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Recent Revision of the Examination Guidelines in Japan for "Medicinal Inventions" and "Industrially Applicable Inventions"

1. Introduction

Following a review of the Examination Guidelines for medicinal inventions, a set of revised guidelines was published on October 23, 2009. The revised guidelines apply to all pending applications filed in Japan on or after July 1, 1995, and to those examined on or after November 1, 2009.

This article will focus mainly on revised guidelines that affect examination practice of medicinal inventions specified by "dosage and administration" (please refer to the Section 2 below) and of an invention relating to a medical activity (please refer to the Section 3 below). In addition, this article will provide an explanation for new case examples introduced in the revised guidelines relating to a medicinal use of a living organism, such as a cell (please refer to the Section 2 below), and relating to industrially applicable inventions (please refer to the Section 3 below).

(1) Background

Under the Japanese patent practice, a medical use invention of a compound has been protected as a pharmaceutical composition or a therapeutic agent which is defined by an ingredient compound and a medical use thereof or as a diagnostic product; while an invention relating to a so-called "medical activity" which is conducted by a medical doctor, such as an invention of a method for surgery, therapy or diagnosis of a disease in a human, is not considered as industrially applicable, and therefore, is not a patentable subject matter (Japanese patent law, Art. 29(1), main paragraph.)

In April 2005, the Japan Patent Office (JPO) established Examination Guidelines for a medicinal invention to clearly lay down criteria for judgment with regard to requirements for novelty, inventive step, written description and enablement, etc., and to clarify the rationale for judgment and handling of a medicinal invention. Further, upon establishment of the Examination Guidelines in April 2005, it was also clarified that a medicinal invention specified by a combination of two or more medicines and a treatment mode such as a dose interval and a dosage is an "industrially applicable invention" as an invention of a "product." For a more detailed explanation regarding the establishment of the Examination Guidelines for Medicinal Inventions made in April 2005, please refer to an article of YUASA AND HARA, IP NEWS, Vol. 17, pages 3-8 (published in July 2005, which is also available at http://www.yuasa-hara.co.jp/english/news/pdf/ipnews017.pdf).

Meanwhile, relating to the Examination Guidelines for Industrially Applicable Inventions, the JPO revised the guidelines twice in August 2003 and in April 2005 to clarify the rationale for examination and handling of an invention relating to a medical activity and to enhance examples of industrially applicable inventions. For more detailed explanations regarding the revisions of the Examination Guidelines for Industrially Applica-

ble Inventions made in August 2003 and April 2005, please refer to articles of YUASA AND HARA, IP NEWS (Vol. 13, pages 17-20 (published in January 2004, which is also available at http://www.yuasa-hara.co.jp/english/news/pdf/ipnews013.pdf) and Vol. 17, pages 9-13 (published in July 2005)).

(2) Movement for revision of the Examination Guidelines

Recently, there has been an increase worldwide in competition in research for realization of advanced medical technologies, including developments in research relating to iPS cells. Thus, there is a corresponding escalation in competition for obtaining intellectual property rights in areas relating to advanced medical technologies. Owing to these recent trends, the "Advanced Medical Patent Exploratory Committee" was established by the Intellectual Property Strategy Headquarters in November 2008. The Committee studied appropriate patent protection in advanced medical technologies, including iPS cell related technologies.

The Advanced Medical Patent Exploratory Committee made some observations on "Patent Protection in Field of Advanced Medical Technologies" in May 2009. Among the conclusions made by the committee were:

- To protect medicinal inventions with new dosage and administration, as inventions of "products," which show an effect exceeding the expectation of a person skilled in the art, Examination Guidelines should be revised and concrete examples added;
- To publicize that an invention characterized in a medicinal use of a cell or a cell-derived material is a patentable subject matter when the medicinal use is novel, concrete examples of such patentable inventions should be added to Examination Guidelines; and
- To publicize that an invention of a method of gathering various kinds of information (such as an invention relating to a mechanism or a principle of taking tomographic images using MRI or X-ray CT etc.) is a patentable subject matter, provided that it does not include a step of surgery of a human or therapy of a disease of a human or a step of judging the physical condition of a human body for the medical purposes.

On the basis of the above conclusions, the JPO revised "The Examination Guidelines for Medicinal Inventions" and "The Examination Guidelines for Industrially Applicable Inventions," in October 2009.

(3) Abstract of the revised Examination Guidelines

In the Examination Guidelines for "Medicinal Inventions," the following two issues are covered by the revision: (1) in medicinal inventions, an invention is regarded as novel when there is a difference between the invention and conventional medicine in application to a specific disease with a specific dosage and administration; (2) addition of examples for inventions characterized in medicinal use of tissue-derived materials (cells etc.) and for those characterized in medicinal use of cells specified by manufacturing process. Regarding the detailed explanation of the revision for "The Examination Guidelines for Medicinal Inventions," please refer to the Section 2 below.

In the Examination Guidelines for "Industrially Applicable Inventions," the following two issues are covered by the revision: (1) an invention of a method of gathering various kinds of information is regarded as industrially applicable provided that it does not include a step of surgery of a human or therapy of a disease of a human or a step of judging the physical condition of a human body for the medical purposes; (2) addition of examples of industrially applicable inventions in comparison with industrially inapplicable inventions (such as inventions which are defined by a combination of two or more products (such as a combination of physical means and biochemical means, etc), those of a method of inducing differentiation of cells, and so on). Regarding the detailed explanation of the revision for "The Examination Guidelines for Industrially Applicable Inventions," please refer to the Section 3 below.

For your reference, a full English translation of the revised Examination Guidelines is available from the JPO website (http://www.jpo.go.jp/cgi/linke.cgi?url=/tetuzuki_e/t_tokkyo_e/1312-002_e.htm). The Examination Guidelines for Medicinal Invention are included as Part VII, Chapter 3 of the Examination Guidelines for Patent and Utility Model in Japan and the Examination Guidelines for Industrially Applicable Inventions are as Part II, Chapter 1.

2. Details of Revision for "The Examination Guidelines for Medicinal Inventions"

(1) Change in Definition of Medicinal Invention

In the revised Guidelines, a definition of a medicinal invention has been changed. Before the revision, a medicinal invention was defined as "a use invention that belongs to a technical field of medicine, and is described as an invention of a product." The revised Examination Guidelines altered the definition of a medicinal invention to mean " 'an invention of a product' which is intended to provide a new medicinal use of a material, based on discovering an unknown attribute of the material" In this regard, a "material" 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. Further, "a medicinal use" means (i) an application to a specific disease, or (ii) an application to a specific disease in which dosage and administration such as dosing time, dosing procedure, dosing amount or administration areas (hereinafter referred to as "dosage and administration") is specified.

Due to the alteration of the definition of "a medicinal invention," a medicinal invention specified by "a treatment mode" as defined in the previous Guidelines is now recognized as a medicinal invention specified by "dosage and administration." The revised Examination Guidelines explain the alteration in the practice of medicinal invention characterized in its "dosage and administration" to be applied.

In addition, to clarify the examination practice of an invention that is characterized in a medicinal use of tissue-derived materials such as cells, the revised Examination Guidelines newly introduce some case examples for such inventions.

Further, there is no substantial change in the prosecution practice for medicinal inventions in general or for medicinal inventions of a combination of more than two medicines. In this regard, please refer to an article authored by the present writer, regarding the Examination Guidelines for medicinal invention established on April 2005 (Yuasa and Hara, IP News, Vol.17, pages 3-8, published in July 2005.)

(2) Medicinal invention specified by "dosage and administration"

(2-1) Novelty

Under the revised Guidelines, a condition of specific "dosage and administration" applied for a drug is regarded as a feature constituting a medicinal use. Thus, a medicinal invention is regarded as novel when there is difference between the invention and the conventional medicine in application to a specific disease with a specific dosage and administration.

Under the previous Guidelines, a medicinal invention specified by "a treatment mode" was regarded as novel only when (a) the target patient groups of the claimed and cited inventions are clearly distinguishable; or (b) the treated area of the claimed and cited inventions are clearly distinguishable. Thus, there were significant difficulties in overcoming novelty of a medicinal invention specified by "a treatment mode" under the previous Guidelines. In this regard, the revised Examination Guidelines define that a difference in "dosage and administration," such as a difference in dosing time, dosing procedure, dosing amount or administration areas, and the like, will be regarded as a difference in a medicinal use. Thus, under the revised Guidelines, novelty of a medicinal invention that is characterized in application to a specific disease with a specific dosage and administration will be acknowledged, due to its novel "dosage and administration."

(2-2) Inventive Step

As for the inventive step of a medicinal invention characterized in medicinal use of an application for a specific disease with a specific dosage and administration, the revised Examination Guidelines describe as follows:

> *"As for a specific disease, 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 an adverse effect or the improvement in drug compliance, the optimization of dosage and administration of medicine is among exercise of ordinary creativity of a person skilled in the art. Accordingly, in the case where the advantageous effect compared with the cited invention can be foreseen by a person skilled in the art, 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."*
>
> *(Excerpt from the revised Guidelines)*

Therefore, for inventive step of a medicinal invention characterized in medicinal use of an application to a specific disease with a specific dosage and administration to be acknowledged, it is necessary to show a significant effect superior to those described in a cited invention. The revised Examination Guidelines provide several case examples regarding a medicinal invention characterized in medicinal use of an application to a specific disease with a specific dosage and administration.

(2-3) Case Examples

The following Case Examples 1-3 are excerpted from case examples described in the revised Examination Guidelines, which clarify concrete practice regarding judgment of novelty and inventive step of a medicinal invention characterized in medicinal use of an application for a specific disease with a specific dosage and administration.

Case Example 1 (Patentable example)

[Claim]

[Claim 1] 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.

[Outline of Detailed Explanation of the Invention]

Although it has been publicly known that the symptom of asthma is reduced by daily oral administration of 1 μg/kg/day of compound A to asthma patients, the reduction of the symptom is only during the administration period of compound A. It was necessary thus to continue to administer compound A daily, because the symptom relapses if the administration is stopped. In addition, in case of the daily oral administration of 1 μg/kg/day of compound A, it has been pointed out that the side effect B arises with high frequency.

It was found in this invention that the symptom of asthma is improved for a long term and the incidence of side effect B is reduced compared to before, by orally administering 30-40 μg/kg of compound A to asthma patients once per 3 months.

It is described in the example with the result of the pharmacological test that the symptom of asthma was reduced at least for 3 months by every single oral administration of 30-40 μg/kg of compound A to a group of asthma patients (weighing 30 kg to 90 kg,) that body weights didn't bring clear difference in pharmacological efficacy, and the incidence of side effect B significantly decreased from the case of daily oral administration of 1 μg/kg/day of compound A.

[Result of Prior Art Search]

It is publicly known that the symptom of asthma is reduced by daily oral administration of 1 μg/kg/day of compound A and that side effect B arises with high frequency in that case. However, administering 30-40 μg/kg of compound A once per 3 months is not described in the prior art documents.

Furthermore, from the state of the art as of the filing, it is not possible to predict that the symptom of asthma decreases at least for 3 months by a single oral administration of 30-40 μg/kg of compound A and that the incidence of side effect B decreases compared to the prior art.

[Outline of Reasons for Refusal]

No reason for refusal.

[JPO's 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 30-40 μg/kg of compound A, the symptom of asthma is reduced at least for 3 months and the incidence of side effect B significantly decreases compared to the case of the daily oral administration of 1 μg/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 claim 1 involves an inventive step.

(Excerpt from the revised Guidelines)

Case Example 2 (Patentable example)

[Claim]

[Claim 1] A therapeutic agent for ovary cancer containing compound A as an active ingredient wherein 100-120 μg/kg of compound A is administered to the particular site Z in human brain.

[Outline of Detailed Explanation of the Invention]

It has been known that compound A exhibits growth-inhibitory effect against ovary cancer by intravenous administration to humans but arises hepatotoxicity as a side effect at the same time.

In this invention, it is found that the blood level of hormone Y secreted from the pituitary gland changes by ad-

ministration of compound A to the particular site Z in the human brain, and consequently ovary cancer significantly diminishes compared to the conventional treatment by intravenous administration.

It is described in the example with the result of the pharmacological test that the blood level of hormone Y secreted by the pituitary gland changes by administration of compound A to the particular site Z in the human brain, and that as a result ovary cancer diminishes more compared to the conventional treatment by intravenous administration. It is also described in the example with the result of the pharmacological test that compound A is not delivered to the liver and does not show hepatotoxicity when it is administered to the particular site Z in the brain.

[Result of Prior Art Search]

It is publicly known that compound A exhibits growth-inhibitory effect against ovary cancer by intravenous administration to humans and hepatotoxicity as a side effect. However, it is not described in the prior art documents that the intravenously administered compound A is delivered to the brain through the blood brain barrier, or the administration of compound A to the particular site Z in the human brain results in more shrinking of ovary cancer that the prior art.

Furthermore, from the state of the art as of the filing it is not possible to predict that ovary cancer diminishes without causing a side effect of hepatotoxicity by administering compound A to the particular site Z in the human brain.

[Outline of Reasons for Refusal]

No reason for refusal.

[JPO's Explanation]

Regarding dosage and administration of compound A for ovary cancer treatment, dosage and administration is different from the already known dosage and administration (intravenous administration.) Therefore, the medicinal invention of claim 1 is novel.

Moreover, as it is a remarkable effect which cannot be foreseen from the state of the art as of the filing that compound A does not cause a side effect of hepatotoxicity by administration to the particular site Z in the brain, or ovary cancer diminishes more compared to the treatment b intravenous administration, the medicinal invention of claim 1 has an inventive step.

(Excerpt from the revised Guidelines)

Case Example 3 (Unpatentable example)

[Claim]

[Claim 1] An antitussive agent containing compound A wherein 400-500 μg/kg per dose of compound A is orally administered to humans once per day.

[Outline of Detailed Explanation of the Invention]

Although it has been known that orally administering 160 μg/kg per dose of compound A to humans three times a day has the antitussive effect, it was found in this invention that the antitussive effect improves compared to before by oral administration of 400-450 μg/kg per dose of compound A to humans.

It is described in the example with the result of the pharmacological test that oral administration of 400 μg/kg per dose of compound A to a patient once per day improves the antitussive effect compared to the oral administration of 160 μg/kg per dose of compound A to a patient three times per day. Furthermore, it is also described that drug compliance improves because the number of doses per day decreases.

[Result of Prior Art Search]

It is publicly known that the antitussive effect is obtained by oral administration of 160 μg/kg per dose of compound A three times per day. Furthermore, the degree of the antitussive effect and improvement of drug compliance disclosed in the detailed explanation of the invention falls under the predictable range in the light of the state of the art as of the filling.

[Outline of Reasons for Refusal]

It is publicly known that an antitussive agent including compound A as n active ingredient is orally administered. In general, in order to solve a problem well known to a person skilled in the art, such as an increase in a medicinal effect and improvement of drug compliance, optimization of dosage and administration of a medicine is among exercise of ordinary creativity of a person skilled in the art. Therefore, it would have been easily arrived at by a person skilled in the art to experimentally decide appropriate dosage and administration of compound A. Furthermore, that a medicinal effect and drug compliance can be improved by optimizing dosage and administration of a medicine can normally be foreseen to a person skilled in the art, and the degree of improvement in this invention is not remarkable one unforeseeable from the state of the art as of the filing.

[Measures for Reasons for Refusal]

Ordinarily, the above-described reason for refusal is not overcome.

[JPO's Explanation]

How much effect is "remarkable one unforeseeable from the state of the art as of the filing" is judged individually taking into consideration the content of disclosure of the description, results of the prior art search, and common general technical knowledge as of the filing or the like.

(Excerpt from the revised Guidelines)

(3) An invention characterized in a medicinal use of tissue-derived material

In the revised Examination Guidelines, a material that is a component used as an active ingredient of a medicinal invention is defined to include 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. That is, it is clarified that not only a medicine comprising a compound as an active ingredient, but also a medicine comprising biological materials such as tissue-derived materials including cells is a subject matter to be protected by a patent. To clarify the examination practice relating to an invention that is characterized in a medicinal use of tissue-derived materials such as cells, the revised Examination Guidelines newly introduce the following two case examples for such inventions.

Case Example 4

(Medical materials (cells etc.) derived from a living organism that is publicly known, but for which a medicinal use is novel)

[Claim]

[Claim 1] An implant material for treatment of cardiac infarction, which contains cell sheets consisting of A-cells.

[Outline of Detailed Explanation of the Invention]

It was found that cardiac function was recovered by transplantation of cell sheets consisting of A-cells to a site of cardiac infarction.

It is described in the example with the result of the pharmacological test that cardiac function is recovered and the symptom of cardiac infarction is reduced by transplantation of the said cell sheets to the site of cardiac infarction in a model rat of cardiac infarction.

[Result of Prior Art Search]

It is publicly known that cell sheets are obtained from A-cells and that they are used as implant materials. However, it is not described in any prior art documents that the said cell sheets are transplanted to the site of cardiac infarction and that the symptom of cardiac infarction is reduced by the transplantation.

Furthermore, from the state of the art as of the filing, it is not possible to predict that cardiac function is recovered and the symptom of cardiac infarction is reduced by transplantation of A-cells.

[Outline of Reasons for Refusal]

No reason for refusal.

[JPO's Explanation]

The medicinal invention of the claim 1 is considered to be novel because the medicinal use (treating cardiac infarction) of cell sheets consisting of A-cells is different from the conventionally-known medicinal use of the sheets.

The medicinal invention of the claim 1 is considered to involve the inventive step because the prior art documents have not been publicly known which describe the relationship between the A-cell and recovery of cardiac function etc., and then motivate the use of cell sheets consisting of A-cells for treatment of cardiac infarction.

[JPO's Remark]

It should be noted that, if the claimed invention is related to the cell with the limitation of use such as "A-cell for the treatment of cardiac infarction," such limitation of use usually only indicates the utility of the cell itself and the claim should be construed to represent the cell per se with no limitation of use. Therefore, in this case, the difference between "A-cell for the treatment of cardiac infarction" and publicly known "A-cell" with no limitation of use cannot e acknowledged in view of composition of matters (refer to Examination Guidelines, Part II; Chapter 2, 1.5.2(2))

(Excerpt from the revised Guidelines)

Case Example 5

(Medicine characterized in a medicinal use of cells specified by manufacturing process)

[Claim]

[Claim 1] An anticancer gent 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 comprising 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) a step of 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.

[Outline of Detailed Explanation of the Invention]

It was found that the anticancer agent containing cells obtained by the process consisting of steps of (1) and (2) as an active ingredient inhibited angiogenesis peculiar to a cancer tissue and diminished the cancer growth.

It is described in the example with the result of the pharmacological test that the cells obtained by a process consisting of the steps of (1) and (2) in the example have an excellent inhibitory effect of angiogenesis and diminishing effect of the cancer growth.

[Result of Prior Art Search]

It is publicly known that W-cell obtained from a human body is processed through the steps of (1) and (2) and that cells processed through the steps have an immunosuppressive effect. However, it has not been known that W-cell itself or the cells processed through the steps consisting of (1) and (2) has an inhibitory effect of angiogenesis and an anticancer effect.

Furthermore, from the state of the art as of the filing, it is not possible to predict that the cells obtained by processing W-cells derived from the human body through the steps consisting of (1) and (2) have an inhibitory effect of angiogenesis and an anticancer effect.

[Outline of Reasons for Refusal]

No reason for refusal.

[JPO's Explanation]

The medicinal invention of claim 1 is considered to be novel because a medicinal use (anticancer) of cells obtained form the steps consisting of (1) and (2) is different from the conventionally-known medicinal use (immunosuppression.)

The medicinal invention of claim 1 is considered to involve inventive step because the prior art documents have not been publicly known which disclose the relationship between an immunosuppressive effect and angiogenesis and then motivate the use of the cells obtained by the steps consisting of (1) and (2) as an anticancer agent.

In addition, the invention of claim 2 is considered to be novel and to involve inventive step based on the same idea of the invention of claim 1.

It should be noted that the cells could be specified by manufacturing process, even when it is difficult to specify the cells with cell markers, etc. In this example, the inventions of claims 1 and 2 are considered to be clear, because original cells and culture condition are identified in details in the steps consisting of (1) and (2). As for handling of claims including specification of a product by the manufacturing process, please refer to Part I, Chapter 1, 2.2.2.1(7); as well as, Part II, Chapter 2, 1.5.5(4) and 2.7 of the Examination Guidelines.

(Excerpt from the revised Guidelines)

(4) Conclusion of Section 2

The revised "Examination Guidelines for Medicinal Inventions" are briefly explained above. Under the revised Guidelines, a medicinal invention is regarded as novel when there is difference between the invention and conventional medicine in medicinal application to a specific disease with a specific dosage and administration. However, the JPO stands on a point that inventive step of a medicinal invention characterized by specific dosage and administration lies in a remarkable effect achieved by the novel dosage and administration. An extent of remarkableness for which inventive step of the invention may be acknowledged will be considered by JPO examiners depending on circumstances in each case. Further, under Japanese patent practice, to satisfy enablement requirement of a medicinal invention, at least one pharmacological test result or equivalent result should be described in the specification as originally filed. Therefore, for a medicinal invention that

is specified by a novel dosage and administration, it should be noted that an applicant should describe its remarkable effect in the specification as originally filed.

3. Details of Revision for "The Examination Guidelines for Industrially Applicable Inventions"

(1) Background

The fundamental policy relating to determination of Industrial Applicability under the Japanese practice is that an invention relating to a so-called "medical activity" (i.e., a method of surgery, therapy or diagnosis of a disease in a human which is conducted by medical doctors) is to be considered as an Industrially Inapplicable Invention.

Specifically, an invention relating to a "medical activity" includes not only an invention of a method for surgery, therapy or diagnosis of a disease in a human, but also an invention that comprises, as a part, a step involving a "medical activity" (such as a step of obtaining a blood sample from a human, a step of determining malignancy of a neoplastic tissue, or a step of giving a stimulus to a ventricle of a patient's heart with pacemaker pulses).

As described above, the Examination Guidelines for Industrially Applicable Inventions were revised in October 2009. However, the fundamental policy relating to the Industrial Applicability of an invention relating to a "medical activity" has not been changed in the revised Examination Guidelines.

The purpose of the revision is to clarify the extent of types of invention that do not correspond to an invention of "a method for surgery, therapy or diagnosis of a disease in a human" (i.e., an Industrially Applicable Invention) more specifically than before (please refer to the descriptions of the Sections 2.1.1.2 and 2.1.1.3 and Examples of the Section 4 of the Examination Guidelines for Industrially Applicable Inventions). Detailed explanations are provided as follows.

(2) Details of Guidelines for Industrially Applicable Inventions

(2-1) Fundamental Policy

An invention of a method for surgery, therapy, or diagnosis of a disease in a human is generally considered as "an Industrially Inapplicable Invention." If you consider it is difficult to know whether a claimed invention is Industrially Applicable, we suggest checking the following points:

(i) Is the claimed invention directed to a method? (If the claimed invention relates to a product, the invention is, in principle, Industrially Applicable);

(ii) Does the claimed invention include a step involving a "medical activity" (i.e., a step either relating to (ii-1) "an action of a medical doctor" or (ii-2) "an influence on the human body by a device")? (If the claimed invention includes neither step, the invention is Industrially Applicable).

A step (ii-1) relating to "an action of a medical doctor" is illustrated in the Examination Guidelines as "a step where a medical doctor operates a device to provide medical treatment in accordance with a symptom" and also includes a step practiced by a medical doctor (such as a step of obtaining a blood sample from a human, a step of determining malignancy of a neoplastic tissue, or a step of giving a stimulus to the ventricle of the patient's heart with pacemaker pulses).

A step (ii-2) relating to "an influence on the human body by a device" is illustrated in the Examination Guidelines as a step of incision and/or excision of a specific part of a patient by a device, or a step of irradiating radiation, electromagnetic wave or sound wave by a device.

Even when a claimed invention is considered to be an Industrially Inapplicable Invention in the examination procedure, it is often possible to overcome such a problem by appropriately revising the description of any relevant steps. Therefore, if any difficulties arise relating to Industrially Applicability, please let us know. We will provide our proposed amendment of the description of the claims to the greatest extent possible.

(2-2) Examples of Industrially Applicable Inventions

(2-2-1) Combination of two or more products

An invention of a product relating to a medical field (such as a medical device or a medical substance) is, in principle, Industrially Applicable (please refer to (2-1)(i) above). Therefore, regardless of whether a claimed invention relates to a combination of two or more products, such an invention of

the combination is naturally considered as an Industrially Applicable Invention.

Policy of Industrially Applicability relating to the combination of two or more products is explained in Section 2.1.1.2(1) of the Examination Guidelines for Industrially Applicable Inventions and examples of industrially applicable inventions are exemplified as Examples 13-2, 14-2, and 15-2 as follows.

Example 13-2 (Patentable example)

[Claim] 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 the image data showing the position of the tumor, means to focus the convergence supersonic wave on the position of the tumor, and means to irradiate the convergence supersonic wave onto the micro capsule X.

Example 14-2 (Patentable example)

[Claim] 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 by the biocompatible polymeric material Z, characterized in that the implant is transplanted to a joint of humans.

Example 15-2 (Patentable example)

[Claim] A composition for treating cardiac infarction containing A-cells and cell growth factor W as active ingredients, characterized in that the composition is administrated to the site of cardiac infarction of humans.

(2-2-2) "A Method for Controlling Operation of a Medical Device"

An invention of "a method for controlling operation of a medical device" is considered to be classified as an "Industrially Applicable Invention," provided that the method recited in the claims does not include any steps relating to "an action of a medical doctor" or "an influence on the human body by a device" (please refer to (2-1)(ii) above). In a case where the claimed invention is considered to include a step relating to "an action of a medical doctor" or "an influence on the human body by a device" (such as Examples 8-1, 9-1, 10-1, 11-1, 12-1, 16-1, 17-1, 18-1, 19-1, 20-1, 24-1, and 25-1), if such a step can be eliminated from the description of the claims, it is possible to overcome such problem.

Policy of Industrially Applicability relating to "A Method For Controlling Operation Of a Medical Device" is explained in Section 2.1.1.2(2) of the Examination Guidelines for Industrially Applicable Inventions and examples of Industrially Applicable Inventions are exemplified as Examples 8-2, 9-2, 10-2, 11-2, 12-2, 16-2 to 16-4, 17-2, 18-2, 19-2, 20-2, 24-2, and 25-3.

(2-2-3) "A Method for Gathering Various Kinds of Information"

An invention of "a method for gathering various kinds of information by, for example, measuring structures and functions of the various organs of the human body" is considered to be an Industrially Applicable Invention, provided that it does not include a step of judging the physical condition (such as diseases and physical health, the mental condition of a human) of a human body for medical purposes, or for the purposes of prescription or treatment/surgery regimens based on these conditions.

The Examination Guidelines describe that (a) a method of extracting samples and data from the human body, or a method of analyzing, e.g., comparing such samples and data with standards and (b) a method of preparatory treatment for measuring structures or functions of various organs of the human body are exemplified as examples of Industrially Applicable Inventions (please refer to Examples 19-1, 20-1, and 21). In addition to these Examples, the following six cases are also additionally exemplified as Industrially Applicable Inventions. Cases 1-5 are examples of (a) above and Case 6 is an example of (b) above:

Case 1 : A method of collecting oral mucous membranes with cotton bud for an influenza test;

Case 2 : A method for capturing an image of the lung obtained by a step of irradiating X-ray to the chest;

Case 3 : A method for measuring body temperature by inserting an electronic ear thermometer into external ear canal;

Case 4 : A method for determining urine sugar level by steps of dipping the test strip in the collected urine sample and comparing the developed color of the

test strip with the color chart;

Case 5 : A method of examining the susceptibility of a subject to hypertension by steps of determining an nucleotide at n^{th} position of the nucleic acid sequence of the X gene of the subject and comparing the nucleotide with a standard in which, when the nucleotide of interest is A the susceptibility risk is low, and when the nucleotide of interest is G the susceptibility risk is high; and

Case 6 : A method of preventing an uneven application of jelly that is spread on the body during ultrasound inspection.

On the other hand, even though the claimed invention is entirely directed to a method for gathering various kinds of information, presence of a step involving a "medical activity" (such as a step of determining malignancy of a neoplastic tissue on the basis of gathered information) makes the claimed invention Industrially Inapplicable (please refer to (2-1)(ii) above).

Policy of Industrially Applicability relating to "A Method For Gathering Various Kinds Of Information" is explained in the Section 2.1.1.2(3) of the Examination Guidelines for Industrially Applicable Inventions and examples of Industrially Applicable Inventions are exemplified as Examples 19-1, 20-1, and 21.

(2-2-4) "A Method for Treating Samples that have been Extracted from a Human Body"

A method for treating samples *in vitro* that have been taken from a human body (e.g., blood, urine, skin, hair, cells or tissue samples) and a method for gathering data by analyzing such samples are considered to be Industrially Applicable Inventions (please refer to Example 25-2).

On the other hand, if a method for treating these samples or analyzing the samples *ex vivo* is performed on the assumption that the samples are to be returned to the body of the same person from which the samples are originated (e.g., a method of dialyzing blood), such a method is generally qualified to be placed under the category of "a method of surgery or therapy of a human" (i.e., an Industrially Inapplicable Invention) (please refer to Examples 24-1 and 25-1).

However, even if a method for treating these samples is performed *ex vivo* on the presumption that the samples are to be returned to the body of the same person from which the samples are originated, the following cases are considered to be Industrially Applicable Inventions (please refer to Examples 22-2, 23-1, 23-2, and 23-3):

(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 22-2);

(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;

(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 (Examples 23-1 and 23-2); and

(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 (Example 23-3).

Policy of Industrially Applicability relating to "A Method for Treating Samples that have been Extracted from a Human Body" is explained in the Section 2.1.1.3 of the Examination Guidelines for Industrially Applicable Inventions and examples of Industrially Applicable Inventions are exemplified as Examples 22-2, 23-1, 23-2, 23-3, and 25-2.

(2-2-5) A Method Relating To Assisting Devices

This category of an invention of "a method relating to assisting devices" has been newly incorporated into the Examination Guidelines. However, policy of Industrially Applicability of this inventive category is not explained in the Examination Guidelines for Industrially Applicable Inventions. Instead, examples of Industrially Applicable Inventions are only exemplified as Examples 26-1, 26-2, and 26-3.

The Examination Guidelines exemplify the following three types of inventions as Industrially Applicable Inventions regarding a method relating to assisting devices:

Example 26-1 : An invention of "a method of judging walking conditions with a power assisting equipment coupled to a leg of a worker to reduce his burden";

Example 26-2 : An invention of "a method for controlling a power assisting equipment coupled to a worker to reduce his burden"; and

Example 26-3 : An invention of "a power assisting method to assist movements of workers by a power assisting equipment coupled to workers to reduce their burden".

The Examination Guidelines describe in these Examples that it is not supposed that the power assisting equipment of this invention assists movements of those who lost muscle strength or those who lost physical motor function for medical purposes (i.e., a physically-disabled person such as a person who needs nursing-care). Thus, the underlying common concept of these Examples is that the power assisting device is aimed at assisting "a worker" to reduce his burden but not assisting "a physically-disabled person" (the term "worker" is defined as a person who is involved in hard work in the Examination Guidelines). On the other hand, if the claimed invention is aimed at assisting a physically-disabled person, the claimed invention will be considered as a method of therapy.

For your general interest, examples of a power assisting device envisioned in the Examination Guidelines include devices such as Robot Suit HAL® of CYBERDYNE Inc., and Walking Assist Technologies such as Stride Management Assist and Bodyweight Support Assist being developed by Honda Motor Co., Ltd.

(3) Abstract of Case Examples

Examples of Industrially Inapplicable Inventions and Industrially Applicable Inventions are listed in Table below.

Table Abstract of Case Examples

Industrially Inapplicable		Industrially Applicable
A method of surgery of a human		
8-1 (A method for treating an affected part by micro operation robot)	→	**8-2** *2 (A method for controlling the operation of a micro operation robot system)
9-1 (A method for sampling body fluid)	→	**9-2** *2 (A method for controlling the operation of a body fluid sampling device)
10-1 (A method for the observation of the celom by using an endoscope)	→	**10-2** *2 (A method for controlling the operation of an endoscope)
11-1 (A method for contrast magnetic resonance imaging)	→	**11-2** *2 (A method for controlling a magnetic resonance imaging device)
12-1 (A method for displaying superimposed images of an object being cut and a cutting apparatus)	→	**12-2** *2 (A method for controlling a device for displaying superimposed images of an object being cut and a cutting apparatus)
A method of therapy of a human		
13-1 (A method for the treatment of cancer)	→	**13-2** *1 (A system for cancer treatment)
14-1 (A method for regenerating cartilage)	→	**14-2** *1 (An implant material for cartilage regeneration)
15-1 (A method for the treatment of cardiac infarction)	→	**15-2** *1 (A composition for treatment of cardiac infarction)
16-1 (A method for giving electrical stimulus by a pacemaker)	→	**16-2**, *2 **16-3** *2 (A method for controlling a pacemaker) **16-4** *2 (A method for controlling the operation of a pacemaker)
17-1 (A method for retinal stimulation using an artificial eye system)	→	**17-2** *2 (A method for controlling an artificial eye system)
18-1 (A method for X-ray irradiation)	→	**18-2** *2 (A method for operating an X-ray device)

A method for gathering data	
	19-1 *3 (A method for X-ray CT scanning) **19-2** *2 (A method for controlling an X-ray CT scanner)
	20-1 *3 (A method for magnetic resonance imaging) **20-2** *2 (A method for controlling magnetic resonance imaging device)
	21 *3 (A method for nuclear medicine imaging)

A method for gathering data	
22-1 (A method for Gene therapy) →	**22-2** *4 (A method for manufacturing cell formulation for gene therapy)
	23-1 *4 (A method of inducing differentiation of cells) **23-2** *4 (A method of separating and purifying differentiation-induced cells) **23-3** *4 (A method of analyzing a ratio of separated and purified cells)
24-1 (A method for blood purification) →	**24-2** *2 (A method for controlling the operation of a blood purifying device)
25-1 (A method for measuring hematocrit values of blood) →	**25-2** *4 (A method for measuring hematocrit values of extracted blood) **25-3** *2 (A method for controlling the operation of a blood hematocrit measuring device)

A method for gathering data
26-1 *5, **26-2** *5, **26-3** *5 (A Method relating to assisting devices)

*1 Explanation is provided in Section (2-2-1) of this article.
*2 Explanation is provided in Section (2-2-2) of this article.
*3 Explanation is provided in Section (2-2-3) of this article.
*4 Explanation is provided in Section (2-2-4) of this article.
*5 Explanation is provided in Section (2-2-5) of this article.

Shinobu Hirose (Ms., Ph.D.) for Sections 1 and 2;
Patent Attorney of the Patent Division

Norihiro Fukazawa (Mr.) for Section 3;
Patent Attorney of the Patent Division

Court Case Review – Similarity of Combination Marks

Appellant (plaintiff) : Agatha Diffusion (French Corporation)
Appellee (defendant) : A Smart Kabushiki Kaisha (Japanese Corporation)
Case Numbers : Hei-20(Wa) 21018, Tokyo District Court, decided on February 27, 2009
Hei-21(Ne) 10031, IP High Court, decided on October. 13, 2009

1. Introduction

It is sometimes difficult to judge similarity between a combination mark and a one-word mark which includes one element of the combination mark.

Recently, interesting rulings for a trademark infringement case were issued, in which judgments regarding similarity of a combination mark and such a one-word mark made by the Tokyo District Court and its appeal court, i.e. the IP High Court, were different, though both courts followed the same criteria for assessing similarity of a combination mark shown in a precedent of the Supreme Court.

2. Background

The plaintiff, Agatha Diffusion established in 1974 in Paris, produces and sells jewelry, personal ornaments, and so on. Agatha Diffusion has a trademark right for "AGATHA" (see below) (hereinafter "Plaintiff's Mark" or "Appellant's Mark") in Classes 6, 14 and 26 for "buckles, jewelry, personal ornaments or accessories, and so on".

AGATHA

The defendant, A SMART K.K. (hereinafter "A SMART"), is an importer and seller of jewelry, personal ornaments and so on. In 2006 or earlier, A SMART opened a website, whose URL was www.agathanaomi.com. On the website, they started selling and advertising their goods, displaying the following marks (see below) (hereinafter collectively "Defendant's Marks" or "Appellee's Marks").

Defendant's Marks:

1. Agatha Naomi
2. Agatha Naomi
3. Agatha Naomi
4. Agatha Naomi
5. Agatha Naomi

Agatha Diffusion filed a lawsuit with the Tokyo District Court, claiming infringement of their trademark right for Plaintiff's Mark against the A SMART's use of Defendant's Marks.

3. Judgment made by the Tokyo District Court on February 27, 2009

In ruling, the Tokyo District Court cited a precedent, the 2008 judgment of the Second Petty Bench of the Supreme Court in Case No. Hei-19(Gyo-hi) 223, September 8, 2008, "TSUTSUMINOOHINAKKO-YA in Hiragana" ("つつみのおひなっこや") vs. "TSUTSUMI in Hiragana" ("つつみ") and "TSUTSUMI in Chinese Characters" ("堤").

In the cited case, the following criteria of judging trademark similarity were introduced.

> "In principle, a mark composed of inseparable series of letters should be recognized as an inseparable single unit when judging similarity of marks. It is not acceptable to compare only some part of a combination mark with a mark in question. Only when a certain portion of the combination mark provides a strong impression and dominant to serve as a source indicator of goods or services among traders and consumers, or when any sound or idea that can identify the origin of goods/services does not arise from the other part of the combination mark, and so on, it is allowed to divide

the combination mark when judging similarity of marks."

The Supreme Court held that, although the plaintiff's mark contained "TSUTSUMI" as part thereof, the "TSUTSUMI" portion was not so impressive or dominant enough to serve as a goods-source identifier, and added that the remaining part could possibly function as a source indicator. The Supreme Court thus determined that the plaintiff's combination mark "TSUTSUMINOOHINAKKOYA" should be treated as an inseparable single unit, and therefore was not similar to the defendant's mark "TSUTSUMI". The court concluded that the plaintiff's mark should not have been invalidated and the case has been remanded back to the IP High Court, whose decision is to be made in due course.

Following the above criteria of the precedent shown by the Supreme Court, the Tokyo District Court stated that Defendant's Marks "Agatha Naomi" were written in a unified form (in view of the size/style of the letters, color, etc.) and thus should naturally be read through as a single term. Further, like Agatha Christie, "Agatha Naomi" would be recognized as a name of a woman. Also, the Tokyo District Court did not accept from the evidence the Agatha Diffusion's assertion that "AGATHA" was well-known as their abbreviated name and their house-mark among consumers, and held that the part "AGATHA" of Defendant's Marks would not give a strong impression nor be dominant as an indication of source of the goods to traders and consumers. In addition, the Tokyo District Court added that since "Naomi" is a woman's name, it was not possible to accept that any sound or idea that could identify the origin of goods/services did not arise from the part "Naomi" of Defendant's Marks.

Thus, the Tokyo District Court held that Defendant's Marks "Agatha Naomi" should be recognized as a single unit as a whole and they were not similar to Plaintiff's Mark "AGATHA", and rejected all of the Agatha Diffusion's assertions claiming the defendant's trademark infringement.

4. Judgment made by the IP High Court on October 13, 2009

Agatha Diffusion appealed to the IP High Court, asserting that, since Appellee's Marks were composed of two separable parts "Agatha" and "Naomi" in terms of appearance, sound and idea, they should not be regarded as "a single unit". Agatha Diffusion added that, since "AGATHA" was well-known for "personal ornaments" among Japanese consumers, the part "Agatha" of Appellee's Marks would give a strong impression and be dominant, and thus the part should be regarded as the main part of Appellee's Marks.

The IP High Court cited almost the same criteria of judging similarity of combination marks as shown in the above Supreme Court case and other Supreme Court cases. The IP High Court explained their similarity assessment criteria as follows:

> "In principle, a combination mark should be recognized as an inseparable single unit when judging similarity of marks, if the constituent elements are so well integrated that it is unnatural to separately observe one or more elements away from the other elements in trade. It is not acceptable to compare only some part of such a combination mark with a mark in question. Only when a certain portion of the combination mark provides a strong impression and dominant to serve as a source indicator of goods or services among traders and consumers, or when any sound or idea that can identify the source of goods/services does not arise from the other part of the combination mark, and so on, it is allowed to divide the combination mark when judging similarity of marks."

In view of the number of Agatha Diffusion's shops, advertisement on magazines, sales volumes of their products and so on in Japan*, the IP High Court accepted that "AGATHA" had already obtained a wide recognition as an abbreviated trade name of Agatha Diffusion and also as a well-known trademark for "personal ornaments" among Japanese consumers and traders before A SMART started using Appellee's Marks in October, 2006.

* The appellant had sold their products in Japan at their 25 shops operated in department stores since 1989 and had 280 shops worldwide. Sales of accessories and jewelry bearing "AGATHA" were 1.3 to 1.4 billion per year from 2006 to 2008 on the basis of wholesale price.

In accordance with the above criteria, the IP High Court judged that Appellee's Marks were confusingly similar to Appellant's Mark, showing the following reasons.

— The first letter of each element "Agatha" and "Naomi" of

Appellee's Marks are represented in capital letters and there is a space between the two elements "Agatha" and "Naomi". These elements of Appellee's Marks are therefore not combined closely enough to say that it is unnatural to separate the part "Agatha" from the other part in trade.

— In view of the fact that "AGATHA" has obtained a wide recognition for "personal ornaments" and is considered to give a strong impression and dominant as a source indicator of goods, the sound and idea of "Agatha" would arise from Appellee's Marks in addition to the sound and idea arising from the entire Appellee's Marks.

Accordingly, the IP High Court concluded that A SMART's use of Appellee's Marks constituted infringement of the Agatha Diffusion's trademark right for Appellant's Mark and thus overturned the decision of the Tokyo District Court.

Emi Aoshima (Ms);
Patent & Trademark Attorney of the
Trademark & Design Division

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