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SPECIAL
REPORT

# USPTO ISSUES INTERIM GUIDELINES REGARDING "LAWS OF NATURE" PATENT ELIGIBILITY ISSUES

**July 12, 2012**

Further to our April 6, 2012 Special Report on the *Mayo v. Prometheus* decision,[1] on July 3 the USPTO issued further "interim" guidelines on implementation of the *Mayo* decision in patent examination. A copy of the USPTO's "*2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature"* is attached.

The USPTO considers these interim guidelines particularly relevant to examination of patent applications in Technology Center 1600 ("Biotechnology and Organic Chemistry"). However, it also considers them applicable, regardless of the Technology Center, for applications including "any process claim in which a law of nature, a natural phenomenon, or [a] naturally occurring relation or correlation is a limitation."

The reach of these guidelines is limited. First, the USPTO recognizes that the law is rapidly changing in the area of §101 patent eligibility, and the USPTO thus emphasizes that these are interim guidelines, and are likely to change as further court decisions are issued in cases such as *Myriad* [2] and *Ultramercial.*[3]

Second, the USPTO emphasizes that these interim guidelines apply only to those process claims that focus on use of a law of nature, a natural phenomenon, or a naturally occurring relation or correlation (collectively referred to in the guidelines as a "natural principle"). These interim guidelines thus do not apply to product claims (e.g., claims directed to compositions, machines or manufactures), which continue to be evaluated for compliance with §101 under 2009 USPTO guidelines.[4] The new interim guidelines also do not apply to process claims raising "abstract idea" or the like issues, which are addressed in 2010 USPTO guidelines[5] and ongoing case law developments.[6]

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[1] "*U.S. Supreme Court Again Addresses Scope of Patentable Subject Matter Under 35 U.S.C. §101,"* April 6, 2012.

[2] *Assn. For Molecular Pathology v. Myriad Genetics*, currently on remand to the Federal Circuit for reconsideration in view of *Mayo*. See our August 3, 2011 Special Report, "*Federal Circuit Addresses Patent Eligibility of Isolated DNA and Related Diagnostic Methods.*"

[3] *WildTangent v. Ultramercial*, also currently on remand to the Federal Circuit for reconsideration in view of *Mayo*.

[4] "*New Interim Patent Subject Matter Eligibility Examination Instructions,*" (August 24, 2009).

[5] "*Interim Guidance for Determining Subject Matter Eligibility for Process Claim in View of Bilski v. Kappos*," 75 Fed. Reg. 43922 (July 27, 2010). See our July 29, 2010 Special Report, "*Patent Office Issues Interim Guidance on Patent Eligibility for Process Claims.*"

[6] See, e.g., this week's Federal Circuit decision in *CLS Bank International v. Alice Corporation Pty. Ltd.*, Appeal No. 2011-1301 (Fed. Cir. July 9, 2012).

July 12, 2012

## I. Substance of the Guidelines

The interim guidelines lay out a three-step inquiry for determining the patent eligibility of affected claims. Inquiry 1 is whether the claims are directed to a process or method. Inquiry 2 is whether the subject claim focuses on use of a natural principle – i.e., whether a natural principle is a limiting feature of the claim. Inquiry 3 is "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'?)"

### A. Inquiry 1 - Process or Method Claims

Resolving Inquiry 1 is very straightforward. The guidelines only apply to process or method claims, and not to product, apparatus or system claims. Thus if a claim does not satisfy Inquiry 1, the interim guidelines do not apply. If a claim satisfies this inquiry, the analysis moves on to Inquiries 2 and 3.

### B. Inquiry 2 - Focus on Use of a Natural Principle

Inquiry 2 is whether the subject claim focuses on use of a natural principle – i.e., whether a natural principle is a limiting feature of the claim. If a claim satisfies Inquiry 1 but does not satisfy Inquiry 2, these interim guidelines do not apply. If a claim satisfies both Inquiry 1 and Inquiry 2, the analysis moves on to Inquiry 3.

The USPTO has adopted the Supreme Court's premise in *Mayo* that a "natural principle" can be very specifically defined. For example, the guidelines state 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 because, while it takes a human action to trigger a manifestation of the correlation, the correlation exists in principle apart from any human action" … " So, for instance, a claim that recites a correlation used to make a diagnosis focuses on a natural principle …". The USPTO acknowledges that this is a significant change in its practice: "Prior to *Mayo*, the [USPTO] did not treat these relationships – which come about as a result of an administration of a man-made drug – as laws of nature for purposes of application of the judicial exceptions. This aspect of *Mayo* changes that practice."

The USPTO's interim guidelines focus on medical diagnostic and medical treatment claims. Even so, the new definition of "natural principle" arguably has very wide application, because all processes rely to some extent on application of natural principles, and many process claims focus on broad application of such principles (e.g., that a particular man-made chemical compound bonds to natural substances such as wood, or a particular man-made shovel structure counteracts natural forces of gravity on natural substances such as rocks). Contrary to the admonitions of the Supreme Court in *Mayo*, the interim guidelines in effect rely on semantics of claim drafting to avoid this conundrum, distinguishing claims that expressly recite the natural principle from claims that only implicitly focus on it.

This reliance on claim semantics is reflected in the examples provided in the interim guidelines. According to those guidelines, the following claim example does not satisfy Inquiry 2, and thus could be patent eligible: "For example, a claim directed to simply administering a man-made drug that does not recite other steps or elements directed to use of a natural principle, such as a naturally occurring correlation, would be directed to eligible subject matter." In contrast, the interim guidelines defer to Inquiry 3 similar claims that recite the natural principle underlying such a method: "Further, 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 to be eligible because the claim would amount to significantly more than the natural principle itself."[7] Correlating this distinction to European claiming practice, the USPTO appears now to distinguish between "first medical use" and "second medical use" method claims, and suggests that the analysis can end with Inquiry 2 for "first medical use" method claims, but must proceed to Inquiry 3 for "second medical use" claims.

Thus, as noted in recommendation 1 of our April 6, 2012 Special Report, we recommend avoiding reciting a "natural law" in the claims, even though the claims may be based on application of such a "natural law."

### C. Inquiry 3 - Practical Application and Presumption

If a claim satisfies both Inquiry 1 and Inquiry 2, the analysis moves on to Inquiry 3. If the claim satisfies this inquiry, it is patent eligible under these interim guidelines. If it does not satisfy this inquiry, it is not patent eligible under these interim guidelines.

The primary focus of the interim guidelines is thus on Inquiry 3. It accordingly merits detailed study by anyone drafting process claims, and particularly medical diagnostic- or medical treatment-related claims. The various examples provided on pages 4 and 8-12 should be especially carefully studied.

Inquiry 3 can be broken down into two separate sub-inquiries. The first sub-inquiry is "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 …?" The second sub-inquiry is "Does the claim include additional elements/steps or a combination of elements/steps that … 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'?)" The second sub-inquiry is also framed in terms of the level of specificity of the additional elements or steps. Both the *Mayo* decision and the interim guidelines indicate that additional elements/steps recited at a high level of generality will not suffice to impart patent eligibility, but some level of specificity, particularly if unconventional, may suffice.

The interim guidelines do not make clear whether a claim may pass only one, or must pass both, of these sub-inquiries to be patent eligible. However, the discussion, analysis and examples of the interim guidelines focus almost exclusively on the second sub-inquiry, emphasizing the importance of what were traditionally §102 and §103 analyses of novelty and nonobviousness of the materials and steps recited in the claims. The implication is that satisfaction of this second sub-inquiry may be controlling.

Novel, or at least non-conventional, method steps are emphasized as providing patent eligibility both in treatment method claims (Example 1, claim 3) and in diagnostic method claims (Example 2, claim 4). On the other hand, the interim guidelines state that conventional steps such as recording a diagnosis on a patient chart would not make a claim patent eligible. While the interim guidelines tie that example to the concept that such recording is "extra-solution activity that is unrelated to the correlation and does not integrate the correlation into the invention," it also fits into the concept that the extra step is "purely conventional, and routinely taken by others." Thus, it fails both sub-inquiries.

[7] Like the Supreme Court in *Mayo*, the USPTO draws into this analysis the novelty of the claimed subject matter, referring to "a novel drug or a new use of an existing drug." This is further emphasized in treatment method Example 1 in Section IV.E. of the guidelines.

A similar analysis can be seen in Example 2 in connection with claims 2 and 4. The only distinction between patent non-eligible claim 2 and patent eligible claim 4 is the use of an unconventional combination of known steps in claim 4 as contrasted with the single conventional known step in claim 2. Thus, claim 4 passes at least the second sub-inquiry. The conclusion that claim 4 is patent eligible does not specifically address the fact that the non-conventional steps are mere data-gathering steps that allow application of the "natural principle," and thus would not appear to pass the first sub-inquiry.

Like the Supreme Court's *Mayo* decision, the interim guidelines appear to be inconsistent in defining laws of nature so specifically as to encompass natural effects of human application of a specific man-made drug to a natural substance (e.g., blood), which effects do not occur without human intervention, while indicating that novel process steps provide patent eligibility. For example, the guidelines state that "A claim that would fail [Inquiry 3] includes, for example, a claim having a limitation that describes a law of nature and additional steps that must be taken in order to apply the law of nature by establishing the conditions under which the law of nature occurs such as a step of taking a sample recited at a high level of generality to test for a naturally occurring correlation." Similarly, the interim guidelines state that "Additional limitations that are necessary for all practical applications of the natural principle, such that everyone practicing the natural principle would be required to perform those steps … would not be sufficient."

However, like the Supreme Court in *Mayo*, the interim guidelines indicate that a claim that recites a novel drug or a new use of an existing drug, whether or not in combination with recitation of a natural principle, would be patent eligible and "would amount to more than the natural principle itself." See the bottom of page 4. This is also emphasized in connection with diagnostic methods in Example 2, claim 3, which uses a novel and nonobvious chemical in a diagnostic data-gathering step. According to the Court's and the USPTO's definition of a natural law, however, the novelty of the drug would appear to be irrelevant.

Thus, it would appear from the definition of a "natural law" that a claim broadly directed to administering a novel drug to a patient with a recited "natural" effect should fail the second sub-inquiry of Inquiry 3. However, both the Supreme Court and the interim guidelines seem to provide an exception for such "typical" patent claims. The only apparent logical explanation is that such claims pass the first sub-inquiry of Inquiry 3 – i.e., the "administering" step constitutes practical application of the natural principle (e.g., not preempting use of the natural principle as a basic tool of scientific and technological work by way of *in vitro* research). However, the courts and/or the USPTO may ultimately resolve this apparent conflict adversely to patentees. Thus, as noted in recommendation 7 of our April 6, 2012 Special Report, we recommend providing a broad range of claims at varying level of specificity in connection with process inventions, particularly in the fields of medical treatment and medical diagnostics.

## II. Recommendations

The interim guidelines provide useful insight on the USPTO's application of the *Mayo* decision. The guidelines also re-emphasize the lack of clarity in the law of patent eligibility, and the likelihood that §101 patent eligibility will therefore arise as an issue in many more patent prosecutions and litigations in view of the *Mayo* decision. However, the USPTO's interim guidelines do not change the recommendations presented in our April 6, 2012 Special Report on the *Mayo* decision itself. Thus, we here simply refer you to the ten recommendations for

applicants and patentees, and the four recommendations for clients who are concerned with potential or actual assertion of a patent against them, presented in that Special Report.

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**MEMORANDUM**

**DATE:** July 3, 2012

**TO:** Patent Examining Corps

**FROM:** Andrew H. Hirshfeld
Deputy Commissioner
For Patent Examination Policy

**SUBJECT:** **2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

The attached guidance memo titled *2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature* (*2012 Interim Procedure for Laws of Nature*) is for use by USPTO personnel in determining subject matter eligibility of process claims involving laws of nature under 35 U.S.C. § 101 in view of the decision by the United States Supreme Court in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012) (*Mayo*). The *2012 Interim Procedure for Laws of Nature* guidance memo should be followed for examination of process claims in which a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle in the guidance) is a limiting element or step.

In summary, process claims having a natural principle as a limiting element or step should be evaluated by determining whether the claim includes 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. If the claim as a whole satisfies this inquiry, the claim is directed to patent-eligible subject matter. If the claim as a whole does not satisfy this inquiry, it should be rejected under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The *2012 Interim Procedure for Laws of Nature* should be consulted for a full explanation of the guidance.

It is expected that claims impacted by this guidance will predominantly be those examined in Technology Center 1600. However, any process claim in which a law of nature, a natural phenomenon, or naturally occurring relation or correlation is a limitation, should be examined under this procedure, regardless of the assigned Technology Center.

Under the principles of compact prosecution, Office personnel should 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.

The examination procedure set forth in the attached document is effective today and supersedes the March 21, 2012 memorandum to the corps titled *Supreme Court Decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc.* Process claims that do not include a law of nature, a natural phenomenon, or naturally occurring relation or correlation as a claim limitation should continue to be examined using the *Interim Guidance for Determining Subject Matter Eligibility for Process Claim in View of Bilski v. Kappos*, 75 Fed. Reg. 43922, July 27, 2010 (*2010 Interim Bilski Guidance*).

# 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature

## I. SUMMARY

The following guidance is intended for use in subject matter eligibility determinations during examination of process claims that involve laws of nature/natural correlations, such as the claims in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. __, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012) (*Mayo*).[1] Process claims that are directed to abstract ideas, such as the claims in *Bilski*,[2] should continue to be examined using the *Interim Guidance for Determining Subject Matter Eligibility for Process Claim in View of Bilski v. Kappos*, 75 Fed. Reg. 43922, July 27, 2010 (*2010 Interim Bilski Guidance*). The examination procedure set forth in this document supersedes the March 21, 2012 memorandum to the corps titled *Supreme Court Decision in Mayo Collaborative Services v. Prometheus Laboratories, Inc.*

The Office is issuing this guidance as an interim measure to provide instruction to examiners in technology areas impacted by the *Mayo* decision while pending cases[3] at the Federal Circuit are reheard in view of *Mayo*. While *Mayo* has provided additional details for the eligibility analysis that the Office developed after *Bilski*, the technology areas currently being addressed by the Federal Circuit, most notably in *Myriad* and *Ultramercial*, will provide insight regarding the full reach of *Bilski* and *Mayo*. The Office believes that the prudent course of action is to wait for resolution of these cases before issuing comprehensive updated guidance.

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[1] *Mayo* claim 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,

wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and

wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

[2] *Bilski* claim 1. A method for managing the consumption risk costs of a commodity sold by a commodity provider at a fixed price comprising the steps of:

(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumer;

(b) identifying market participants for said commodity having a counter-risk position to said consumers; and

(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of market participant transactions balances the risk position of said series of consumer transactions.

[3] The Supreme Court has recently vacated and remanded two cases for reconsideration by the Federal Circuit in view of *Mayo*. 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*).

# 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature

## II. ESSENTIAL INQUIRIES FOR SUBJECT MATTER ELIGIBILITY UNDER 35 U.S.C. § 101

After determining what applicant invented and establishing the broadest reasonable interpretation of the claimed invention, conduct the following three inquiries on the claim as a whole to determine whether the claim is drawn to patent-eligible subject matter. Further details regarding each inquiry are provided below.

**1. Is the claimed invention directed to a process, defined as an act, or a series of acts or steps?**

If no, this analysis is not applicable. For product claims, see the *Interim Examination Instructions for Evaluating Subject Matter Eligibility Under 35 U.S.C. § 101* issued August 24, 2009. If yes, proceed to Inquiry 2.

**2. Does the claim focus on use of a law of nature, a natural phenomenon, or naturally occurring relation or correlation (collectively referred to as a natural principle herein)? (Is the natural principle a limiting feature of the claim?)**

If no, this analysis is complete, and the claim should be analyzed to determine if an abstract idea is claimed (see the *2010 Interim Bilski Guidance*). If yes, proceed to Inquiry 3.

**3. 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"?)**

If no, the claim is not patent-eligible and should be rejected. If yes, the claim is patent-eligible, and the analysis is complete.

## III. DETAILED GUIDANCE FOR USING THE INQUIRIES

### A. Determining What Applicant Invented and the Broadest Reasonable Interpretation

Review the entire specification and claims to determine what applicant believes that he or she invented. Then review the claims to determine the boundaries of patent protection sought by the applicant and to understand how the claims relate to and define what the applicant has indicated is the invention.

Claim analysis begins by identifying and evaluating each claim limitation and then considering the claim as a whole. It is improper to dissect a claimed invention into discrete elements and then evaluate the elements in isolation because it is the combination of claim limitations functioning together that establish the boundaries of the invention and limit its scope.

Establish the broadest reasonable interpretation of the claims when read in light of the specification and from the view of one of ordinary skill in the art. This same interpretation must be used to evaluate the compliance with each statutory requirement. See MPEP 2111 and 2173 *et seq.* for further details of claim construction and compliance with 35 U.S.C. 112, second paragraph, respectively.

## B. INQUIRY 1: Process

Under this analysis, the claim must be drawn to a process. A process is defined as an act, or a series of acts or steps. Process claims are sometimes called method claims.

## C. INQUIRY 2: Natural Principle

**Does the claim focus on use of a natural principle, i.e., a law of nature, a natural phenomenon, or naturally occurring relation or correlation? (Is the natural principle a limiting feature of the claim?)**

A natural principle is the handiwork of nature and occurs without the hand of man. For example, the disinfecting property of sunlight is a natural principle. The relationship between blood glucose levels and diabetes is a natural principle. 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 because, while it takes a human action to trigger a manifestation of the correlation, the correlation exists in principle apart from any human action. These are illustrative examples and are not intended to be limiting or exclusive.

For this analysis, a claim focuses on a natural principle when the natural principle is a limiting element or step. In that case, the claim must be analyzed (in Inquiry 3) to ensure that the claim is directed to a practical application of the natural principle that amounts to substantially more than the natural principle itself. So, for instance, a claim that recites a correlation used to make a diagnosis focuses on a natural principle and would require further analysis under Inquiry 3.

If a natural principle is not a limitation of the claim, the claim does not focus on the use of a natural principle and requires no further analysis under this procedure. If the claim focuses on an abstract idea, such as steps that can be performed entirely in one's mind, methods of controlling human activity, or mere plans for performing an action, refer to the *2010 Interim Bilski Guidance* to evaluate eligibility.

## D. INQUIRY 3: Practical Application and Preemption

**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"?)**

A claim that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself. *See Mayo*, 101 USPQ2d at 1966. To show integration, the additional elements or steps must relate to the natural principle in a significant way to impose a meaningful limit on the claim scope. The analysis turns on whether the claim has added enough to show a practical application. *See id.* at 1968. In other words, the claim cannot cover the natural principle itself such that it is effectively standing alone. A bare statement of a naturally occurring correlation, albeit a newly discovered natural correlation or very narrowly confined correlation, would fail this inquiry. *See id.* at 1965, 1971.

It is not necessary that every recited element or step integrate or relate to the natural principle as long as it is applied in some practical manner. However, 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. Elements or steps that do not integrate the natural principle and are merely appended to it would not be sufficient. In other words, the additional elements or steps must not simply amount to insignificant extra-solution activity that imposes no meaningful limit on the performance of the claimed invention. *See id.* at 1966. For example, a claim to diagnosing an infection that recites the step of correlating the presence of a 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 eligible because the step of recording the diagnosis on the chart is extra-solution activity that is unrelated to the correlation and does not integrate the correlation into the invention.

Along with integration, the additional steps must be sufficient to ensure that the claim amounts to significantly more than the natural principle itself by including one or more elements or steps that limit the scope of the claim and do more than generally describe the natural principle with generalized instructions to "apply it." *See id.* at 1965, 1968. The additional elements or steps must narrow the scope of the claim such that others are not foreclosed from using the natural principle (a basic tool of scientific and technological work) for future innovation. 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. *See id.* at 1968. A claim with steps that add something of significance to the natural laws themselves would be eligible because it would confine its reach to particular patent-eligible applications of those laws, such as a typical patent on a new drug (including associated method claims) or a new way of using an existing drug. *See id.* at 1971; *see* also 35 U.S.C. § 100(b). In other words, 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. The process must have additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. *See id.* at 1968.

A claim that would fail this inquiry includes, for example, a claim having a limitation that describes a law of nature and additional steps that must be taken in order to apply the law of nature by establishing the conditions under which the law of nature occurs such as a step of taking a sample recited at a high level of generality to test for a naturally occurring correlation. *See id.* at 1970. Adding steps to a natural biological process that only recite well-understood, routine, conventional activity previously engaged in by researchers in the field would not be sufficient. *See id.* at 1966, 1970. A combination of steps that amounts to nothing significantly more than an instruction to doctors to "apply" applicable natural laws when treating their patients would also not be sufficient. *See id.* at 1970.

Claims that do not include a natural principle as a limitation do not raise issues of subject matter eligibility under the law of nature exception. For example, a claim directed to simply administering a man-made drug that does not recite other steps or elements directed to use of a natural principle, such as a naturally occurring correlation, would be directed to eligible subject matter. Further, 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 to be eligible because the claim would amount to significantly more than the natural principle itself. However, a claim does not have to be novel or non-obvious to qualify as a subject matter eligible claim. Moreover,

a claim that is deemed eligible is not necessarily patentable unless it also complies with the other statutory and non-statutory considerations for patentability under § § 101 (utility and double patenting), 102, 103, and 112, and non-statutory double patenting.

The weighing factors used in the *2010 Interim Bilski Guidance* are useful tools for assisting in the evaluation. For convenience, these factors and how they may assist in the analysis are summarized below.

## E. RELEVANT FACTORS USEFUL FOR INQUIRY 3

The following factors can be used to analyze the additional features in the claim to determine whether the claim recites a patent-eligible practical application of a natural principle and assist in answering Inquiry 3 above. Many of these factors originate from past eligibility factors, including the 'Machine-or-Transformation' (M-or-T) test. However, satisfying the M-or-T factors does not ensure eligibility if the claim features that include a particular machine or transformation do not integrate the natural principle into the claimed invention to show that the natural principle is practically applied, and are not sufficient to ensure that the claim amounts to significantly more than the natural principle itself.

- Appending conventional steps, specified at a high level of generality, to a natural principle does not make the claim patent-eligible.
- Steps that amount to instructions that are well-understood, routine, conventional activity, previously engaged in by those in the field add nothing specific to the natural principle that would render it patent-eligible.
- A claim that covers known and unknown uses of a natural principle and can be performed through any existing or future-devised machinery, or even without any apparatus, would lack features that are sufficient for eligibility.
- A particular machine or transformation recited in more than general terms may be sufficient to limit the application to just one of several possible machines or just one of several possible changes in state, such that the claim does not cover every substantial practical application of a natural principle. This can be contrasted with only adding features that limit the application to a certain technological environment (e.g., for use in catalytic conversion systems), which would cover every substantial practical application in that field.
- Additional limitations that are necessary for all practical applications of the natural principle, such that everyone practicing the natural principle would be required to perform those steps or every product embodying that natural principle would be required to include those features, would not be sufficient.
- A particular machine or transformation recited in a claim can show how the natural principle is integrated into a practical application by describing the details of how that machine and its specific parts implement the natural principle (e.g., the parts of an internal combustion engine apply the concept of combustion to produce energy) or how the transformation relates to or implements the natural principle (e.g., using ionization in a manufacturing process).
- A machine or transformation that is merely nominally, insignificantly, or tangentially related to the steps or elements, e.g., data gathering or data storage, would not show integration. For example, a machine that is simply incidental to execution of the method (using a computer as a counter balance weight and not as a processing device) rather than an object that implements the method or a transformation that involves only a change of position or location of an object rather than a change in state or thing does not show that these additional

features integrate the natural principle into the invention as they are incidental to the claimed invention.

- Complete absence of a machine-or-transformation in a claim signals the likelihood that the claim is directed to a natural principle and has not been instantiated (e.g., is disembodied or can be performed entirely in one's mind.)
- A mere statement of a general concept (natural principle) would effectively monopolize that concept/principle and would be insufficient. This can be contrasted with a tangible implementation with elements or steps that are recited with specificity such that all substantial applications are not covered. Such specificity may be achieved with observable and verifiable steps, for example, rather than subjective or imperceptible steps.

## IV. SAMPLE ANALYSIS

### A. Sample Claim Drawn to a Patent-Eligible Practical Application - *Diamond v. Diehr*

1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:

providing said computer with a data base for said press including at least, natural logarithm conversion data (ln), the activation energy constant (C) unique to each batch of said compound being molded, and a constant (x) dependent upon the geometry of the particular mold of the press,

initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,

constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,

constantly providing the computer with the temperature (Z),

repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is

$\ln v = CZ + x$ where *v* is the total required cure time,

repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and

opening the press automatically when a said comparison indicates equivalence.

The above claim was found to be a patent-eligible practical application in *Diamond v. Diehr*, 450 U.S. 175 (1981). Recently, the Supreme Court looked back to this claim as an example of a patent-eligible practical application as explained in the following excerpt from *Mayo*:

> The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process *integrated the equation into the process as a whole*. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." [ ] It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that

> equation in conjunction with all of the other steps in their claimed process." [ ] These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula. *See Mayo* at 1969 (emphasis added).

This claim would pass Inquiries 1-3 in the above analysis as it is a process that includes the Arrhenius equation as a limitation, with additional steps that integrate the Arrhenius equation into the process and are sufficient to narrow the scope of the claim so that others are not foreclosed from using the Arrhenius equation in different applications.

### B. Sample Claim Drawn to Ineligible Subject Matter - *Mayo v. Prometheus*

> 1. A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The above claim was found to be ineligible in *Mayo*. The Supreme Court determined that the claim focused on use of a law of nature that was given weight during prosecution of the claim[4] – specifically the relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. *See id.* at 1967.[5] The Court analyzed the claim as follows:

> The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add enough to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that apply natural laws? We believe that the answer to this question is no. *See id.* at 1968.
>
> The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the

[4] In *Mayo*, the correlation was recited in a 'wherein' clause, which was deemed to add a patentable distinction over the prior art. Often, 'wherein' clauses do not have a limiting effect on the broadest reasonable interpretation of the claim because language that suggests a feature, or makes the feature optional, does not limit claim scope. See MPEP 2111.04.

[5] Prior to *Mayo*, the Office did not treat these relationships – which come about as a result of an administration of a man-made drug – as laws of nature for purposes of application of the judicial exceptions. This aspect of *Mayo* changes that practice. Additional guidance from the courts on how to identify laws of nature may be forthcoming in cases like *Myriad*.

> scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities. *See id.* at 1968.

This claim would pass Inquiries 1-2 and fail Inquiry 3. It is a process claim that includes a natural principle that was construed as a limiting feature of a claim during prosecution - the natural principle being the naturally occurring relationships noted above, which are a consequence of the ways in which thiopurine compounds are metabolized by the body. The Court emphasized that while it takes a human action to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. *See id.* at 1967. The additional steps integrate the relationship into the process as the administering step involves the thiopurine drug, the determining step establishes the thiopurine drug level and the wherein clauses set forth the critical levels. The steps are not sufficient, however, to narrow the application such that others could still make use of the naturally occurring relationship in other practical applications. The claim essentially sets forth a law of nature with generalized instructions to apply it.

### C. Making A Rejection

After performing the appropriate Inquiries, a claim that fails Inquiry 3 should be rejected under 35 U.S.C. 101 as not being drawn to patent-eligible subject matter. When making the rejection, identify the natural principle, identify that the claim is effectively directed to a natural principle itself, and explain the reason(s) that the additional claim features or combination of features, when the claim is taken as a whole, fail to integrate the natural principle into the claimed invention so that the natural principle is practically applied, and/or fail to be sufficient to ensure that the claim amounts to significantly more than the natural principle itself.

A sample rejection of the following claim could read as follows:

Claim 1. A method of determining effective dosage of insulin to a patient, comprising the steps of administering a dose of insulin to a patient, testing the patient's blood for the blood sugar level, and evaluating whether the insulin dosage is effective based on the blood sugar level.

*Analysis:* *The claim passes Inquiry 1 because it is drawn to a process.*

*The claim passes Inquiry 2 because a naturally occurring correlation between insulin and blood glucose levels is a limitation of the claim.*

*The claim does not pass Inquiry 3 because, although the additional steps integrate or make use of the correlation in the process by administering insulin in one step and testing for the correlation in another step, the steps are not sufficient to ensure that the claim amounts to significantly more than the correlation itself since every application of the correlation would require an administration of insulin and testing of blood to observe the relationship between insulin and blood glucose levels.*

<u>The rejection</u>:

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter because it is not a patent-eligible practical application of a law of nature. The claim is directed to a naturally occurring correlation between insulin and blood glucose

levels. The combination of steps recited in the claim taken as a whole, including the steps of administering insulin to a patient and testing blood sugar levels, are not sufficient to qualify as a patent-eligible practical application as the claim covers every substantial practical application of the correlation.

### D. Evaluating a Response

A proper response to a rejection based on failure to claim patent-eligible subject matter would be an amendment adding additional steps/features or amending existing steps/features that integrate the natural principle into the process (by practically applying or making use of the principle) and are sufficient to limit the application of the natural principle to more than the principle itself + steps that do more than simply "apply it" at a high level of generality. Examples of both eligible and ineligible hypothetical claims follow. It would also be proper for the applicant to present persuasive arguments that the additional steps add something significantly more to the claim than merely describing the natural principle. A showing that the steps are not routine, well-known or conventional could be persuasive.

For example, 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.

### E. Claim Examples

EXAMPLE 1:

It is a well-documented phenomenon (law of nature) that white light, such as sunlight, affects a person's mood. The mood changes are correlated to a change in neuronal activity due to white light striking a person's photoreceptors eliciting a chemical reaction that starts an electrical response in the receptor cells modulating neuronal circuitry.

What is claimed is:

1. A method for treating a psychiatric behavioral disorder of a patient, the disorder associated with a level of neuronal activity in a neural circuit within a brain of the patient, the method comprising:

exposing the patient to sunlight to alter the level of neuronal activity in the neural circuit to mitigate the behavioral disorder.

2. A method for treating a psychiatric behavioral disorder of a patient, the disorder associated with a level of neuronal activity in a neural circuit within a brain of the patient, the method comprising:

exposing the patient to a source of white light to alter the level of neuronal activity in the neural circuit to mitigate the behavioral disorder.

3. A method for treating a psychiatric behavioral disorder of a patient, the disorder associated with a level of neuronal activity in a neural circuit within a brain of the patient, the method comprising:

providing a light source that emits white light;

filtering the ultra-violet (UV) rays from the white light;

positioning the patient adjacent to the light source at a distance between 30-60 cm for a predetermined period ranging from 30-60 minutes to expose photosensitive regions of the brain of the patient to the filtered white light to mitigate the behavioral disorder.

Analysis:

**Inquiry 1**: All of the claims are process claims.

**Inquiry 2**: All of the claims focus on the use of a law of nature that is a limitation of the claim, which in this case, is the effect of white light, such as sunlight, on a person's neuronal activity related to mood.

**Inquiry 3**: All of the claims integrate the effect of the sunlight/white light into the claimed process. However, claims 1 and 2 do not include steps that are sufficient to ensure that the claim amounts to significantly more than the natural principle itself. Claim 3 does include sufficient steps such that the claim is significantly more than a law of nature + "apply it".

Claim 1: The additional step of exposing a patient to sunlight integrates the law of nature (the effect of sunlight) into the claimed process as the exposure creates the condition under which the patient can experience the effect of the sunlight. However, that step adds nothing significant to the law of nature other than what is well-understood, routine, conventional activity, previously engaged in by people seeking mood elevation. This claim amounts to no more than the law of nature (sunlight elevates mood) + telling people to "apply it" by exposing the person to sunlight without any significant limitations as to how to do so.

Claim 2: The additional step of exposing the patient to a source of white light integrates the law of nature (the effect of white light) into the claimed process as the exposure creates the condition under which the patient can experience the effect of the white light. However, that step, which is broad enough to cover sunlight, adds nothing significant to the law of nature other than what is well-understood, routine, conventional activity, previously engaged in by people seeking mood elevation. This claim amounts to no more than the law of nature + "apply it" (white light elevates mood + expose the person to white light).

Claim 3: The additional step of providing a light source integrates the law of nature (the effect of white light) into the claimed process as the exposure creates the condition under which the patient can experience the effect of the white light; the additional step of filtering the UV rays from the white light manipulates the white light; and the additional step of positioning the patient relates to the conditions under which the patient is exposed to the light. These steps are also sufficient to narrow the claim to an eligible application as the combination of steps when taken together, including filtering the light and positioning the patient to limit the exposure time and intensity, amount to substantially more than conventional exposure to sunlight to alter neuronal activity (the law of nature). The additional step of positioning the patient establishes conditions that limit the application of the principle to exposure under certain specifically defined conditions. These precise conditions are not necessary to apply the law of nature because a person situated outside such that their photoreceptors are exposed to the sun's rays would

experience the effect on the neuronal circuitry. When the claim is considered as a whole with the combination of steps, the process is sufficient to ensure that the claim does not cover every substantial practical application of the law of nature.

Claims 1 and 2 are ineligible and should be rejected as being directed to non-statutory subject matter. Claim 3 is a patent-eligible practical application. While claim 3 is eligible, this claim should be further examined to determine patentability. A patentability evaluation of claims 1 and 2 should also be made to promote compact prosecution.

EXAMPLE 2:

There is a naturally occurring correlation (natural principle/law of nature) between a patient having rheumatoid arthritis and their level of rheumatoid factor IgM. Increased levels of rheumatoid factor IgM shown by increased binding of an anti-IgM antibody indicate a higher likelihood of a patient being diagnosed with rheumatoid arthritis. For purposes of the following example, anti-IgM antibody XYZ does not occur in nature and is novel and non-obvious. Assays M and N can be used for comparing the anti-IgM antibody to a control sample, but are not routinely used together.

What is claimed is:

1. A method of determining the increased likelihood of having or developing rheumatoid arthritis in a patient, comprising the steps of:

obtaining a serum sample from a patient;

contacting the serum sample with an anti-IgM antibody; and

determining that the patient has rheumatoid arthritis or an increased likelihood of developing rheumatoid arthritis based upon the increased binding of the anti-IgM antibody to IgM rheumatoid factor in the serum sample.

2. The method of claim 1 further comprising:

providing a positive control sample; and

contacting the positive control sample with an anti-IgM antibody,

wherein the step of determining that the patient has rheumatoid arthritis or increased likelihood of developing rheumatoid arthritis comprises a step of comparing the anti-IgM antibody in the serum sample to the positive control sample.

3. The method of claim 1 or 2, wherein the anti-IgM antibody is antibody XYZ.

4. The method of claim 2, wherein the step of comparing the anti-IgM antibody to the positive control sample includes performing assay M and then performing assay N.

Analysis:

**Inquiry 1**: All of the claims are process claims.

**Inquiry 2**: All of the claims include the limitation of the correlation between rheumatoid arthritis and the rheumatoid factor IgM, which is a natural principle/law of nature.

**Inquiry 3**: All of the claims integrate the law of nature into the recited process steps. However, claims 1 and 2 do not include steps that are sufficient to ensure that the claim amounts to significantly more than the natural principle itself, while claims 3 and 4 do include sufficient steps such that the claim is significantly more than a law of nature + the general instruction to simply "apply it".

Claim 1: All of the additional steps integrate or relate to the correlation, with the steps of obtaining and contacting the serum sample directly associated with preparing the serum for testing, and the step of determining the diagnosis making direct use of the correlation. However, the additional steps of obtaining and contacting are well-understood steps that are routinely conducted to analyze a serum sample. The steps are also recited at a high level of generality and do not require substantially more than simply obtaining a sample to investigate and contacting it with a generically recited antibody (recited at a high level of generality). Moreover, when the claim is considered as a whole, the steps taken together amount to no more than recognizing the law of nature itself.

Claim 2: The additional steps relate to using a control sample in the testing and therefore directly integrate the law of nature. These steps are typically taken by those in the field to perform testing of a sample and do not add anything substantial to the process of claim 1.

Claim 3: The additional step of using a particular anti-IgM antibody, and especially an antibody that is not known in the field, integrates the law of nature as it is used to express the principle and is also sufficient to limit the application of the law of nature. While it is not necessary that the particular antibody be novel or non-obvious to render the claim eligible, in this case use of the particularly claimed antibody does transform the claim to a patent-eligible practical application as it does not cover substantially all practical applications of the correlation because it is limited to those applications that use the antibody XYZ.

Claim 4: The additional step of comparing the anti-IgM antibody to the positive control sample includes performing assay M and then performing assay N, which integrates the correlation into the process because use of the control sample facilitates testing for the correlation. This step additionally uses assays M and N, which are not routinely used together. Thus, the claim is limited to a process that involves particular assays M and N and uses those assays in a particular combination. So, the claim does not cover substantially all practical applications of testing for the correlation. For purposes of this example, use of these assays together is not well-known, routine or conventional, but at this stage of examination it has not been determined whether such use is novel or non-obvious. While claim 4 is eligible, further examination would be required to determine whether the claim 4 is patentable.

Claims 1 and 2 are ineligible and should be rejected as being directed to non-statutory subject matter. Claims 3 and 4 are patent-eligible practical applications. Claims 3 and 4 require further examination to determine patentability. A patentability evaluation of claims 1 and 2 should also be made to promote compact prosecution.