IP Alert: Year-End Brings New Developments in Patent Eligibility

YEAR-END BRINGS NEW DEVELOPMENTS IN PATENT ELIGIBILITY

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Section 101 of the Patent Act (35 U.S.C. 101) continues to be of concern for patent practitioners, patent applicants and patent owners. The language of this statute defines what constitutes patent eligible subject matter, as follows:

“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.”

Using the statutory language as a guide, the courts and the United States Patent and Trademark Office (USPTO) have defined subject matter that is not eligible for patent protection. This is an update of that process.

USPTO ISSUES NEW SECTION 101 GUIDELINES FOR PATENT ELIGIBILITY

On December 16, 2014, the USPTO published its new "2014 Interim Eligibility Guidance on Patent Subject Matter Eligibility" in the Federal Register (79 Fed. Reg. 74618). In this document, the USPTO gives patent examiners instructions for analyzing patent claims for subject matter eligibility under 35 U.S.C. §101 with respect to the judicial exceptions to patent eligibility of "abstract ideas, natural phenomena, and products of nature."

This version replaces the guidelines issued in March 2014 and updates those guidelines on the "product of nature exception" in light of the Mayo and Myriaddecisions. The new guidelines also supplement the June 2014 guidelines regarding the "abstract idea exception" in light of the Alice decision.

The March guidelines were issued in response to the Supreme Court decisions in Association for Molecular Pathology v. Myriad Genetics, Inc., 133 S. Ct. 2107 (2013) and Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S. Ct. 1289 (2012). The June guidelines were issued in response to the Supreme Court's decision in Alice Corporation Pty. Ltd. v. CLS Bank International, 134 S. Ct. 2347 (2014).

The new guidelines provide an updated view of subject matter eligibility in line with Alice, Myriad, Mayo, and recent case law. The new guidelines also respond to the public comments received pertaining to the March and June versions.

One important note is that the new guidelines do not constitute substantive rulemaking and do not have the force and effect of law. The guidelines are merely provided to the examiners (and the public) to provide better understanding and implementation of Section 101 analysis of patent claims, particularly with respect to the provisions of MPEP Sections 2105, 2106 and 2106.01.

Another important note is that the new guidelines are not intended to create any right or benefit, substantive or procedural, enforceable by any party against the Office. Rejections will continue to be based upon the substantive law, and it is these rejections that are appealable. Failure of any USPTO personnel to follow the guidelines is not, in itself, a proper basis for either an appeal or a petition.

With respect to the "product of nature" guidance, the December guidelines are distinguished from the prior versions as follows:

1. separates the "product of nature" analysis from the "significantly more" analysis for overcoming the exception;

2. focuses on claims “directed to” a product of nature, rather than claims that merely “involve” a product of nature; and
3. uses a “markedly different” analysis of characteristics that can include a product’s structure, function, and/or other properties as compared to its naturally occurring counterpart in its natural state.

The new guidelines regarding nature-based products replace the prior set of explanatory examples with a new set of examples, and according to the Office, include many examples suggested in public comments.

The new guidelines include a decision-making flowchart with the following instructions for claim analysis under Section 101:

Prior to evaluating a claim for patentability, establish the broadest reasonable interpretation of the claim and analyze the claim as a whole when evaluating for patentability.

Step 1 – is the claim to a process, machine, manufacture or composition of matter?

If yes – go to Step 2A.
If no – the claim is not eligible subject matter under 35 U.S.C. §101.

Step 2A – (Mayo test – Part 1) – is the claim directed to a law of nature, a natural phenomenon, or an abstract idea (the judicially recognized exceptions to patentable subject matter)?

If no – the claim qualifies as eligible subject matter under 35 U.S.C. §101.
If yes – go to Step 2B

Step 2B (Mayo test – Part 2) – does the claim recite additional elements that amount to significantly more than the judicial exception?

If no – the claim is not eligible subject matter under 35 U.S.C. §101.
If yes – the claim qualifies as eligible subject matter under 35 U.S.C. §101.

Notable changes from prior guidelines include:

- All claims (product and process) with a judicial exception (of any type) are subject to the same steps.
- Claims including a nature-based product are analyzed in Step 2A to identify whether the claim is directed to (i.e., recites) a “product of nature” exception.
- This analysis compares the nature-based product in the claim to its naturally occurring counterpart to identify markedly different characteristics based on structure, function, and/ or properties.
- The analysis proceeds to Step 2B **only** when the claim is directed to an exception (i.e., when no markedly different characteristics are shown).

The new guidelines further explain the Section 101 claim analysis as follows:

1. Determine what the claim is “directed to.”
2. Identify the judicial exception recited in the claim.
3. Determine if recited nature-based product has characteristics “markedly different” from natural product.
4. Determine if the structure, function or other properties of the recited nature-based product are “markedly different” from natural product.
5. Determine if any element in the claim ensures that the claim is “significantly more” than the judicial exception.

According to the new guidelines, a claim is “directed to” a judicial exception when a law of nature, a natural phenomenon, or an abstract idea “is recited (i.e., set forth or described) in the claim.”

Claims that recite a judicial exception may nonetheless be patent eligible if they are “directed to inventions that clearly do not seek to tie up the judicial exception.” Included in the new guidelines is an extensive collection of examples to show what subject matter has been found either eligible or ineligible under Section 101.

The new guidelines became effective as of December 16, 2014, and apply to all applications filed before, on, or after that date.

Public comment is invited and must be received on or before March 16, 2014.

NEW SECTION 101 CASE LAW

On December 17, 2014, the Federal Circuit, in the case of University of Utah Research v. Ambry Genetics, applied Section 101 against patent claims used by Myriad – that had previously not been reviewed by the court.

Four composition of matter claims directed to DNA primers were held to be ineligible subject matter, because they are directed to products of nature – citing the Supreme Court’s Myriad decision. The court’s basis for concluding that the primers are directed to “products of nature” was that they possess the same nucleotide sequence as the naturally occurring DNA.

In addition, two method claims were found to be ineligible subject matter because they were directed to abstract ideas based on the use of the DNA primers – citing the Supreme Court’s Mayo decision.

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