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Comments on the Guidance the Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature, Natural Phenomena, & Natural Products

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I have serious concerns about the "Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws Of Nature, Natural Phenomena, & Natural Products" ("Guidance"). The USPTO should proceed with prudence, reconsider its complex rubric, and leave patent eligibility to its traditional role in determining patentability.

The Supreme Court cases on which the Guidance is predicated are narrow decisions based on specific fact patterns. Prudence dictates proceeding with caution. Yet the Guidance goes far beyond what the Supreme Court has decided. It calls into question the patent eligibility of subject matter there is no evidence it was ever the intention of the Supreme Court to withdraw.

Any inquiry into patent eligibility begins with the Supreme Court's statement in *Diamond v. Chakrabarty*: "Congress intended statutory subject matter to 'include anything under the sun that is made by man'". This is a lax standard that is generous in recognizing subject matter eligibility. It is settled that naturally occurring phenomenon are not patent eligible. Beyond this, the Supreme Court has identified only a few narrow exceptions to patent eligibility for compositions containing natural materials. One narrow exception was identified in *AMP v. Myriad*. The Supreme Court said, "We hold nothing more than that DNA isolated from its natural surroundings and claimed based on its information is not patent eligible subject matter." If the Supreme Court holds nothing more, the USPTO should do likewise.

Another narrow exception was identified in *Funk Bros. Seed Co. v. Kalo Inoculant Co*. In holding that an aggregation of naturally occurring bacteria was not patent eligible, the Court stated that the invention was "hardly more than an advance in the packaging of the inoculants" and that "[e]ach species has the same effect it always had". In other words, the composition was essentially the same as something found in nature.

These narrow decisions withdrew very little from the domain of patent eligibility. The USPTO need not extrapolate to withdraw other things which traditionally have been understood to be patent eligible.

- Does the USPTO really mean to suggest that gunpowder, a composition with explosively different properties than its constituents, is not patent eligible subject matter? Shall we

also say that steel is not patent eligible, because it a mixture of two naturally occurring elements, carbon and iron?

- Does the USPTO really mean to suggest that a vaccine, formulated as a medicine that can prevent disease, is not patent eligible because it includes purified, naturally occurring viruses?

- Does the USPTO really mean to suggest that an article of manufacture, by definition the product of the human hand, may not be patentable if it includes naturally occurring materials?

These would be radical conclusions.

The Guidance takes a flawed approach to determining patent eligibility. It asks whether the claim "recites or involves a judicial exception." Many inventions involve, to some extent, a “law of nature” or a “naturally occurring phenomenon”. Attention should be directed to the invention as a whole, not to the invention disassembled into its constituent parts.

Furthermore, the Guidance fundamentally shifts the focus of the patent examination process. Patent eligibility always will be a line drawing problem. Traditionally, this line has favored a finding of patent eligibility. The serious burden of determining patentability has rested with the doctrines of anticipation and obviousness. These doctrines have a long and rich history in the patent law and are well suited to this task. The Guidance turns this practice on its head, essentially presuming an invention to be patent ineligible until proven otherwise. Unfortunately, the body of case law on patent eligibility is not sufficiently deep to provide clear contours of how “significantly different” a composition must be from something that exists in nature to be patent eligible. All we know for sure is that mixtures of bacteria where there is “no enlargement of the range of their utility”, and isolated DNA “claimed based on its information” are not patent eligible. These narrow exceptions do not provide the doctrine of patent eligibility the strength to bear the weight that the USPTO now proposes. It would be wiser to maintain a relaxed standard, and to let the courts or Congress remove items from patent eligibility as the case arises. The USPTO should apply *Myriad* and *Mayo* judiciously, rejecting as patent ineligible only those things unambiguously consistent with those cases.

Finally, I agree with others who have noted that the Guidance puts American patent law outside international standards and threatens national competitiveness. The Guidance may well exceed the USPTO’s authority for rule making. It certainly will be challenged if implemented.

Thank you for your consideration.

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