

July 30, 2014

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Commissioner for Patents
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Re: Comments Regarding Guidance for Determining Subject Matter Eligibility of Claims
Reciting or Involving Laws of Nature, Natural Phenomena and Natural Products

Dear Commissioner:

Thank you for the opportunity to provide comments on this matter. I have the following comments.

First, it does not appear that there has been any basic change in the law regarding eligibility of laws of nature, natural phenomena and natural products. In both recent decisions, the Court has made clear that the rule against patents on naturally occurring things is "not without limits," because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena or abstract ideas" and "too broad an interpretation of this exclusionary principle could eviscerate patent law." "As we have recognized before, patent protection strikes a delicate balance between creating incentives that lead to creation, invention and discovery" and "impeding the flow of information that might permit, indeed spur, invention." This is a standard enunciated by the Decision in *Myriad* and was a quote from the Decision in *Prometheus*.

Thus, the fundamental premise on which the Guidelines are based — that the basic law relating to this type of subject matter has changed — is essentially incorrect. What the Supreme Court has done is to apply this general principle to two very specific situations which are based on unique sets of facts. There is no need to extrapolate the decisions based on these specific facts to a broader range of possibilities.

The *Prometheus* Decision evaluated the patent eligibility of assigning specific numbers to tests that were already performed in the prior art where the sole invention was assigning these numbers. Thus, there was no distinction over the prior art other than assigning numbers to activities that were already conducted by practitioners. Clearly the numbers were an abstract idea. In *Myriad*, the holding was limited to claims directed simply to "isolated genes" or portions of genes where the point of the isolation was to determine the information contained therein. The Court itself said "It is important to note what is not implicated by this decision." Leaving aside the somewhat

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peculiar distinction made between cDNA and isolated DNA that includes introns (obtaining both involves manipulations which create something new since the gene does not exist isolated in nature) the issue in *Myriad* was whether the information value of the gene was altered by breaking the two bonds that result in its isolation from its normal environment. As stated in the Opinion,

The claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended on the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. The claim is concerned primarily with the information contained in the genetic sequence, not with a specific chemical composition of a particular molecule.
(emphasis added)

This is an important reason the Decision in *Myriad* is limited to genes and nucleic acids. The Decision is based on the concept that it is the information contained in the molecule that is important whether it is isolated or not. The same thing cannot be said for proteins, antibiotics, or anticancer agents that occur in nature, or antibodies. In these cases, the isolation is directed to obtaining the molecule itself and putting it in a position for being used in a practical manner.

Of course, one might be able to claim, for example, a pharmaceutical composition comprising the naturally occurring anticancer agent or the antibody that has been isolated from, for example, a human source. It is hoped that the Guidelines will make clear that at least this would be sufficient. There is simply no analogy between the rationale set forth in the Opinion in support of the holding in *Myriad* with respect to anything other than nucleic acids.

The delicate balancing referred to in both decisions should surely be such that the balance would encourage placing natural products in contexts that are useful whereas previously they were not.

With regard to the factors presently in the Guidelines, I would change (a) to delete "in structure" — context is all important. This is particularly apparent in Example C. The implication that gun powder itself is not patentable because it is a mixture of naturally occurring saltpeter, sulfur and charcoal is clearly at odds with reality. The elements of the composition may be as they occur in nature if considered individually, but when placed together they behave in a very different way from the way they behave individually under the relevant conditions. To ignore this simply makes no technical or scientific sense.

Similarly, Example D based on *Funk Bros.* quotes the claim that was considered in the Decision, but overlooks the fact that the claim is entirely generic. It is not at all clear that the Court would have rejected a claim that was specific to the species that were actually in the composition claimed. This is clear from the concurring opinion of Justice Frankfurter. The claim at issue in *Funk Bros.*

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prevented others from finding other species that could be mixed together that were not discovered by the patentee.

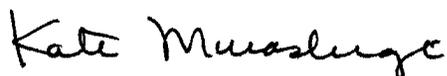
Similarly, claims to isolated antibodies when made specific to the antibody isolated do not prevent others from isolating competing antibodies. Further, claims to homogeneous compositions of monoclonal antibodies do not claim anything that exists in nature, nor do claims to homogeneous compositions of proteins or anticancer agents.

Turning, then, to the *Prometheus* Decision, this, too, should be confined to its facts. At least one issue in the Guidelines as presently drawn is certainly correct — *i.e.*, item (f) — that the claim recites one or more elements/steps in addition in to the judicial exception that add a feature that is more than well understood, purely conventional or routine in the relevant field. This Guideline, however, seems to be misapplied in the sample claim on page 13 of the Guidelines in Example F. As in previous iterations of the Guidelines, this appears to require that the antibody XYZ be included in the claim, when in reality, the non-routine aspect of this claim is assaying for ABC in the first place. This is not routine, unlike the assay for metabolites conducted in *Prometheus*. The claim as presented is not commensurate with the scope to which a patentee should be entitled based on the new and important discovery that one could perform the diagnosis by assaying for ABC. Placing into the art an entirely new activity is itself worthy of protection. This distinguishes a claim for detecting a newly discovered marker from the claims in *Prometheus*. Considering such subject matter outside subject matter eligibility extrapolates the Decision in *Prometheus* way beyond the facts and is clearly an impediment to useful research.

I hope these comments are helpful. The basic point is that the law has not changed — a balance needs to be created between over-excessive claim scope and incentivizing research. Each set of facts needs to be examined based on its own merits. The two recent Decisions in *Prometheus* and *Myriad* relate to highly specific circumstances which have been extrapolated far beyond their metes and bounds by the current Guidelines proposed 4 March 2014 and their examples.

I again wish to point out that the *Funk Bros.*' claim was not specific to what the patentee had accomplished, but rather a generalization of the possibility that some strains of *Rhizobium* could coexist.

Respectfully submitted,



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