

From: Chaffee, Kathleen
Sent: Friday, March 8, 2019 3:46 PM
To: Eligibility2019
Subject: Comments on 2019 Revised Subject Matter Eligibility Guidance

Dear Director Iancu:

This letter is to provide comments regarding the USPTO Guidance issued on 07 January 2019 (“New Guidance”). Briefly, the New Guidance fails to provide sufficient guidance or Examples for the Life Sciences, particularly in diagnostics. The USPTO Memorandum, issued on 07 June 2018, updated Example 29 to reflect the decision in *Vanda*, but updates with respect to the New Guidance are absent.

I was pleased to see that the New Guidance appears to provide additional paths to patent eligibility. The New Guidance requires Examiners to find claims eligible if they “integrate” any abstract ideas into a “practical application.” The New Guidance emphasizes that mere inclusion of an abstract idea in a claim is not fatal, because such ideas form the basic building blocks of all patent claims. Furthermore, the New Guidance does not require the practical application itself to be unconventional (for purposes of eligibility).

But, it is unclear, in the Life Sciences, what is meant by “integrated into a practical application”. It appears that a claim could meet this standard if the applicant could show that the claimed invention had practical utility. For example, under the New Guidance, practical utility in a diagnostic method being rejected as being an abstract idea, would be thought to be satisfied if the claimed invention solves a problem in the prior art, or offers some benefit to patients. For example, the applicant could show that the claimed invention had practical utility (e.g., identification or stratification of a group of patients that would benefit or not benefit from a particular treatment).

Under prior guidance, applicants often had to show that the claimed invention provided additional elements that amount to significantly more (e.g., an unconventional step) than the judicial exception under new Step 2B. This could be difficult in many cases because the additional element might not be viewed by the USPTO as an element that is “significantly more” in nature, but instead, a well-understood, routine, or conventional activity. The New Guidance appears to indicate that an inventive solution will be considered to have a “practical application”, whether or not elements are well-known or conventional.

As recited in the New Guidance:

A claim is not “directed to” a judicial exception, and thus is patent eligible, if the claim as a whole integrates the recited judicial exception into a practical application of that exception. A claim that integrates a judicial exception into a practical application will apply, rely on, or use the judicial exception in a manner that imposes a meaningful limit on the judicial exception, such that the claim is more than a drafting effort designed to monopolize the judicial exception.

...

In the context of revised Step 2A, the following exemplary considerations are indicative that an additional element (or combination of elements) may have integrated the exception into a practical application:

- an additional element reflects an improvement in the functioning of a computer or other technology.

- an additional element applies or uses a judicial exception to effect a particular treatment or prophylaxis for a disease or medical condition.
- an additional element implements a judicial exception with, or uses a judicial exception in conjunction with, a particular machine or manufacture that is integral to the claim.
- an additional element effects a transformation or reduction of a particular article to a different state or thing.
- an additional element applies or uses the judicial exception in some other meaningful way beyond generally linking the use of the judicial exception to a particular technological environment, such that the claim as a whole is more than a drafting effort designed to monopolize the exception.

In addition to the above considerations recited in the New Guidance, new Examples 37-42 were issued on 07 January 2019 (“new Examples”). According to the new Examples, mental processes or organization of human activity can be integrated into a practical application by providing an improvement over prior systems (see new Examples 37 (claim 1), 40 (claim 1), and 42 (claim 1)). Furthermore, limiting the use of an “abstract idea” (e.g., a mathematical concept) to a practical application of transmitting a signal to a computer terminal, even though the step is well-understood, routine, and conventional (see e.g., new Example 41) appear to be enough to show a practical application.

These new Examples describe various practical applications that are not available in the Life Science Examples. Thus, it is requested that the considerations outlined in the New Guidance and the new Examples be translated into updated Life Science Examples.

Respectfully,

Kathleen Chaffee