

JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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May 9, 2014

The Honorable Michelle K. Lee
Deputy Under Secretary of Commerce for Intellectual Property and
Deputy Director of the United States Patent and Trademark Office
United States Patent and Trademark Office
Alexandria, Virginia

Re: JIPA Comments on the "Guidance For Determining Subject Matter Eligibility of Claims
Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products"

Dear Deputy Under Secretary Lee:

We, the Japan Intellectual Property Association, are a private user organization established in Japan in 1938 for the purpose of promoting intellectual property protection, with about 900 major Japanese companies as members. When appropriate opportunities arise, we offer our opinions on the intellectual property systems of other countries and make recommendations for more effective implementation of the systems. (<http://www.jipa.or.jp/english/index.html>)

Having learned that the "Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products", published by the United States Patent and Trademark Office (USPTO) in the Federal Register, Vol.79, No.74, on April 17, 2014. We would like to offer our opinions as follows. Your consideration on our opinions would be greatly appreciated.

JIPA again thanks the USPTO for this opportunity to provide these comments and welcomes any questions on them.

Sincerely, yours,

(Hiroshi MORITA)

Managing Director

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JAPAN

**JIPA Comments on the “Guidance For Determining Subject Matter Eligibility of Claims
Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products”**

Japan Intellectual Property Association

JIPA has closely and carefully examined the proposed changes, publicized in the Federal Register issued by the United States Patent and Trademark Office (USPTO) as of April 17, 2014, under the title of “Guidance For Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products”. JIPA hereby presents its comments on the proposed changes.

1. Our concern on the guidance

- (1) We understand that the guidance was prepared in view of recent court decisions including *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012). We feel, however, that a scope of the guidance is obviously beyond the range of those decisions. If the guidance is applied as it is, we are convinced that an incentive to create an invention would be lowered significantly in pharmaceutical and biotechnology areas in which chemical compounds useful as a medicine have been found from natural sources and they have contributed to a life science. We also think that company's activities with a huge investment would not be protected by a patent and therefore it would affect business of many companies significantly.
- (2) If the guidance is applied, there is a possibility that existing patents for the chemical compounds could be invalidated. It is also unclear how to handle if an existence of the chemical compound has been found in nature after a patent issuance. Those situations may damage a legal stability of patent rights and also lead unexpected disputes.
- (3) If the guidance is applied, in efforts to harmonization of patent system in some countries including the United States, it obviously means that only the United States introduces a special eligibility criteria and it is contrary to the international trend of intellectual property protection.

2. Requirement on the guidance from JIPA

- (1) We strongly require that a new guidance would be applied to only technologies which have been determined that there is no eligibility in the above mentioned decisions. We suggest, that is, in addition to an abstract idea which has been determined that there is no eligibility conventionally, only a naturally occurring genomic DNA and a process reciting a law of nature would be described in the guidance and other case studies would be excluded from the guidance.
- (2) We suggest that at least case studies B, D and E are excluded from the guidance. For example, like case B Claim 2, even if a compound is not derived from a natural resource, it may exist in the natural resource functionally or accidentally. We require that the guidance would not be applied to such compound strictly.

(3) Considering the above mentioned (2), we strongly expect that the following inventions would be determined to be eligible.

(i) Product:

① Novel compound isolated from a natural resource:

For example, we cannot predict whether or not an antibiotic derived from a microorganism exists in nature in advance. We require that it is determined to be eligible.

② Antibody:

An antibody has a specific structure and a reaction specificity individually, and an option of its amino acid sequence is countless. Therefore, it is difficult to prove whether or not an antibody produced artificially is structurally different from an antibody existing in nature. We expect that it is determined to be eligible.

③ Vaccine:

Since vaccine such as attenuated vaccine, inactivated vaccine which is useful in pandemic, etc. does not exist in nature. we require that it is determined to be eligible.

④ Antisense DNA and siRNA:

Since useful siRNA, etc. can be selected after synthesizing many sequences with different lengths and conducting gene walk experiment, we expect that it is determined to be synthesized compound even if there is a possibility that siRNA with the same sequence and length may exist in nature. Therefore, case study E may be excluded from the guidance.

⑤ Food composition:

A health food composition containing lactic acid bacteria is produced by combining specific components in a specific ratio. Such artificially combined food composition does not exist in nature and is determined to be eligible. We expect to exclude case study D from the guidance.

⑥ Product-by-Process:

In a biotechnology area, there is a novel substance which is difficult to be defined in a structure. In such a case, we need to use a product-by-process claim. We are convinced that it is eligible considering Factors a)-f).

(ii) Laws of Natural:

① Treatment method including a diagnostic method:

A new useful treatment method can be created by combining a measurement of a biomarker existing in a body. Such a treatment method would be useful to patients having specific SNPs. Therefore, we expect that a treatment method including a diagnostic method is determined to be eligible.

(EOD)