

## Protection for Medical-Related Inventions in Japan

Japan has the second largest medical market in the world. For instance, there has been active development in recent years concerning regenerative medical technology utilizing iPS cells. We provide an outline of the characteristics of medical-related inventions which can be protected under Japanese Patent Law.

1. Scope of protection of medical-related inventions from the standpoint of “industrially applicable inventions” which is a requirement for statutory inventions

1.1 Methods of surgery, therapy or diagnosis of humans

The Japanese Patent Office (JPO) Examination Guidelines does not regard the following to be “industrially applicable inventions”.

*Methods of surgery, therapy or diagnosis of humans have been termed “medical activity” and are normally practiced by medical doctors (including those who are directed by medical doctors, hereinafter referred to as “medical doctors”).*

*Even if methods of surgery, therapy of diagnosis are practiced on animal bodies in general, unless it is clear that the methods practiced on a human body are explicitly excluded, the methods are deemed as being “methods of surgery, therapy of diagnosis of humans”.*

As shown above, if it is clear that the methods are not practiced on a human body, methods of surgery, therapy or diagnosis can be protected under Japanese Patent Law.

In addition, the following court decision asserts that diagnostic methods practiced on humans are not identified as patentable subject matter protected under Japanese Patent Law. The Tokyo District Court (Case No. Hei 12 (Gyo-ke)-65) in 2003 stated that:

*It is rational to think it to be inconsistent to consider only medical activities as not being patentable while medical devices and medicinal substances are found to be patentable.*

*However, there is an important difference between medicinal substances or medical devices as compared to medical activities themselves.*

*Even though medicines or medical devices are patentable subject matter, when doctors try to practice medicine by operating a medical device or applying a medicine, they are able to do so without concern as to whether this medical device or medicine is the subject of patent*

*protection even if it is protectable.*

*Under a system which accepts medical activities as patentable subject matter, there is the possibility that doctors would be concerned that the medical activities they are attempting to carry out are the subject of patent protection. It must be considered that a system which results in such a situation is grossly inexpedient from the viewpoint of the nature of medical activities in and of themselves. Therefore, it is rational that the Japanese patent system does not accept such circumstances.*

*Unless Japanese Patent Law provides measures for avoiding such situations, interpreting inventions relating to medical activities as not being industrially applicable is the only thing that can be done.*

## 1.2 Methods for treating samples that have been extracted from the human body

Regarding “industrially applicable inventions”, the Examination Guidelines also mention the following with regard to methods for treating samples that have been extracted from the human body.

*Methods for treating samples that have been extracted from the human body (e.g., blood, urine, skin, hair, cells or tissue) and methods for gathering data by analyzing such samples are not considered to be “methods of surgery, therapy or diagnosis of humans”.*

*However, if a method for treating these samples or analyzing the samples in the process is performed on the presumption that the samples are to be returned to the same body (e.g., a method of dialyzing blood), then, such a method is qualified to be placed under the category of “methods of surgery, therapy or diagnosis of humans”.*

*Even if a method for treating these samples is performed on the presumption that the samples are to be returned to the same body, the following are not considered to be “methods of surgery, therapy or diagnosis of humans”.*

- (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*
- (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*

*(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*

The above Examination Guidelines become controversial when materials for regenerative medicine are utilized. Even though abstract exemplifications are provided in the Examination Guidelines, the border is still unclear as to which cases are judged as being “methods of surgery, therapy or diagnosis of humans” and which are not.

### 1.3 Other

Medical devices, medicinal substances, methods for operating medical devices, etc. do not correspond to “methods of surgery, therapy or diagnosis of humans”, and can be considered as patentable subject matter protectable under Japanese Patent Law.

Furthermore, the stipulation below was added to the revised Examination Guidelines of 2009.

*The following methods for gathering various kinds of information by, e.g., measuring structures and functions of the various organs of the human body, are not considered to be methods of diagnosis of humans unless they include the steps of judging, for 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.*

For example, a method for capturing an image of a lung by radiation of X-rays on the chest can be protected under Japanese Patent Law.

## 2. Scope of protection of medical-related inventions from the standpoint of inventive step

A separate set of Examination Guidelines is provided for medicinal inventions. The revised Examination Guidelines of 2009 prescribe a medicine characterized by a medicinal use of applying the medicine to a specific disease where the dosage and manner of administration are specified, as follows.

*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.*

When an advantageous effect is produced by a dosage using a new manner of administration, it is considered to involve an inventive step, and can be protected under Japanese Patent Law.