to 48 hours, and collecting them, and
- (3) producing a pharmaceutical formulation by using the cells collected in the step (2), wherein the anticancer agent contains the cells obtained by the process consisting of the steps (1) and (2) as an active ingredient.

Diagnostic method

- **“Methods of surgery, therapy or diagnosis of humans” is not patentable under Japanese Patent Law.**

Diagnostic method ~ exceptions

- The following (see next slide) methods for gathering various kinds of information by, e.g., measuring structures and functions of the various organs of the human body, is not considered to be methods of diagnosis of humans unless it includes the steps of judging for the medical purposes the physical condition of a human body such as diseases and physical health, the mental condition of a human body, or prescription or treatment/surgery plans based on these conditions.

Diagnostic method ~ exceptions (Examples of patentable inventions

- Example 1: A method for an influenza test by extracting oral mucous membranes with cotton bud
- Example 2: A method for capturing the image of the lung by X-ray irradiation to the chest
- Example 3: A method for measuring the body temperature by inserting an electronic ear thermometer into external ear canal
- Example 4: A method for judging the sugar level in the urine by dipping the test strip in the collected urine sample, and comparing the color of the test strip with the colors on the color chart
- Example 5: A method of examining the susceptibility of the subject to hypertension by determining the type of nucleotide on the specific position in the nucleotide sequence of the X gene of the subject and comparing the nucleotide with a criteria in which when the nucleotide is A the susceptibility is low, and when the nucleotide is G the susceptibility is high
- Example 6: A method of preventing the uneven smear of the jelly for the ultrasonography that is spread on the body

In vitro method is allowable

- Example 1: A method for manufacturing a medicinal product (e.g., blood preparation, vaccine, genetically modified preparation and cell medicine) by utilizing raw material collected from a human body.
- Example 2: A method for manufacturing a medical material (e.g., an artificial substitute or alternative for a part of the human body, such as an artificial bone, a cultured skin sheet, etc.) by utilizing raw material collected from a human body.
- Example 3: A method of manufacturing an intermediate product for a medicinal product or a medical material (e.g. methods for differentiation and induction of the cells, methods for separation and purification of the cells) by utilizing raw material collected from a human body.
- Example 4: A method of analyzing a medicinal product or a medical material, or intermediate product thereof which is manufactured by utilizing raw material collected from a human body.

Method of operating a medical device

- The following claims are allowable.

- Example 1: A method for controlling the operation of an endoscope, wherein means of rotating the imaging unit whose light axis is tilted to the insertional axis of the endoscope is operated by receiving an instruction signal to rotate.
- Example 2: A method for controlling the operation of a magnetic resonance imaging device, wherein means of shifting to high resolution imaging is operated by the device when the signal strength within the desired domain drastically changes from the threshold value.
- Example 3: A method for controlling the X-ray generator by control means of the X-ray device; wherein the control means change ethe tube voltage and the tube current of the said X-ray generator each time the generator rotates one lap inside the gantry.