



16 March 2015

Comments On “2014 Interim Guidance on Patent Subject Matter Eligibility”

Japan Pharmaceutical Manufacturers Association (JPMA) is a voluntary organization established in 1968, and represents the R&D-oriented pharmaceutical companies in Japan. Counting about 72 leading R&D-oriented pharmaceutical companies as members (as of July, 2014), the JPMA is devoted to contribute to the promotion of health and welfare in the global population through development of innovative medicines prescribed in medical facilities including hospitals and clinics.

The Intellectual Property Committee of JPMA submits recommendations and proposals to the relevant authorities and organizations with regard to the establishment and improvement of intellectual property systems for the pharmaceutical industry.

As for your invitation for the public to comment on “2014 Interim Guidance on Patent Subject Matter Eligibility”, we submit our comments especially on the important issues for JPMA’s member companies. Your deep consideration on these matters would be appreciated.

Very truly yours,

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JPMA'S comments on Draft "2014 Interim Guidance on Patent Subject Matter Eligibility"

We would like to submit our opinions relating to the USPTO's guidance memorandum released on December 16, 2014.

We take objection to expand the Supreme Court *Myriad* decision into chemicals derived from natural sources, especially, small molecule compounds purified or isolated from plant, microbial or animal, as stated in our previous comments on draft "Guidance for Determining Subject Matter Eligibility of Claims Reciting or Involving Laws of Nature, Natural Phenomena, & Natural Products".

Example 3 "Amazonic Acid, Pharmaceutical Composition & Method of Treatment" concerns chemical substances purified from nature, and claim 1, "purified amazonic acid" is concluded not to qualify as eligible subject matter as the same as Example B of the previous guidance.

However, compound claim for a new small molecule compound which was found to be produced through fermentation by naturally-occurring microorganism has been granted in major jurisdictions including U.S. for a long period of time, and we believe that such new small molecule compound (fermentation product) should continue to be eligible for granting patent.

Such new small molecule compound is produced through fermentation by a microorganism in artificial culture medium, and it is not produced depending on fermentation condition. Accordingly, nobody knows whether the microorganism that exists in nature state (for example, in the earth) produces the compound or not.

It would be unfair if an applicant for patent application relating to fermentation product is required to prove that a claimed compound is not produced by a microorganism in nature state or that the claimed compound is structurally different from a compound produced by the microorganism in nature state. We believe that examiner should not refuse eligibility unless the examiner shows that the compound is produced by the microorganism in nature state.

To summarize, we strongly request not to apply Example 3 easily to new small molecule compounds which were found to be produced through microbial fermentation, and request to continue to grant compound claims for such fermentation products.