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Practice Group:

IP Procurement and Portfolio Management

U.S. Patent Office Issues New Examples of Patent Eligibility Analysis of Life Sciences Claims

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Introduction

On May 4, 2016, the United States Patent Office published a subject matter eligibility update[1] for determining patent eligibility under 35 U.S.C. § 101.[2] The Update supplements the previous guidelines[3] and includes additional life science claim examples to assist patent examiners ("Examiners") in making eligibility determinations.[4] The Update indicates that Examiners should use the additional claim examples in conjunction with the prior guidelines which were published by the Patent Office on December 16, 2014.[5,6] The additional examples include illustrative claim sets directed to vaccines, methods of diagnosing and treating a disorder, dietary sweeteners, gene screening, a paper-making machine, and a method of hydrolyzing fat.[7]

The most noteworthy aspect of the illustrative claim sets in the Update may be the eligibility analysis of the methods of diagnosing and treating a disorder.[8] Specifically, the Update provides more clarity than the prior guidelines regarding eligibility of diagnostic methods and also possible approaches to achieving eligibility for such methods.

Previous Analysis of Diagnostic Methods

The prior guidelines included an example claim directed to a diagnostic method[9], and this claim was taken from *Mayo v. Prometheus*.[10] Under the analysis of the prior guidelines, this claim which recited only "administering" and "determining" steps[11] was determined to be ineligible. In this regard, the analysis by the Patent Office asserted that the claim was ineligible because the metabolic relationship identified in the "determining" step exists apart from any human action, and thus the claim is directed to a natural law (Step 2A of the *Mayo* test).[12] Furthermore, the "wherein" portion of the step, namely "wherein the level of 6-thioguanine less than [the threshold] indicates a need to increase the amount of said drug administered to said subject and wherein the level of 6-thioguanine greater than [the threshold] indicates a need to decrease the amount of said drug administered to said subject" was merely routine, conventional activity that did not add significantly more to the natural law recited in the claim (Step 2B of the *Mayo* test).[13]

Analysis of Diagnostic Methods in the Update

The additional examples provided by the Update include a claim set drawn to diagnostic methods, specifically methods of diagnosing and treating julitis (a fictional autoimmune disease).[14] Analysis of this claim set indicates that the patent eligibility of a diagnostic method is based on the specific language of the claim, particularly the steps recited therein, and demonstrates that the ineligibility of the example claim analyzed in the prior guidelines does not necessarily extend to all diagnostic methods.[15]

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The first claim in the set of example diagnostic methods recites, in part, a method comprising: a. obtaining a plasma sample from a human patient; and b. contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.[16] The Patent Office asserts that this claim is patent eligible because the steps of obtaining a plasma sample from a patient (step a) and detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting resultant binding between JUL-1 and the antibody (step b) are not directed to a natural principle or an abstract idea.[17] This analysis by the Patent Office relies on language in *Mayo* by the Court stating that the administering of a drug providing 6-thioguanine and the determining of the resultant level of 6-thioguanine in the patient in the claim therein "are not themselves natural laws."[18,19]

Notably, the second claim in the set of example diagnostic methods recites the same two steps as the first claim and then adds a third step, namely "diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected."[20] The Patent Office asserts that this claim is ineligible because the "diagnosing" step involves a correlation that is a consequence of natural processes, and furthermore this step could be performed by a human mentally (i.e., an abstract idea).[21] This analysis is significant because an additional step can render otherwise eligible subject matter patent ineligible. Furthermore, the "detecting" step that requires contacting the plasma sample with an anti-JUL-1 antibody does not bestow eligibility on the claim because this step is recited at a high level of generality, i.e., any anti-JUL-1 antibody and any detection method, and thus is not a meaningful limitation restricting the claim to a particular application of the natural principle or abstract idea.[22]

The third and fourth example diagnostic method claims recite the same subject matter as the ineligible second claim, including the "diagnosing" step, but additionally require contacting the plasma sample with porcine anti-JUL-1 antibody and antibody mAb-D33 respectively.[23] Contrary to the ineligible second claim which merely recites "an anti-JUL-1 antibody," the Patent Office asserts that the specific antibodies required by the third and fourth example claims are more than a mere instruction to apply the natural principle, and consequently these claims amount to significantly more than the natural principle itself.[24] In the discussion of the specific antibodies, the Patent Office notes that the background facts for these examples state that such antibodies were not conventionally or routinely used to detect human proteins such as JUL-1.[25] This discussion indicates that the determination of whether a claim element is "conventional or routine" is not conducted in isolation, i.e., were such antibodies known generally, but rather whether their use in the specific context of the claim was well known, i.e., to detect human proteins such as JUL-1.[26]

The fifth and sixth example claims recite diagnostic methods which do not specify how the detection of JUL-1 in the plasma sample is performed,[27] but nevertheless have eligibility because these claims additionally require administering an effective amount of topical vitamin D and an effective amount of anti-tumor necrosis factor (TNF) antibodies respectively.[28] Significantly, the Patent Office indicates that administering anti-TNF antibodies to a patient with julitis was conventional, but nevertheless, when the claim elements are viewed in combination, the claim as a whole adds meaningful limits on the natural principle recited in the claim.[29]

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Effect of the Update

The Update establishes the specific procedures that the Examiners apply for determining patent eligibility during examination of patent applications. However, the Update does not have the force of law. Moreover, a federal district court recently held that claims which satisfy examination for eligibility conducted by the Patent Office are not necessarily valid under 35 U.S.C. § 101.[30] For example, the court stated "the fact that the PTO may have considered Alice-based guidelines before issuing the patents-in-suit does not mandate a finding that the patents are valid."[31] As a result, practitioners should be aware that the absence of a patent eligibility rejection or a withdrawal of such a rejection does not preclude an invalidity challenge in court based on 35 U.S.C. § 101.

Prosecution Strategies

The additional life sciences claim examples provided by the Update, along with the eligibility thereof as asserted by the Patent Office, demonstrates that diagnostic methods can be patent eligible, and these examples provide more clarity with respect to this issue relative to the prior guidelines. For example, avoiding recitation of a "diagnosing" step, reciting specific materials or specific methods used in the method, or reciting an "administering" step can achieve patent eligibility for diagnostic methods. Practitioners may wish to use these approaches in a variety of claims to prevent or overcome a patent eligibility rejection. Also, dependent claims can be implemented as fallback positions for potential validity challenges in court.

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[1] May 2016 Subject Matter Eligibility Update, 81 Fed. Reg. 27,381 (May 4, 2016) (to be codified at 37 C.F.R. pt. 1), https://www.federalregister.gov/articles/2016/05/06/2016-10724/may-2016-subject-matter-eligibility-update [hereinafter the "Update"].

[2] 35 U.S.C. § 101 states 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."

[3] The Update, *supra* note 1, at p. 27,381.

[4] "Subject Matter Eligibility Examples: Life Sciences," http://www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf [hereinafter the "additional examples"].

[5] 2014 Interim Guidance on Patent Subject Matter Eligibility, 79 Fed. Reg. 74,618 (December 16, 2014) (to be codified at 37 C.F.R. pt. 1), https://www.federalregister.gov/articles/2014/12/16/2014-29414/2014-interim-guidance-on-patent-subject-matter-eligibility [hereinafter "prior guidelines"].

[6] The Update, *supra* note 1, at 27,381.

[7] The additional examples, *supra* note 4, at 1–31.

[8] *Id*. at 9–16.

[9] The prior guidelines, *supra* note 5, at 74,627.

[10] *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289, 1296–97 (2012) [hereinafter "*Mayo*"].

[11] Example claim in its entirety:

> A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> (a) administering a drug providing 6-thioguanine to a subject having said immunemediated gastrointestinal disorder; and
>
> (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per 8x108 red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per 8x108 red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

[12] The prior guidelines, *supra* note 5, at 74,627.

[13] *Id.*

[14] The additional examples, *supra* note 4, at 9–16.

[15] *Id.*

[16] *Id.* at 10.

Example Claim 1 in its entirety:

> A method of detecting JUL-1 in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient; and
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

[17] *Id.* at 11.

[18] *Id.*

[19] *Mayo*, *supra* note 10 at 1297.

[20] The additional examples, *supra* note 4, at 10.

Example Claim 2 in its entirety:

> A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
>
> c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

[21] *Id.* at 11–12.

[22] *Id.* at 12.

[23] *Id.* at 10.

Example Claim 3 in its entirety:

> A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and
>
> c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

Example Claim 4 in its entirety:

> A method of diagnosing julitis in a patient, said method comprising:
>
> a. obtaining a plasma sample from a human patient;
>
> b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with antibody mAb-D33 and detecting binding between JUL-1 and antibody mAb-D33; and

c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

[24] *Id.* at 13–14.

[25] *Id.*

[26] *Id.*

[27] *Id.* at 10–11.

Example Claim 5 in its entirety:

A method of diagnosing and treating julitis in a patient, said method comprising:

a. obtaining a plasma sample from a human patient;

b. detecting whether JUL-1 is present in the plasma sample;

c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected; and

d. administering an effective amount of topical vitamin D to the diagnosed patient.

Example Claim 6 in its entirety:

A method of diagnosing and treating julitis in a patient, said method comprising:

a. obtaining a plasma sample from a human patient;

b. detecting whether JUL-1 is present in the plasma sample;

c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is

detected; and

d. administering an effective amount of anti-tumor necrosis factor (TNF) antibodies to the

diagnosed patient.

[28] *Id.* at 14–15.

[29] *Id.* at 15.

[30] *MacroPoint, LLC v. FourKites, Inc.*, No. 1:15CV1002, 2015 WL 6870118, at*3 (N.D. Ohio Nov. 6, 2015).

[31] *Id.*