From: David A. Gass [mailto:REDACTED]
Sent: Thursday, July 31, 2014 1:29 PM
To: myriad-mayo_2014
Cc: alice_2014
Subject: Written Comments on Guidance For Determining Subject Matter Eligibility Of Claims Reciting Or Involving Laws of Nature, Natural Phenomena, & Natural Products

Dear Ladies and Gentlemen:

Please consider the two attached articles published in Law360 pertaining to substantive issues in the Myriad-Mayo guidelines. The articles are posted with permission from the publisher on the Marshall, Gerstein, & Borun website. [http://www.marshallip.com/newsroom.php?search=news&special_search=all&category=Publications&page=1 OR http://marshallip.com/professionals/34/david-a-gass]

As stated in the articles, these writings reflect the opinions of the author and should not be viewed as positions taken by the author's firm or any of the firm's clients. The same is true for the additional comments below.

In *Diamond v. Diehr*, 101 S.Ct. 1048, 1057-58 (1981) the Supreme Court stated, "In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter." The Court purported to *follow Diehr* in its *Prometheus* decision, not disregard or overrule it, calling *Diehr* one of the two "cases most directly on point." *Prometheus,* 101 USPQ2d at 1969. The office's current Guidance pays lips service to "claim-as-a-whole" but analyzes claims (especially method claims) only with respect to individual elements or steps. To illustrate this important legal principle, I would urge the Office to include several training examples in its updated Guidance in which individual elements or steps are neither novel or unconventional, but the combination is patent-eligible because the combination is neither well-known or conventional.

Please also consider the following procedural suggestions when updating the Guidance, with respect to examination under Section 101:

(1) In an "Examiner Note" at the very end of the Guidance, Examiners are instructed to "identify the judicial exception(s) that is/are recited or involved in the claim…." The updated Guidance should more prominently instruct/require Examiners to explicitly state two things: the category of "judicial exception" that is being applied (for example, the "law of nature" exception); and what the Examiner believes to be the fact-specific judicial exception implicated by specific claims (for example, the claims involve the following natural law:

David A. Gass
Marshall, Gerstein & Borun LLP
233 South Wacker Drive
6300 Willis Tower
Chicago, IL 60606-6357
Direct: (312) 474-6624
Firm: (312) 474-6300
Fax: (312) 474-0448
[email redacted]
www.marshallip.com

(2) _____). A clear statement of the "judicial exception" as perceived by the examiner is vital to evaluating whether the statute is being applied correctly, and whether the claims are directed to the exception itself, or a practical application of the exception.
(3) The updated Guidance should clearly state that an Examiner has a burden to support a rejection under Section 101 with reasoning and/or evidence, and articulate that reasoning on the record. Although this may seem self-evident, at least one experienced Examiner has concluded that while the Guidance "states that the analysis should carefully consider every relevant factor and related evidence, the guidance does not specifically teach any requirements of format that should take in an office action and does not state that every factor must be addressed in the office action."
(4) The updated Guidance should be clear that if an Applicant responds to a rejection with reasoning or evidence, the Examiner should reconsider the rejection and address the merits of the arguments/evidence on the record. By way of example, if a claim is rejected because it is alleged to implicate a "natural law", then an Examiner should be required to weigh arguments or evidence from an applicant that there are avenues for future research and innovation involving the natural law that are not foreclosed by the claims. When available, such evidence goes to the heart of the question of whether the claims are impermissibly directed to a natural law, or directed to a patent-eligible application of the natural law.

Thank you for your consideration.

Sincerely,

David Gass
Partner
Marshall, Gerstein & Borun LLP

Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

10 Problems In The USPTO's New Training Memo

Law360, New York (March 10, 2014, 12:19 PM ET) -- On March 4, 2014, the U.S. Patent and Trademark Office issued a memorandum to its patent examiners outlining patent eligibility under 35 USC §101. The 2014 memorandum is at least the sixth attempt in five years by the PTO to articulate the types of inventions that its patent examining corps may consider as eligible for a patent, following related efforts in June 2013, July 2012, July 2010, January 2010 and August 2009. Only the 2013 memo is explicitly superseded by the newest memorandum.

Section 101 of the patent statute has not changed since it was enacted by Congress in 1952, broadly stating, "Whoever 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 therefor, subject to the conditions and requirements of this title."[1] The U.S. Supreme Court, however, has created and/or altered "judicial exceptions" to Congress' broad categories of patent-eligible subject matter, in decisions such as Bilski v. Kappos (2010),[2] Mayo Collaborative Services v. Prometheus Laboratories Inc.,[3] and Association for Molecular Pathology v. Myriad Genetics(2013),[4] necessitating repeated reinterpretation and reevaluation by the PTO.

The 2014 memorandum attempts to interpret the court's Mayo, Myriad and Diamond v. Chakrabarty (1980)[5] decisions, which collectively pertain to biotechnology processes and biochemical compositions. The 2014 memorandum emphasizes that its guidance pertains to "all claims (i.e., machine, composition, manufacture and process claims) reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products."[6]

Although it carries no force of law, the 2014 memorandum is an important policy document from the PTO, because it likely will be used to train patent examiners in the near future about how to examine all patent applications on this important issue that still poses difficulty for the Supreme Court. Because of the focus on "natural" principles, phenomena, and products, patent applications in the biotechnology and chemical fields are those likely to be most heavily affected.

Unfortunately, the 2014 memorandum, like some of its predecessors, was not subject to public notice or comment. The 2014 memorandum is flawed and, as written, may result in flawed examination of patent applications.

1. The 2014 memorandum espouses a "significantly different" standard for evaluating the patent-eligibility of a chemical compound under Section 101 that is not rigorously justified by the Supreme Court decisions that the PTO purports to interpret.

In Myriad, for example, a cDNA was deemed patentable because it was not naturally occurring. The

Supreme Court's decision in Myriad neither turned on, nor articulated any importance to the magnitude/significance of the differences between cDNA (deemed patent-eligible) and isolated genomic DNA (deemed unpatentable): "[W]e hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring."[7]

Justice Antonin Scalia concurred: "It suffices … that complementary DNA (cDNA) is a synthetic creation not normally present in nature." Under the PTO's "significantly different" standard, the PTO risks training examiners to refuse patent-eligible inventions that satisfy the plain language of the statute and also would satisfy the court.

2. Insufficient guidance on how to weigh the 12 factors.

Section II of the 2014 memorandum lists 12 factors[8] and instructs the patent examining corps to weigh them, but provides insufficient guidance on the weight to accord to each factor. Appropriate guidance would apply the 12 factors to the judicial precedents motivating the memorandum, and demonstrate how those factors and the weight to attribute them will lead to the same conclusion of patent eligibility or ineligibility that the judiciary reached. The memorandum should be revised accordingly.

3. Misunderstanding of "preemptive effect" factor.

In Mayo, the Supreme Court explained that the purpose of its "judicial exceptions" to Section 101 is to assure that laws of nature, phenomena and abstract ideas are available to those conducting research, so as not to unduly or disproportionally inhibit future research or innovation.

At least some judges on the Federal Circuit have since suggested that this is the most important factor and should be central to an analysis under Section 101. See, e.g., Ultramercial Inc. v. Hulu LLC (2013).[9] The 2014 memorandum fails to mention "preemption" at all.

"Factor (b)" in the memorandum instructs examiners to analyze whether others are "substantially foreclosed from using the judicial exception(s)," but factor (b) fails to mention the context: future research and innovation. An examiner could misunderstand the memorandum as stating or implying that the "foreclosure" factor weighs against patentability unless the patent applicant leaves real-world uses (perhaps invented by the applicant) freely available to the public by limiting claims in a manner that invites design-around.

For instance, U.S. patent law has recognized that a new use of an existing drug is patent-eligible under §101, but patent examiners could misread the 2014 memorandum as suggesting that, henceforth, a new use is only patent-eligible if limited to a specific dosage and treatment duration, so that others are not foreclosed from using the same drug for the inventor's same new indication, using other doses or durations.[10] The law does not require such charity. The Section 101 inquiry articulated by the court is focused on whether the natural principle, practically applied by the inventor, will still be available to other innovators and researchers to develop new practical applications, such as a third use for the drug.

4. Claim as a whole.

The Supreme Court has repeatedly emphasized that a Section 101 analysis must be performed with respect to a claim as a whole. This is especially true with method claims, as the court warned in Diehr,[11] because a method claim can be patent-eligible even if every single one of its steps, standing

alone, appears to be conventional.

Section II of the PTO's 2014 memorandum, "How to Analyze 'Significantly Different,'" takes the exact opposite approach. Not once, in the list of 12 "Factors" does the memorandum mention weighing the claim as a whole or weighing combinations of limitations. If anything, the enumerated 12 factors imply that a proper analysis of particular "elements/steps" may be performed in isolation, without consideration of the claims as a whole. The examples in the memorandum mention "claim as a whole" analysis, but the critical Section II, describing what factors an examiner should analyze, never mentions the claims as a whole.

5. Machine-or-transformation test.

The 2014 memorandum contains conclusory, incorrect treatment of the "Machine-or-Transformation" test, "Factor (e)" of the proposed 12-factor balancing test. The Supreme Court considers the "Machine-or-Transformation" test to provide an important clue as to patent eligibility under Section 101, as articulated in its Bilski opinion.

Training Example E of the memorandum, pertaining to a method of amplifying nucleic acid by using free nucleotides and a polymerase, involves chemical transformation, and (as written) arguably involves a heating apparatus (machine). Training Example F of the memorandum, pertaining to a diagnostic method involving obtaining and analyzing a blood sample, involves a transformation of a human subject (when obtaining a blood sample) and a transformation of a blood sample by assaying it. Training Example G of the memorandum, involving exposing a patient to a synthetic source of white light to treat a mood disorder, involves a machine: a source of synthetic white light. In each instance, the memorandum states, without explanation, "no machine or transformation is recited."

Just because the PTO has promulgated other memoranda that address Bilski does not excuse repeated conclusory, incorrect analysis in the 2014 memorandum of this important factor.

6. Lack of clear grounding in judicial precedent.

Very few of the training examples in the 2014 memorandum are explicitly based on Supreme Court or Federal Circuit case law. Section 101 of the patent statute broadly defines patent-eligible subject, and courts have created narrow exceptions to the statute. To the extent that the memorandum is identifying new "examples" of ineligible subject matter that are not based on controlling (precedential) case law, the PTO is creating/defining new categorical "judicial exceptions" to the statute — a role that should be reserved for the courts.

For instance, the Supreme Court's order granting certiorari in Myriad was limited to the question, "Are human genes patentable?" The court limited its holding to this issue and the closely related issue of patentability of a cDNA corresponding to the coding sequence of an isolated human gene.[12] The court explicitly declined to consider patentability of method claims, of applications of knowledge about human genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered.

The court apparently intended a limited holding, yet the PTO has concluded in the 2014 memorandum that Myriad also applies to "chemicals derived from natural sources (e.g., antibiotics, fats, oils, petroleum derivatives, resins, toxins, etc.); foods (e.g., fruits, grains, meats and vegetables); metals and metallic compounds that exist in nature; minerals; natural materials (e.g., rocks, sands, soils); nucleic

acids; organisms (e.g., bacteria, plants and multicellular animals); proteins and peptides; and other substances found in or derived from nature." The majority of the training examples in Section III of the memorandum are not supported by citations to relevant case law.

7. The 2014 memorandum implies that an otherwise novel, non-naturally occurring compound should possess a functional difference from a natural compound to satisfy Section 101.[13]

The court's decision in Myriad does not support that implication. The court did not require a functional difference between ineligible isolated genomic DNA and eligible cDNA. The court's decision arguably implies the opposite, insofar as the court in Myriad recognized that cDNA and isolated genomic DNA code for the same protein. The "coding function" of the patent-eligible subject matter was not different.

8. The 2014 memorandum repeatedly concludes that gunpowder, a non-naturally occurring composition of matter, is "not markedly different from what exists in nature."[14]

The memorandum offers no analysis in support of that conclusion. Gunpowder is a composition that does not exist in nature. Gunpowder as a composition also is functionally different than any of its component ingredients. By virtue of its compositional and functional differences, gunpowder would appear to satisfy the PTO's eligibility test of Example B. Insofar as the memorandum suggests that chemical and functional characteristics of gunpowder are insufficient to make gunpowder eligible under Section 101, the analysis about gunpowder in Example C contradicts the analysis in Example B.

9. Training Example H in the memorandum, purportedly based on the Federal Circuit's Myriad opinion, is legally and factually inaccurate.[15]

A premise of Example H is that a nucleotide sequence is a "natural product." The district court in Myriad construed "sequence" as merely information, rather than a physical molecule. The Federal Circuit did not overturn this construction. Myriad's claim failed the machine-or-transformation test and was deemed unpatentably abstract in part because analysis of a "sequence" did not require analysis of a "product" as the claims were construed.

10. The memorandum offers no explanation why a "transformation" (Factor (e)) would not be relevant to patent-eligibility of a product.

A chemical transformation of one or more natural products into a new, non-natural product appears to be relevant under Myriad.

The 2014 memorandum likely will not be the last PTO memorandum on the topic of patent eligibility, as the Supreme Court is expected to issue yet another decision by late June in Alice Corp. v. CLS Bank, involving §101 and computer-implemented inventions. Hopefully, the PTO will see the wisdom of a public comment period before training its examiners using the current, flawed memorandum. Improvement is possible.

—By David Gass, Marshall Gerstein & Borun LLP

David Gass is a partner and registered patent attorney in Marshall Gerstein & Borun's Chicago office.

information purposes and is not intended to be and should not be taken as legal advice.

[1] 35 USC §101.

[2] 561 U.S. ___ , 130 S.Ct. 3218, 95 USPQ2d 1001 (2010)

[3] 566 U.S. _, 132 S.Ct. 1289, 101 USPQ2d 1961 (2012).

[4] 569 U.S. ___, 133 S.Ct. 2107, 2116, 106 USPQ2d 1972 (2013)

[5] 447 U.S. 303 (1980)

[6] See Memorandum cover letter from Deputy Commissioner Andrew Hirshfeld to Patent Examining Corps.

[7] Myriad slip opinion at p. 1.

[8] Factors that weigh toward eligibility (significantly different):

(a) Claim is a product claim reciting something that initially appears to be a natural product, but after analysis is determined to be non-naturally occurring and markedly different in structure from naturally occurring products.

b) Claim recites elements/steps in addition to the judicial exception(s) that impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s).

c) Claim recites elements/steps in addition to the judicial exception(s) that relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s).

d) Claim recites elements/steps in addition to the judicial exception(s) that do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s).

e) Claim recites elements/steps in addition to the judicial exception(s) that include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application. (See MPEP 2106(II)(B)(1) for an explanation of the machine or transformation factors).

f) Claim recites one or more elements/steps in addition to the judicial exception(s) that add a feature that is more than well-understood, purely conventional or routine in the relevant field.

Factors that weigh against eligibility (not significantly different):

(g) Claim is a product claim reciting something that appears to be a natural product that is not markedly different in structure from naturally occurring products.

h) Claim recites elements/steps in addition to the judicial exception(s) at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered.

i) Claim recites elements/steps in addition to the judicial exception(s) that must be used/taken by others to apply the judicial exception(s).

j) Claim recites elements/steps in addition to the judicial exception(s) that are well-understood, purely conventional or routine in the relevant field.

k) Claim recites elements/steps in addition to the judicial exception(s) that are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s).

l) Claim recites elements/steps in addition to the judicial exception(s) that amount to nothing more than a mere field of use.

[9] 722 F.3d 1335 (Fed. Cir. 2013)

[10] See Training Example B in the memorandum, analysis of Claim 3, factor (b) at p. 8.

[11] Diamond v. Diehr, 450 U.S. 175, 188-89, 101 S.Ct. 1048, 1057-58, 209 U.S.P.Q. 1 (1981) ("In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The "novelty" of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.")

[12] "This case … requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U. S. C. §101 by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins."

[13] See Training Example B in the memorandum, pertaining to a chemical derivative of a hypothetical anti-cancer compound isolated from plant leaves, "Factor (a)" analysis, at p. 8.

[14] See Training Example C in the memorandum, pertaining to a firework comprised of gunpowder and other components, at pp. 9-10.

[15] See Training Example H in the memorandum at p. 18.

Portfolio Media. Inc. | 860 Broadway, 6th Floor | New York, NY 10003 | www.law360.com
Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

USPTO Training Memo Lacks Sound Basis In The Law

Law360, New York (June 12, 2014, 10:31 AM ET) -- On March 4, 2014, following a nine-month conclave, the U.S. Patent and Trademark Office published examination guidelines, instructing patent examiners how to decide what types of inventions involving "laws of nature/natural principles, natural phenomena, and/or natural products" may be patent-eligible. The guidelines (and additional training materials published shortly thereafter) provoked immediate outcry from stakeholders in the biotechnology, pharmaceutical and chemical industries because the guidelines (1) were drafted and implemented without public comment; (2) are more restrictive than decades of PTO examination practice prior to March 2014; and (3) threaten to leave many valuable innovations unprotectable. (In fact, the guidelines could be read as the PTO calling into question the continued validity of many patents that the PTO issued before March 2014.) The guidelines have numerous shortcomings that invite criticism, a selection of which were highlighted in my March 10 Law360 guest column, "10 Problems In The USPTO's New Training Memo." The most fundamental problem is the guidelines' questionable interpretation of the patent statute and U.S. Supreme Court interpretations of that statute.

Section 101 of the patent statute provides, "Whoever 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 therefor, subject to the conditions and requirements of this title." The Supreme Court has created limited exceptions to the literal language of the statute to assure that patent applicants do not claim laws of nature, natural phenomena, products of nature, or abstract ideas. To be patent-eligible, a claimed invention must fall within a statutory category and "avoid the judicial exceptions."

The Supreme Court has warned that, "in dealing with the patent laws, we have more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed." Diamond v. Diehr (1981). Instead of heeding the court's instructions, the PTO guidelines create new conditions on patentability that neither Congress, nor the Supreme Court, have expressed.

Supreme Court Precedent Fails to Support the "Markedly Different in Structure" Test for Claims Directed to Compositions or Manufactures

The litmus test of the PTO's guidelines asks whether any claimed invention "involving" a law of nature, natural phenomenon, or product of nature is "markedly" or "significantly" different than the relevant "judicial exception." The 2013 Myriad case held that two related compositions fell on different sides of the eligibility line. By comparing/contrasting the subject matter on each side of the line, insight is obtained into the degree to which an invention must differ from "nature" to be patent-eligible.

The court held that a naturally occurring segment of genomic DNA was not patent eligible simply on the basis that it had been isolated from surrounding genetic material. However, the court also held that cDNA encoding the same protein as the ineligible genomic DNA "is patent eligible because it is not naturally occurring." The court never stated that cDNA satisfied, or needed to satisfy, the PTO's "markedly different (from nature)" standard to be patent-eligible. In fact, the court acknowledged that the cDNA sequence was "dictated by nature," but still held that cDNA was eligible because it was "new."

The PTO has suggested that the court's 1980 Chakrabarty decision, involving a genetically engineered bacteria invention, established the "markedly different" standard, but the PTO is mistaken. The holding in Chakrabarty was that Chakrabarty's "micro-organism plainly qualifies as patentable subject matter" because it was "a nonnaturally occurring manufacture or composition of matter." In dicta, the court observed that Chakarabarty's bacteria had "markedly different characteristics from any found in nature," but the holding was premised on the bacteria not being "nature's handiwork." The observation about "marked differences" served to "underscore [the point] dramatically" — not to articulate a test that must be met by future inventions.

The PTO has suggested that the court's 1948 Funk Brothers and 1931 American Fruit Growers decisions influenced the 2014 guidelines. There are several reasons why these cases should be viewed with caution in the context of patent-eligibility, but for purposes of this discussion it is sufficient to observe that the court did not state or apply a "markedly different" test; and the court's decisions preceded the 1952 patent act that separated the definition of patent-eligible subject matter (§101) from the conditions and requirements for patentability such as novelty (§102) and inventiveness/unobviousness (§103).

In both cases, the court discussed prior art in a manner indicating that the patent claims in question failed the test for "invention" that is now embodied in §103. In Funk Brothers, involving a mixture of bacterial inoculants, "[i]t was the general practice, prior to the Bond patent, to manufacture and sell inoculants," and the patented mixture was criticized because the combination/mixture produced no change in the component parts and no enlargement of their use. "Their use in combination does not improve in any way their natural functioning." In American Fruit Growers, the invention involved borax treatment of fruit to retard mold growth, but "the underlying conception had been adequately revealed" in a prior patent more than 20 years earlier.

The Importance of Function in Patent-Eligibility Analysis

The PTO's new test for patent-eligibility is flawed for the additional reason that it fails to give due weight to functional benefits of an invention. Although Myriad stands for the proposition that non-natural structure is sufficient for patent-eligibility, the court cases discussed above also collectively stand for the proposition that novel function is a factor that can weigh in favor of patent-eligibility.

For example, the patent-eligible bacteria in Chakrabarty had a "distinctive use" (for oil breakdown) that natural bacteria lacked. The bacterial mixture in Funk Brothers did not: "No species acquires a different use. The combination of species produces … no enlargement of the range of their utility." In American Fruit Growers, the addition of borax to the rind of fruit "only protects the natural article" and did not produce a new article with "distinctive form, quality, or property."

The court states or hints that new uses or properties is a factor that should weigh in favor of patent-eligibility, but the PTO has ignored this factor. The Myriad case involved a case of "mere isolation" and left open the question of whether isolation, in combination with markedly different function or use for the isolated composition, would satisfy the requirements of patent-eligibility. The PTO's new requirement for marked structural differences wrongly excludes novel functional properties as an eligibility factor.

The PTO Has Proposed an Unworkable, Unjustified 10-Factor Balancing Test for Evaluating Whether a Claim to a Method Is "Significantly Different" Than a "Law of Nature"

The PTO's new "markedly different in structure" test for assessing claims directed to compositions is unnecessarily subjective and lacks solid basis in the law, but at least has the virtue of simplicity. The same cannot be said for the PTO's guidance for examination of claims directed to process inventions.

The PTO has instructed patent examiners to balance ten Mayo "factors" when evaluating process claims. Factors that allegedly weigh toward eligibility look at whether a claim recites elements/steps in addition to the "judicial exception(s)" that: (1) impose meaningful limits on claim scope, i.e., the elements/steps narrow the scope of the claim so that others are not substantially foreclosed from using the judicial exception(s); (2) relate to the judicial exception in a significant way, i.e., the elements/steps are more than nominally, insignificantly, or tangentially related to the judicial exception(s); (3) do more than describe the judicial exception(s) with general instructions to apply or use the judicial exception(s); (4) include a particular machine or transformation of a particular article, where the particular machine/transformation implements one or more judicial exception(s) or integrates the judicial exception(s) into a particular practical application; and (5) add a feature that is more than well-understood, purely conventional or routine in the relevant field.

Factors that weigh against eligibility look at whether a claim recites elements/steps in addition to the judicial exception(s) that: (6) are recited at a high level of generality such that substantially all practical applications of the judicial exception(s) are covered; (7) must be used/taken by others to apply the judicial exception(s); (8) are well-understood, purely conventional or routine in the relevant field; (9) are insignificant extra-solution activity, e.g., are merely appended to the judicial exception(s); and (10)

amount to nothing more than a mere field of use.

The PTO was unquestionably attempting to interpret and make sense of the court's 2012 Mayo v. Prometheus decision when it derived its 10 "Mayo factors" test, and presumably the PTO could identify a phrase or paragraph in Mayo or another Supreme Court decision from which each "factor" was derived. However, these phrases are not set forth in the Mayo decision as discrete "factors" but appear to be the court's attempt to articulate why particular claims of one particular patent failed to satisfy §101.

The PTO's drafters appear to be pleased to have derived a 10-factor balancing test, having publicly stated that examiners are familiar with the seven Wands factors for evaluating a different patentability requirement: enabling disclosure under §112.

The Wands factors stand on clear ground: a 1980 Federal Circuit appellate court decision in which the court explicitly listed eight factors "to be considered."[1] In contrast, neither the Supreme Court nor the Federal Circuit has articulated that 10 different factors exist; or that the factors should be balanced; or if they should be balanced, what weight should be given to each factor.

Because the alleged "factors" pertain to a judicial exception, and the court has "more than once cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed," balancing is arguably unjustifiable. In view of the policy argument against nonlegislative exceptions to the patent statute, a case could be made that a judicial exception should not apply if any single factor points to patent-eligibility — even if the score is 9-1 against. This approach would be consistent with Mayo, a case in which the invalidated claims failed on all 10 "factors."

A second fundamental problem with the Mayo balancing test is that the factors encourage patent examiners to violate a fundamental tenet: that patent-eligibility be evaluated by looking at a claim as a whole. See, e.g., Diamond v. Diehr, 101 S.Ct. 1048, 1057-58 (1981) ("In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The 'novelty' of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.") Although the PTO's training memo pays lip service to "claim as a whole" analysis, every factor that an examiner is instructed to apply involves dissecting claims into parts and evaluating the merits of individual "elements or steps."

A third fundamental problem with the Mayo balancing-of-factors test is the nature of the factors themselves. The Wands factors are all scientifically focused and address a question that is largely scientific in nature: whether a patent application enables a scientist in the field to practice the full scope of an invention without undue experimentation. Patent examiners have science degrees and experience

that provide context for weighing the Wands factors. In contrast, the 10 Mayo factors are fundamentally legal in nature, which patent examiners are typically less well-equipped to evaluate.

Perhaps most troubling, if/when examiners form an opinion about the applicability of the Mayo factors to a claimed invention, the subjective and relativistic nature of almost every single factor make meaningful discourse about the factors (between examiners and patent applicants) an elusive, if not impossible, goal. No common frame of reference exists for consistent application of terms like "meaningful limits"; "substantially foreclosed"; "significant way"; "nominally, insignificantly, or tangentially related"; "general instructions to apply"; "integrates … into a particular practical application"; "well-understood, purely conventional, or routine in the relevant field"; "markedly different"; "high level of generality"; "substantially all"; "insignificant extra-solution activity"; and "mere field of use." Differences of opinion are inevitable, and objective criteria for resolving the differences are impossible to develop.

The USPTO should suspend all application of its 2014 guidelines pending re-evaluation of whether they have sound legal basis, and whether they articulate a truly workable test or are merely buzz words to provoke unproductive argument. And because the original drafters have a personal investment of nine months in the existing guidelines, the re-evaluation would benefit from fresh eyes within the PTO as well as the considered opinion of the affected public who were excluded from the original drafting process. The PTO is accepting public comment on these controversial guidelines until June 30 at myriad-mayo_2014@uspto.gov.

—By David Gass, Marshall Gerstein & Borun LLP

David Gass is a partner and registered patent attorney in Marshall Gerstein & Borun's Chicago office.

The opinions expressed are those of the author(s) and do not necessarily reflect the views of the firm, its clients, or Portfolio Media Inc., or any of its or their respective affiliates. This article is for general information purposes and is not intended to be and should not be taken as legal advice.

[1] In re Wands, 858 F.2d 731 (Fed. Cir. 1988) ("Factors to be considered in determining whether a disclosure would require undue experimentation … include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.").
