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Michelle K. Lee,
Deputy Under Secretary of Commerce

Andrew Hirshfeld
Deputy Commissioner for Patent Examination Policy

The United States Patent and Trademark Office
Alexandria, Virginia 22313

Re: Comments on the December 16, 2014 Interim Guidance on Patent Subject Matter Eligibility

Dear Deputy Under Secretary Lee and Deputy Commissioner Hirshfeld:

We submit for your consideration comments directed at the 2014 Interim Guidance on Patent Subject Matter Eligibility, in particular the examination of claims to diagnostic methods.

Numerous organizations and persons have expressed well-founded concerns that both the Supreme Court's opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S.Ct. 1289 (2012) ("*Mayo*") and Patent Office Examination Guidelines based on that opinion will have a significantly negative effect on the future development of diagnostic methods. We discuss here a part of the *Mayo* opinion that affords the Patent Office the flexibility to award a patent to an inventor who discovers a nonobvious diagnostic method of value to the practice of medicine.

The heart of the Prometheus claim was the clause, "wherein the level of 6-thioguanine less than 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject…" 135 S.Ct. at 1295.

The attitude of the Court towards this clause was at best dismissive, describing it as "at most adding a suggestion that [the doctor] should take those laws into account when treating his patient." 135 S.Ct. at 1297. Furthermore, it considered that the clause merely added precision to

the understanding of the prior art that there was a correlation between the level of 6-thioguanine and whether it should continue to be administered to the patient. 132 S. Ct. at 1295.

That the correlation was already generally understood made *Mayo* a poor test case for the many diagnostic method claims where there was no similar understanding in the prior art. That the clause was "at most a suggestion" was an unfortunate phrasing. At the least, the relationship of that criticism to subject matter eligibility is unclear. In any case, a doctor reading the Prometheus claim and patent would know exactly what Prometheus intended and would likely benefit from the precision of the correlation expressed in the clause and the claim. Whether the information expressed was obvious is a question separate from subject matter eligibility.

As a starting point for dealing with the above-noted limitations of *Mayo,* the Office could take a stringent, but rational, view of what the natural law in question is. An example of a natural law is, "In a person with disease Y, there will be an increased level of compound X in the person's blood". This phrasing only talks about what is truly natural – it ignores anything that is done outside the body; e.g. , analysis of blood taken from the person. This phrasing would contrast with the actual patent claim under consideration. Such a claim might, for example, be, "A method of diagnosing disease Y, said method comprising the steps of (1) measuring the level of compound X in a person's blood; (2) measuring that level in a person not having disease Y, and (3) assigning a diagnosis of disease Y to the person of step (1) if the level measured in step (1) exceeds that measured in step (2)." The contrast should make it clear why the claimed invention is significantly more than the natural law itself.

Additionally, the Patent Office could clarify in its guidelines that a diagnostic method that is of significant medical value – and distinct from the natural principle (as stated above) - cannot be refused patentability on the grounds of subject matter eligibility. To clarify that it is not contradicting *Mayo* the Office can require an Examiner to explicitly acknowledge that the method under consideration is not one wherein there is at most a mere suggestion to a doctor but rather is a valuable indication to a doctor that the diagnostic results acquired by the method be considered in future therapeutic steps.

The opinions expressed here are the opinions of the individual authors and may not reflect the opinions of the Firm, any individual attorney of the Firm, or any client of the Firm.

We thank the USPTO for the opportunity to comment on the Interim Guidance.

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