Published on *The National Law Review* https://www.natlawreview.com

USPTO October 2019 Patent Eligibility Guidance Update Includes New Guidance And Examples For Life Sciences

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The USPTO has released additional patent eligibility guidance to supplement the guidance released in January. While much of the October 2019 Patent Eligibility Guidance Update relates to claims falling under the "abstract idea" judicial exception to eligibility, there is new guidance and new examples pertinent to personalized medicine, therapeutic methods and pharmaceutical products.

New Eligibility Guidance For Life Sciences

The October 2019 PEG Update is said to respond to public comments received in response to the January 2019 Revised Patent Subject Matter Eligibility Guidance (the "2019 PEG"). In particular, the October 2019 PEG Update provides more information on the following aspects of the January guidance:

- evaluating whether a claim recites a judicial exception
- the groupings of abstract ideas enumerated in the 2019 PEG
- evaluating whether a judicial exception is integrated into a practical application
- the *prima facie* case and the role of evidence with respect to eligibility rejections
- application of the 2019 PEG in the patent examining corps.

The discussion of "evaluating whether a judicial exception is integrated into a practical application" includes a specific discussion of personalized medicine claims. The October 2019 PEG Update also includes new examples, including two new Life Sciences examples.

Integration of a Judicial Exception into a Practical Application

Pages 13-15 of the October 2019 PEG Update address patent eligibility under *Vanda*, and when a "treatment/prophylaxis" step "can integrate a judicial exception into a practical application by applying or using the judicial exception to effect a particular treatment or prophylaxis for a disease or

medical condition." The October 2019 PEG Update identifies three factors to be considered:

- the particularity or generality of the treatment or prophylaxis
- whether the limitation(s) have more than a nominal or insignificant relationship to the exception(s)
- whether the limitation(s) are merely extra-solution activity or a field of use

Under the first point, the guidance advises that "[t]he treatment or prophylaxis limitation must be 'particular,' *i.e.*, specifically identified so that it does not encompass all applications of the judicial exception(s)." For example, a claim limitation that recites administering a specific class of drug might integrate a judicial exception into a practical application, whereas a claim that generally recites "administering a suitable medication" would not.

Under the second point, the guidance advises that "[t]he treatment or prophylaxis limitation must have more than a nominal or insignificant relationship to the exception(s)." That is, the treatment or prophylaxis must be known or taught to treat or prevent the condition at issue. The guidance provides as an example "a claim that recites a natural correlation (law of nature) between blood glucose levels over 250 mg/dl and the risk of developing ketoacidosis." A step of treating the subject with insulin might integrate the judicial exception into a practical application, whereas a step of treating the subject with aspirin (which the example says has no relation to the glucose levels or ketoacidosis) would not.

Under the third point, the guidance advises that "[t]he treatment or prophylaxis limitation must impose meaningful limits on the judicial exception, and cannot be extra-solution activity or a field-of-use." As an example, the guidance states that, in "a claim that recites (a) administering rabies and feline leukemia vaccines to a first group of domestic cats in accordance with different vaccination schedules, and (b) analyzing information about the vaccination schedules and whether the cats later developed chronic immune-mediated disorders to determine a lowest-risk vaccination schedule," step (a) is a data-gathering step that does not adequately integrate the abstract idea step (b) into a practical application. However, if the claim also recites a step (c) of "vaccinating a second group of domestic cats in accordance with the lowest-risk vaccination schedule," step (c) would support eligibility, because it "integrates the abstract idea into a practical application."

New Life Sciences Example 43

New Example 43 illustrates the application of this guidance to claims relating to the treatment of a specific kidney disease, "Nephritic Autoimmune Syndrome Type 3 (NAS-3)." The example includes 5 claims:

1. A treatment method comprising:
(a) calculating a ratio of C11 to C13 levels measured in a blood sample from a patient diagnosed with Nephritic Autoimmune Syndrome Type 3 (NAS-3) to identify the patient as having a non-responder phenotype;
(b) administering a treatment to the patient having a non-responder phenotype.

2. The method of claim 1, wherein the treatment is a non-steroidal agent capable of treating NAS-3.

3. The method of claim 1, wherein the treatment is rapamycin.

4. The method of claim 1, wherein the treatment is a course of plasmapheresis.

5. A treatment method comprising administering rapamycin to a patient identified as having Nephritic Autoimmune Syndrome Type 3 (NAS-3).

Claim 1 is deemed ***ineligible***, while all other claims are deemed eligible.

Analyzing claim 1, the guidance finds under Step 2A, Prong 1, that step (a) recites a judicial exception that includes a mathematical concept abstract idea, a mental process abstract idea, and a law of nature. The guidance finds under Step 2A, Prong 2, that step (b) is recited "at such a high level of generality that it does not even require a doctor to take the calculation step's outcome (the patient's phenotype) into account when deciding which treatment to administer." The guidance finds under Step 2B that "the claim as a whole" does not amount to "significantly more" than the recited judicial exception. Thus, the claim is ineligible.

Claims 3-4 are found eligible at Step 2A, Prong 2, because the recited treatments are relatively specific and treat the phenotype identified in step (a). For Step 2A, Prong 2, it does not matter if the recited treatment is well-understood, routine, and conventional, it still can support eligibility.

Claim 5 is found eligible at Step 2A, Prong 1, because "[t]he recited step of administering rapamycin to a patient having NAS-3 does not set forth or describe any recognized [judicial] exception."

New Example 44 relates to a naturally-occurring pharmaceutical product, and will be reviewed in a separate article.

What About Diagnostic Methods?

Neither the October 2019 PEG Update or the new examples address the trickier question of what it takes for a diagnostic method claim to satisfy 35 USC § 101. However, the USPTO is granting some patents to diagnostic methods that do not include a treatment step, such as this one, this one, and this one.

National Law Review, Volumess IX, Number 295