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Comments On “Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products”

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 April, 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 “Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products”, 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 “Guidance for Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products”**

We would like to submit our opinions relating to the USPTO’s guidance memorandum released on March 14 and training slides released on March 19.

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.

Although the Supreme Court *Myriad* decision was limited to human DNA sequences and the USPTO’s initial guidance in the wake of *Myriad* was limited to “naturally occurring nucleic acids or fragments thereof,” the draft guidance have an expansive reach and include claims reciting: “chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature” . . . “regardless of whether particular words (e.g., "isolated", "recombinant", or "synthetic") are recited in the claim”.(see page 3)

Example B of the draft guidance (see page 7) concerns chemical substances purified from nature, and claim 1, “purified amazonic acid” is concluded not to qualify as eligible subject matter. Similar example, “purified 2-methyl-2-pentenoic acid” is introduced in pages 41-42 in Training Slides.

On the other hand, 59 new chemical entities were approved by the FDA as new drug from 1981 to 2010. (David J. Newman and Gordon M. Cragg, “Natural Products as Sources of New Drugs over the 30 Years from 1981 to 2010”, *Journal of Natural Products*, 2012; 75(3), 311-35) Accordingly, change of patent eligibility of such compounds purified from natural source has great influence in pharmaceutical industries.

Assuming that the Supreme Court *Myriad* decision is applicable to isolated naturally occurring compounds other than DNA, *Myriad* can still be interpreted to mean that such compounds are patent eligible if the inventors reveal some characteristic distinguishing them from their natural counterparts, thereby demonstrating a “new and useful . . . composition of matter.”

We strongly request your reconsideration regarding expansion of the Supreme Court *Myriad* decision into chemicals derived from natural sources.