JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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March 11, 2015

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 "2014 Interim Guidance on Patent Subject Matter Eligibility"

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 "2014 Interim Guidance on Patent Subject Matter Eligibility", published by the United States Patent and Trademark Office (USPTO) in the Federal Register, Vol.79, No.241, on December 16, 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,

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JIPA Comments on the "2014 Interim Guidance on Patent Subject Matter Eligibility"

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 December 16, 2014, under the title of "2014 Interim Guidance on Patent Subject Matter Eligibility". JIPA hereby presents its comments on the proposed changes.

1. Concerns about the Guidance

We understand that this guidance supplements the "June 2014 Preliminary Instructions" dated June 25, 2014 and replaces the "2014 Procedure For Subject Matter Eligibility Analysis Of Claims Reciting Or Involving Laws Of Nature/Natural Principles, Natural Phenomena, to be intended to And/Or Natural Products" dated March 4, 2014. However, we believe that the scope of this guidance is still beyond the scope pointed out by the Supreme Court decisions on Myriad (Association for Molecular Pathology v. Myriad Genetics, Inc., 569 US _, 133 S. Ct. 2107 (2013)) and Mayo (Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 US _, 132 S. Ct. 1289 (2012)) and other existing Supreme Court decisions. In addition, we believe that the specific determination approach involves unclear parts in two-step analysis. Therefore, we request you to clarify the following points.

2. JIPA's requests for the Guidance

(1) Two-part analysis for judicial exceptions:

With regard to the method for comparing the claimed invention and its naturally occurring counterpart in step 2A (Section IA3.a and Example 3-4), it is provided that when the claimed invention is compared to its naturally occurring counterpart to determine whether the claimed invention has markedly different characteristics from its naturally occurring counterpart, if there is no naturally occurring counterpart to the claimed invention, the comparison should be made to the closest naturally occurring counterpart.

However, for example, when the invention relates to an antibiotic purified from a microorganism, the applicant does not know what structure the antibiotic has in the microorganism. Example 3 is created on the assumption that the purified amazonic acid is the same in structure as the amazonic acid in the amazonian cherry tree, whereas Example 4 is created on the assumption that the purified Antibiotic L is different in structure from the naturally occurring Antibiotic L. However, we believe that there may be cases where the applicant and the examiner do not know whether the purified antibiotic maintains the same

structure as in the microorganism. Besides, there may be cases where there is no natural product having a similar structure, and in such cases it would be difficult for the applicant and the examiner to compare the claimed invention and its naturally occurring counterpart. We request you to clarify how the examiner can determine whether the claimed invention has markedly different characteristics in the above-mentioned cases.

(2) Examples directed to nature-based products:

The end of the decision of the Supreme Court on Myriad recites "We merely hold that genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material." From this recitation, we consider, with respect to inventions relating to natural products, that the decision of the Supreme Court on Myriad should not be applied to any inventions other than those relating to genes and the information they encode. 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. Therefore, We propose that Example 3 (isolated material from a natural product such as amazonic acid), Example 4 (purified proteins), Example 8 (antibodies), and Example 9 (cells), whose patent eligibility is not addressed in any of the decisions on Myriad and Mayo and other existing Supreme Court decisions, should be modified to cases where patent eligibility is accepted . Alternatively, we propose that at least the following points should be clarified.

(i) Example 3 directed to amazonic acid, etc.:

This case is not related to DNA or the proteins encoded thereby, and we think that Supreme Court decision on Myriad should not be applied thereto. Therefore, we consider that the patent eligibility of "Purified amazonic acid" of claim 1 should be accepted.

(ii) Example 4 directed to purified proteins:

For this Example, the patent eligibility of claim 3 directed to the "tetrahedral crystal form" is accepted. However, it can be assumed that the tetrahedral crystal form is found naturally occurring for the first time after the patent right was registered. In such a case, if the patent is invalidated after the registration of the patent right, it would significantly impair the stability of the right. Therefore, we consider that the approach of comparing the nature-based product in the claim and its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/or properties to determine the patent eligibility is not appropriate from the viewpoint of the stability of rights.

(iii) Example 6 directed to bacterial mixtures:

Analysis of claims (claim 2) in Example 6 recites "Note that unless the examiner can show that this particular mixture of bacteria exists in nature, this mere possibility does not

bar the eligibility of this claim." However, we believe that the information which the examiner can know at the examination stage may be limited, and therefore that problems with the stability of rights might be caused when such an interpretation is made. Accordingly, as for Example 4, we consider that the approach of comparing the nature-based product in the claim and its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/or properties to determine the patent eligibility is not appropriate from the viewpoint of the stability of rights.

(iv) Example 7 directed to nucleic acids:

We propose that in order to clarify the results of the decision Supreme Court on Myriad, it should be made clear that claim 1 directed to cDNA having the nucleotide sequence of SEQ ID NO:1 has patent eligibility. Furthermore, when the amino acid sequence of Protein W in Example 7 is assumed to be SEQ ID NO:2, we consider that the patent eligibility of cDNA claims specified by SEQ ID NO:2 should also be accepted. Therefore, we propose that the following claims should be added as claims having patent eligibility in Example 7.

1. cDNA encoding a polypeptide having the amino acid sequence represented by SEQ ID NO:2.

2. The cDNA of claim 1, having SEQ ID NO:1.

In addition, the Myriad Supreme Court decision recites, in line 14 on p. 3, "DNA's informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells." In view of this recitation, we consider that the Supreme Court decision on Myriad only discusses a "region of the genome that encodes a protein (protein-coding ORF) or a nucleotide sequence comprising the region" among genes and is silent on other regions (e.g., a non-coding region, part of the protein-coding ORF). Therefore, we consider that patent eligibility should be accepted for an invention relating to a nucleic acid which itself exhibits a function, namely a nucleic acid having a function other than the amino acid sequence information of a protein (e.g., antisense DNA, siRNA, miRNA, pair of primers, other ones which will be discovered in the future) by specifying the nucleotide sequence (by distinguishing it from the amino acid sequence information of the protein) regardless of the sequence being inside or outside of the ORF.

(v) Example 8 directed to antibodies:

Note that the patent eligibility of an antibody or a monoclonal antibody specified by an epitope is not addressed. We consider that it should be made clear that as is the CDR-specific antibody set forth in claim 3 of Example 8, the patent eligibility of such antibodies is accepted unless the examiner can prove that the antibodies are naturally occurring.

(vi) Example 9 directed to cells:

Pharmaceutical and biotechnology companies have aggressively pursued the development of vaccines against neglected diseases in emerging countries. In order to protect the health of patients in the emerging countries, such vaccines should be protected by patents to maintain an incentive for the pharmaceutical and biotechnology companies. Therefore, we propose that a case relating to a vaccine should be added.

Specifically, vaccines include live vaccines, inactivated vaccines, and toxoids and all of these are different at least in function from naturally occurring pathogens. Therefore, we consider that the patent eligibility of these vaccines should be accepted even if this Guidance is maintained.

(EOD)