

JAPAN INTELLECTUAL PROPERTY ASSOCIATION

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July 15, 2016

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

Re: JIPA Comments on the "May 2016 Subject Matter Eligibility Update"

Dear 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 940 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.

We were pleased to learn the "May 2016 Subject Matter Eligibility Update", published by the United States Patent and Trademark Office (USPTO) in the Federal Register, Vol.81, No.88, on Friday, May 6, 2016. 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,

(Hirotugu TAKAYAMA)

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JIPA Comments on the “May 2016 Subject Matter Eligibility Update”

JIPA has closely and carefully examined the "Subject Matter Eligibility Examples: Life Science" and "Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection" of "May 2016 Subject Matter Eligibility Update", publicized in the Federal Register issued by the United States Patent and Trademark Office (USPTO) as of May 6, 2016. JIPA hereby presents its comments on the proposed changes.

I. Subject Matter Eligibility Examples: Life Science

1. Example 28: Vaccines

Regarding Claim 3 which is ineligible, we suggest to describe in the end of explanation that if the claim 3 is amended to a process of practically applying the product to treat a particular disease, it will be eligible as described in Claims 7 and 8 of Example 3: Amazonic Acid, Pharmaceutical Compositions, & Method of Treatment of "Nature-Based Products" published on December 16, 2014.

2. Example 29: Diagnosing and Treating Julitis

Regarding Claim 2 which is ineligible, we suggest to describe in the end of explanation that if "anti-JUL-1 antibody" of Claim 2 is amended to "anti-JUL-1 antibody other than an anti-JUL-1 antibody of the human patient" or "non-human anti-JUL-1 antibody", the Claim 2 will be eligible because the Claim 2 does not include a naturally occurring antibody anymore.

II. Formulating a Subject Matter Eligibility Rejection and Evaluating the Applicant's Response to a Subject Matter Eligibility Rejection

Section B. When making a rejection, explain why the additional claim elements do not result in the claim as a whole amounting to significantly more than the judicial exception (Step 2B)

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We suggest that the USPTO show examples regarding the additional elements both individually and as a combination when the Examiner determines whether the claim as whole recites eligible subject matter. Furthermore, we hope that a 101 rejection is determined after the all Examiner are trained about the guidance very well.

However, the guidance issued in May 2016 recites Diehr decision, it seems that the Examiner does not know whether a new combination of steps in a process is patent eligible even though all the steps of the combination were individually well known and in common use before the combination was made without the above decision.

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The guidance recites, "A prior art search should not be necessary to resolve whether the additional element is a well-understood, routine, conventional activity" and then, "the

examiner should provide a reasoned explanation that supports that conclusion."

However, we worry that "a reasoned explanation that supports that conclusion" becomes vague. Thus, we suggest that USPTO make concrete examples in training material for the Examiner or eliminate "A prior art search should not be necessary to resolve whether the additional element is a well-understood, routine, conventional activity."

In Japanese Examination Guideline, procedure about well-known art will be defined as below:

"When the examiner cites well-known art or commonly used art for the reasoning in the notice of reason for refusal or decision of refusal, he/she should show their evidence except that no example is required" (Part III Chapter 2 Section 3 Procedure of Determining Novelty and Inventive Step, Examination Guidelines for Patent and Utility Model in Japan)

(http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/1312-002_e.htm)

(EOD)