

INSIGHTS

USPTO Preliminary Guidelines Spread Mayo on Patent-Eligibility

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A day after the United States Supreme Court delivered its decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*,¹ the United States Patent and Trademark Office issued preliminary guidance² instructing examiners to reject process claims that invoke laws of nature and only add steps which constitute "well-understood, routine, conventional activity" that is described in the most general of terms regardless of whether there is a transformation involved.

According to the Patent Office, although the "machine or transformation test" remains an "important and useful clue," it is not to be considered "the sole or a determinative test" for eligibility as it does not "trump the 'law of nature' exclusion." Moreover, the *Mayo* decision reinforces the need for a patent applicant whose claims include a law of nature, a natural phenomenon, or an abstract idea to ensure the "claimed product or process amounts to significantly **more than** a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto." (emphasis in original). Although the guidelines put special importance on process claims as were at stake in *Mayo*, the guidelines appear to indicate this analysis may apply to all claims related to laws of nature, natural phenomena, or abstract ideas.

Neither the guidelines nor *Mayo* provide specific guidance for what would make a product or process significantly more than a law of nature, a natural phenomenon, or an abstract idea. Nevertheless, the Patent Office sees the claim at issue in *Mayo* as a prime example of one which merely includes a highly general and conventional step of which patent examiners are expected to be more cautious. As explained in the guidelines, the claims in *Mayo* emphasize the "law of nature" correlation between the concentration of the drug and its threshold limits for therapeutic effects and harmful side effects.

Simply adding the well-understood, routine, conventional actions of administering the drug and checking its blood concentration in the most general of terms, however, does not confer patent eligibility as the claims themselves are "effectively directed to the [law of nature] exception itself." Based on the new guidelines, an examiner confronting a similar claim set is directed to reject the claim as non-statutory subject matter under 35 U.S.C. § 101 (utility or patent-eligibility requirement section). The guidelines do specifically note that the applicant in such a case will then have the opportunity to defend the claim and show why it is not drawn to the patentability exception itself. The applicant will have to rely on other claim limitations to support the argument.

The Patent Office's guidelines suggest that the *Mayo* decision should be viewed as a cautionary tale for applicants who intend to direct claims to inventions which arguably incorporate the use of laws of nature, natural phenomena, or abstract ideas.

Should you have any questions, please contact your Bracewell & Giuliani LLP patent attorneys. We will, of course, keep you advised as to any new developments in this area.

¹No. 10-1150, 566 U.S. ___, 2012 WL 912952 (S. Ct. Mar. 20, 2012) (for a more thorough discussion of *Mayo* and the particular facts and determinations involved, see [Update: Can't Touch This – Supreme Court Finds Personalized Medicine Patent Claims Invalid](#), Bracewell & Giuliani LLP (Mar. 20, 2012).

²See [Memorandum](#): Supreme Court Decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* (Mar. 21, 2012).