

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 *Chakrabarty*’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.

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[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.”).