USPTO releases new guidelines on subject matter eligibility for patenting: key points to navigate the rules

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The United States Supreme Court’s recent rulings about what constitutes patent-eligible subject matter have raised substantial uncertainty around whether certain inventions are an “abstract idea, law of nature, or natural phenomenon” (tending not to be patentable) or if, as claimed, the invention contains additional (potentially patentable) elements under Section 101 of the Patent Act. The impact of the Court’s Mayo, Myriad and Alice decisions has fallen especially hard on the biomedical and e-commerce industries, with investors raising concerns about the value of patents being pursued in these areas.

To clarify its position on subject matter eligibility for patenting, the United States Patent and Trademark Office (USPTO) released new guidelines on May 5, 2016 to provide instructions for how eligibility will be determined (the Update). The Update represents the USPTO’s response to public comments solicited to understand the issues facing patent applicants attempting to navigate around the Mayo, Myriad and Alice decisions and their seemingly inconsistent application by the agency.
According to the Update, the USPTO’s current test for subject matter eligibility (per the Alice and Mayo rulings as outlined in the agency's prior 2014 Interim Guidance on the topic) will be retained. The test requires a two-step analysis. The Patent Examiner must determine whether a patent claim is (1) directed to an abstract idea, law of nature, or natural phenomenon or other subject matter exempt from patentability; and (2) contains additional elements that, taken either singly or in combination, make the claim “as a whole significantly more” than one directed only to patent-ineligible material.

A clear and thorough articulation of the Examiner’s rationale for rejecting a claim for lacking patent-eligibility must now be provided – preferably one explicitly based on court decisions. The goal is to prevent examiners from rejecting patent claims based solely on an subjective or otherwise abstract characterization of their subject matter.

The Update also outlines what Examiners must prove to reject a patent claim for lacking patent-eligibility. In this regard, Examiners are instructed to (1) identify claim limitations other than those which are drawn to patent-ineligible material (if any); and (2) provide a clear explanation of why all of the claim limitations – taken alone and in combination – do not, as a whole, require significantly more than the patent-ineligible matter to be present in the invention.

As further guidance, the Update offers six different scenarios for how patent eligibility might be considered in the life sciences space. To that end, hypothetical patent claims are provided which are directed to, respectively, diagnosing and treating disease as well as engineering gene sequences.

One example in particular illustrates how difficult the patent-eligibility question remains, notwithstanding the Update. The example suggests that a claim drawn to detecting a biomarker whose presence is correlated with a specific disease will be regarded as presenting patentable subject matter. In contrast, a claim to providing a diagnosis based on the same correlation will not be considered to present patentable subject matter unless additional steps, such as administering a treatment, are recited in the claims.

Technically, the distinction drawn in the above example may be one without a substantial difference. However, from a patenting perspective, the Update provides some additional insight into the wording which the USPTO will require to define patentable subject matter in a patent claim. DLA Piper patent counsel can assist in navigating the Update to present patent claims which have the best chances for allowance. Learn more by contacting either of the authors.

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