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VIA E-MAIL: myriad-mayo_2014@uspto.gov
The Hon. Michelle K. Lee
Deputy Under Secretary of Commerce
Acting Director
U.S. Patent and Trademark Office
P.O. Box 1450
Alexandria, VA 22313-1450

RE: Comments on Guidance For Determining Subject Matter Eligibility of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products

Gearhart Law LLC respectfully request consideration of the following points when reviewing the Guidance issued on March 4, 2014.

We are concerned about the Guidance to prevent patenting useful, important and lifesaving technologies in the United States and its impact ultimately leading to industries moving overseas. It is our opinion that the Guidance reaches far beyond what the Supreme Court has ruled in cases addressing the subject matter eligibility.

We address here two major flaws in the Guidance:

1. The Guidance instructs the Examiners to review subject matter eligibility based on separate elements in the claims rather than 'as whole'.
2. The Guidance allows the Examiners to include novelty, and obviousness issues in determining the subject matter eligibility.

1. Subject matter eligibility is to be determined by considering the claim as whole.

The Supreme Court has clearly determined in *Diamond v. Diehr*, 101 S.Ct. 1048, 1057-58 (1981) that, “In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole.” The guidance fails to respect this principle.

The Guidance provides a three step process to evaluate patent eligibility. The first step requires determination of whether the claim fall under one of the four patentable subject matter categories. If the claim is toward a process a machine, a manufacture, or a composition of matter, the Guidance instruct to proceed to question two.

Question 2 asks: “Does the claim **recite or involve** one or more judicial exceptions?” By using the verb ‘recite or involve’ this steps instructs to pick any element from the claim that would alone fall under a judicial exception. The Guidance provides the following claim as an example:

“A fountain-style firework comprising: (a) a sparking composition, (b) calcium chloride, (c) gunpowder, (d) a cardboard body having a first compartment containing the sparking composition and the calcium chloride and a second compartment containing the gunpowder, and (e) a plastic ignition fuse having one end extending into the second compartment and the other end extending out of the cardboard body.”

Under the Guidance this claim has to be further analyzed under the twelve step assessment in step three, because calcium chloride and gunpowder (when given its broadest interpretation) are natural products.

It seems to us that under this Guidance claims cannot be considered as whole but rather they are dissected into elements and then subjected to the twelve step analysis. Moreover, giving an example where gunpowder is analyzed as being a natural product (because it is may be combination of three natural elements), indicates that almost anything when given its broadest interpretation may be a natural product. Thus not only does the Guidance instruct the Examiner to dissect the claim into its elements and consider the elements (as opposed to the claim as whole), but the Guidance also instructs the Examiner to dissect compositions into their ingredient components and consider those ingredients without seeing that the composition has features different from any of its components (none of the components of gunpowder alone have the explosive features such as gunpowder has). Following this rationale, one can dissect almost anything to involve products of nature, because everything is made of a handful of atoms. The cardboard of the claim has carbon, hydrogen and oxygen atoms. Why the cardboard isn't similarly a product of nature as is the gunpowder?

In order to improve the Guidance, we suggest that instead of asking whether the claims recites or involves one or more judicial exceptions, the question should be whether

the claim as whole recites a judicial exception. In the exemplary claim above, the claim is toward a fountain –style firework, which cannot be deemed to fall under judicial exception. When the claim as whole recites something else than a judicial exception it should be deemed to be patent eligible under 101.

2. Determination of patent eligibility under section 101 is separate from section 102 novelty determination or section 103 obviousness determination.

The Guidance instructs the Examiners to complete the 101 –evaluation by a twelve step analysis to determine if the claim as a whole recites something significantly different than the judicial exception.

Step f) and j) instructs an evaluation as to whether the claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is **more than well-understood, purely conventional or routine in the relevant field.**

It is our opinion and experience that this step brings 102- and 103- issues in patent eligibility determination. A 101-determination should not be made over prior existing art. Prior art is applied when determining novelty and obviousness.

It should also be noted that a skilled artisan in certain areas, such a biotechnology and medicine, are highly educated. Therefore extremely complicated methods may be well understood or routine in that field. If such issues become determinative in subject matter eligibility evaluation, this leads to 101-rejection of claims in the first office action without proper search.

In conclusion, Gearhart Law urges the USPTO to revise the guidance and respect the Supreme Court’s decisions.

Respectfully submitted by;

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