

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 Only the 2013 memo is explicitly superseded by the newest memorandum.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 disproportionately 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.

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[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-resolution 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.