July 9, 2012

USPTO Issues Interim Guidance for Subject Matter Eligibility in the Wake of *Prometheus*

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On July 3, 2012, the United States Patent and Trademark Office ("USPTO") issued a 13-page memorandum (hereinafter referred to as "the Memorandum") providing interim guidance to patent examiners in view of the U.S. Supreme Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012) ("*Prometheus*"). The interim guidance, entitled *2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature* (the "Interim Procedure"), provides specific guidance with illustrative examples on how patent examiners should determine whether a process claim involving laws of nature or natural correlations is patent eligible. The Memorandum supersedes the three-page memorandum issued the day after the Supreme Court's decision on *Prometheus*,[1] and is intended to serve as an interim measure while two other cases are being reheard at the Federal Circuit in view of *Prometheus*.[2] A more comprehensive and updated guidance is expected to issue once those cases are resolved, but meanwhile, the Memorandum sheds light on how the *Prometheus* ruling is to be applied at the USPTO.

BACKGROUND

35 U.S.C. §101 states that "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore…." In a series of cases dating back into the nineteenth century, the Supreme Court has long held that this section of the Patent Act contains an important exception – that "laws of nature, natural phenomena, and abstract ideas" are not patent eligible. [3] On March 20, 2012, in a unanimous decision, the Supreme Court held that a claim that involves correlating the blood level of a drug metabolite with the drug's efficacy or toxicity is not patent eligible because of the law of nature exception.[4] Although the claim at issue recites specific steps of administering the drug and determining the level of the metabolite, those steps were found to be insufficient to render the claim patent eligible. According to the Supreme Court, "to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words 'apply it.'"[5] The Court, however, provided little guidance on what would constitute a meaningful application of the law of nature that renders the claim patent eligible.

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[1] *See* http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf.

[2] The Supreme Court has recently vacated and remanded two cases for reconsideration by the Federal Circuit in view of *Prometheus*. *See*, Order 11-725, *Assn. for Molecular Pathology v. Myriad Genetics* (March 26, 2012)("*Myriad*") and Order 11-962*, WildTangent v. Ultramercial* (May 21, 2012)("*Ultramercial*"). According to the Memorandum, these cases will provide insight regarding the full reach of *Prometheus* and an earlier case, *Bilski v. Kappos*, 561 U.S. __, __ (2010) (slip op., at 5).

[3] *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *O'Reilly v. Morse*, 56 U.S. 62 (1853); *Diamond v. Diehr*, 450 U.S. 175, 185 (1981)*; Bilski v. Kappos*, 561 U.S. __, __ (2010) (slip op., at 5).

[4] For more background information on the decision in *Prometheus*, see our previous Client Alerts (The Threshold Patentability Question: The Supreme Court Entertains Oral Arguments in *Mayo v. Prometheus*; Back in the High Court Again: *Prometheus v. Mayo*; Clinical Method Claims Dodge a Bullet: *Prometheus v. Mayo*; and *Mayo v. Prometheus*: The Supreme Court Finds Certain Medical Diagnostic Claims Are Not Patent-Eligible).

[5] Prometheus at 3 (citing *Gottschalk* 409 U.S. at 71-72 (1972).

THE INTERIM PROCEDURE

The Interim Procedure was issued in order to provide patent examiners with specific guidance for determining subject matter eligibility in view of *Prometheus* when examining process claims involving laws of nature or natural correlations.

According to the Interim Procedure, after determining what an applicant invented and establishing the broadest reasonable interpretation of the claimed invention, a patent examiner must make three essential inquiries on the claim as a whole to determine whether the claim is drawn to patent-eligible subject matter. The first inquiry is whether the claimed invention is directed to a process, defined as an act or a series of acts or steps. If the answer is no, the analysis is inapplicable. If the answer is yes, then the examiner should make the second inquiry, *i.e.*, whether the claim "focus[es] on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle…)," or, in other words, whether the natural principle is a limiting feature of the claim. [6] If the answer to the second inquiry is no, then the analysis is complete. If the answer to the second inquiry is yes, then the examiner should make the third, most important inquiry:

> Does the claim include additional elements/steps or a combination of elements/steps that integrate the natural principle into the claimed invention such that the natural principle is practically applied, and are sufficient to ensure that the claim amounts to significantly more than the natural principle itself? (Is it more than a law of nature + the general instruction to simply "apply it"?)[7]

If the answer to the third inquiry is no, then the claim is not patent eligible and should be rejected.

As to what constitutes a natural principle under the second inquiry, the Interim Procedure provides several examples, including the disinfecting property of sunlight and the relationship between blood glucose levels and diabetes. The Interim Procedure further states that a correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood, is also considered a natural principle. The Interim Procedure reasons that "while it takes a human action to trigger a manifestation of the correlation [*i.e.* exposing the drug to blood], the correlation exists in principle apart from any human action."[8] The Interim Procedure further states that, for the analysis under the second inquiry, a claim focuses on a natural principle when the natural principle is a limiting element or step. As an example, "a claim that recites a correlation used to make a diagnosis focuses on a natural principle and would require further analysis under Inquiry 3."[9]

A big portion of the Interim Procedure focuses on analysis based on the third inquiry. According to the Interim Procedure, the analysis turns on whether the claim has "added enough to show a practical application."[10] A bare statement of a naturally occurring correlation, albeit a newly discovered natural correlation or very narrowly confined correlation, would fail the third inquiry. Instead, "there must be at least one additional element or step that applies, relies on or uses the natural principle so that the claim amounts to significantly more than the natural principle itself."[11] Such additional

[6] Memorandum at 2.

[7] *Id.*

[8] *Id.* at 3.

[9] *Id.*

[10] *Id; see also Prometheus,* 101 USPQ2d at 1968.

[11] *Id.* at 3-4.

elements or steps must not simply amount to insignificant extra-solution activity that imposes no meaningful limit on the performance of the claimed invention. For example, a claim directed to diagnosing an infection that recites the step of correlating the presence of certain bacterium in a person's blood with a particular type of bacterial infection with the additional step of recording the diagnosis on a chart, would not be patent eligible because the recording step is an extra-solution activity.

According to the Interim Procedure, elements or steps that are well understood, purely conventional, and routinely taken by others in order to apply the natural principle, or that only limit the use to a particular technological environment (field of use), would not be sufficiently specific to satisfy the third inquiry. By contrast, a claim with steps that add something of significance to the natural laws, such as a claim that recites a novel drug or a new use of an existing drug, in combination with a natural principle, would be sufficiently specific. The thrust of the analysis is that the claim must be limited so that it does not preempt the natural principle being recited by covering every substantial practical application of that principle. Consistent with that, the Interim Procedure emphasizes that the additional elements or steps must narrow the scope of the claim such that others are not foreclosed from using the natural principle for future innovation.[12]

The Interim Procedure lists many factors useful for analyzing the additional steps/features in the claims for the purpose of addressing the third inquiry, based largely on the weighing factors provided in the USPTO's 2010 memorandum discussing "Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*,"[13] including the "machine-or-transformation" test. The Interim Procedure clarifies that satisfying the machine-or-transformation test does not ensure patent eligibility if the machine or transformation is merely "nominally, insignificantly, or tangentially related to the steps or elements," and does not integrate the natural principle into the claimed invention to show that the natural principle is practically applied.[14]

To put its guiding principles in context, the Interim Procedure provides the following examples:

> [A] claim that uses the natural disinfecting properties of sunlight would require additional steps beyond exposing an item requiring disinfection to sunlight. The additional steps could involve constructing a sanitizing device that uses ultraviolet light for disinfection with steps that integrate the ultraviolet light into the device and are sufficient to confine the use of the ultraviolet light to a particular application (not so broad as to cover all practical ways of applying ultraviolet light). A claim that sets forth the relationship between blood glucose levels and the incidence of diabetes would require additional steps that do significantly more to apply this principle than conventional blood sample testing or diagnostic activity based on recognizing a threshold blood glucose level. Such additional steps could involve a testing technique or treatment steps that would not be conventional or routine.[15]

[12] *Id.* at 4.

[13] *Id.* at 5; *see also* http://www.uspto.gov/patents/law/exam/bilski_guidance_27jul2010.pdf.

[14] *Id.*

[15] *Id.* at 9.

The Interim Procedure further analyzed two exemplary sets of claims. One set of claims is directed to a method of treating a psychiatric behavioral disorder in a patient by exposing the patient to sunlight or white light. The Interim Procedure explained that, while a claim that broadly recites such a method is not patent eligible, a claim that recites additional steps of manipulating the light and positioning the patient for the light exposure would be patent eligible.[16] The other set of claims is directed to a method of diagnosing rheumatoid arthritis in a patient which involves contacting the serum sample of the patient with an antibody recognizing a specific marker (IgM) for rheumatoid arthritis, and determining that the patient has rheumatoid arthritis based on the increased binding of the antibody to IgM. The Interim Procedure explained that, while a claim that generally recites the use of an anti-IgM antibody is not patent eligible, a claim that recites a specific anti-IgM antibody (which may or may not be novel and non-obvious), or a claim that recites two specific assays not routinely used together, would be patent eligible.[17]

IMPLICATIONS FOR PATENT APPLICANTS

Given the specific guidance provided by the USPTO, it is likely that patent applicants will encounter more rejections based on subject matter eligibility in the future. This is especially true for applications directed to diagnostic methods, as medical diagnosis inevitably involves a natural correlation, for example a correlation between the existence or amount of a biomarker and a disease state. Claims directed to diagnostic methods frequently rely on such correlation as a limiting element or step, thus satisfying the second inquiry requirement. Although claims impacted by this Memorandum will be predominantly those examined in Technology Center 1600 (Technology Center for biotechnology and organic chemistry inventions), according to the Memorandum, any process claim that involves a natural principle will be examined under the Interim Procedure, regardless of the Technology Center.

An obvious response to a subject matter eligibility rejection would be to amend the claim by adding a claim limitation to recite a step/feature that applies the natural principle recited in the claimed process. If such a step/feature is already present, Applicants can consider presenting arguments that such step/feature applies, relies on, or uses the natural principle recited rather than constituting an extra-solution activity. For example, a showing that the step/feature is not routine, well-known, or conventional may be helpful in making the arguments. On the other hand, the additional claim limitation will inevitably narrow the scope of the claim. The more specific the additional limitation is, the more vulnerable the claim would be for possible design-around. The limitation(s) added to a claim in order to overcome a subject matter eligibility rejection therefore should be carefully vetted so that the amended claim still has practical and commercial value.

Moreover, under the principles of compact prosecution, the Memorandum requires that a patent examiner "state all non-cumulative reasons and bases for rejecting claims in the first office Action, and should avoid focusing solely on issues of patent-eligibility under 35 U.S.C. §101 except in the most extreme cases."[18] Patent applicants therefore will have the opportunity to consider the subject matter eligibility rejection in conjunction with all other rejections, including art rejections and rejections based on written description and enablement. It is therefore advisable that patent applicants take a systematic approach in addressing all rejections raised in an Office Action, and develop a coherent claim strategy for their patent applications.

[16] *Id.* at 10-11.

[17] *Id.* at 11-12.

[18] Memorandum cover letter.

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