JONES DAY

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COMMENTARY

U.S. Patent Office Releases "May 2016 Subject Matter Eligibility Update"

On May 4, 2016, the United States Patent and Trademark Office ("USPTO") released a "May 2016 Subject Matter Eligibility Update" ("May 2016 Update"), which provides additional guidance to examiners on patent eligibility under 35 U.S.C. § 101, including providing new Life Sciences Examples.

Included in the May 2016 Update are:

- A Federal Register Notice;
- A Memorandum to the patent examining corps with instructions on formulating subject matter eligibility rejections and responding to applicants' replies ("Memorandum");
- Additional subject matter eligibility examples in the life science area ("Life Sciences Examples");
- An index of eligibility examples; and
- An appendix of subject matter eligibility court decisions.

The May 2016 Update also provides an open-ended comment period to allow ongoing comments on subject matter eligibility topics and announces the selection of subject matter eligibility rejections as a new case study under the Topic Submission for Case Studies Pilot Program.

The Memorandum

The Memorandum provides examination instructions relating to subject matter eligibility as claimed under § 101.

In particular, the Memorandum addresses: (i) how examiners should formulate a subject matter eligibility rejection under § 101, and (ii) how examiners should evaluate an applicant response to such a rejection. These instructions are intended to assist examiners in applying the 2014 Interim Guidance on Patent Subject Matter Eligibility ("2014 Interim Eligibility Guidance") and the July 2015 Update: Subject Matter Eligibility ("July 2015 Update").

The Memorandum states that examiners should:

- Identify the judicial exception by referring to what is recited (i.e., set forth or described) in the claim and explain why it is considered an exception;
- Identify any additional elements (specifically point to claim features/limitations/steps) recited in the claim beyond the identified judicial exception; and
- Explain the reason(s) that the additional elements taken individually, *and* also taken as a combination,

do not result in the claim as a whole amounting to significantly more than the judicial exception.

The Memorandum also suggests how applicants may effectively respond to a § 101 rejection. In particular, according to the Memorandum, applicants may (i) amend the claim, e.g., to add additional elements or modify existing elements so that the claim as a whole amounts to significantly more than the judicial exception, and/or (ii) present persuasive arguments or evidence based on a good-faith belief as to why the rejection is in error. For example, applicants may challenge the identification of an abstract idea if the original rejection did not identify a U.S. Supreme Court or Federal Circuit decision in which a similar abstract idea was found. Applicants can also present a specific argument or evidence that the additional elements in a claim are not well-understood, routine, conventional activities previously engaged in by those in the relevant art. Further, applicants may argue the claim does not preempt all applications of the judicial exception. But the Memorandum notes that the absence of complete preemption does not demonstrate that a claim is eligible.

Life Sciences Examples

The Life Sciences Examples use hypothetical fact scenarios to illustrate analysis under the 2014 Interim Eligibility Guidance, in view of the Supreme Court decisions in *Alice Corp. v. CLS Bank International*, 573 U.S. ___, 134 S.Ct. 2347, 110 USPQ2d 1976 (2014), *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. ___, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972 (2013), and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 566 U.S. ___, 132 S. Ct. 1289, 101 USPQ2d 1961 (2012). Under this analysis, if a claim is directed to a judicial exception (e.g., an abstract idea, a law of nature, a product of nature, or a natural phenomenon), then the claim is evaluated to determine if any element, or combination of elements, in the claim is sufficient to ensure that the claim amounts to "significantly more" than the judicial exception.

The original Nature-Based Products Examples in the 2014 Interim Eligibility Guidance included 10 natural product examples (gunpowder and fireworks; pomelo juice; amazonic acid, pharmaceutical compositions, and methods of treatment; purified proteins; genetically modified bacterium; bacterial mixtures; nucleic acids; antibodies; cells; and food).

The new Life Sciences Examples in the May 2016 Update include:

- Two new natural product examples (vaccines and dietary sweeteners);
- One new law of nature example (diagnosing and treating a disease);
- One new abstract idea example (screening for gene alterations); and
- Two new streamlined analysis examples (paper-making machine and fat hydrolysis).

Two of these examples are highlighted below.

Example 28: Vaccines. New example 28 "Vaccines" illustrates the application of the markedly different characteristics and significantly more analyses to claims reciting hypothetical nature-based products.

In this example, the hypothetical patent applicant filed an application disclosing several types of Pigeon flu vaccines and evaluating their functional characteristics, such as immunogenicity.

Seven exemplary claims are provided by the USPTO. Four of these claims are reproduced below:

1. A vaccine comprising live attenuated Pigeon flu virus.
2. A vaccine comprising inactivated Pigeon flu virus.
3. A vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier.
4. A vaccine comprising: Peptide F; and a pharmaceutically acceptable carrier selected from the group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment.

The example notes that the specification defines "live attenuated Pigeon flu virus" as a live mutant virus that has been attenuated so that it has at least one mutation of its polymerase gene, which reduces its virulence as compared to naturally occurring Pigeon flu virus. No mutations of this polymerase gene are known to occur in nature.

The example also notes that the specification defines "inactivated Pigeon flu virus" as a naturally occurring Pigeon flu

virus that has been contacted with the chemical formalin that causes structural changes to the virus so that it can no longer reproduce.

The example further notes that prior to applicant's invention, water was routinely and conventionally used as a carrier for peptide vaccines. Isolation does not change any structural or functional characteristics of Peptide F (a naturally occurring peptide isolated from the Pigeon flu virus). The example also notes that although a pharmaceutically acceptable carrier, selected from a group consisting of a cream, emulsion, gel, liposome, nanoparticle, or ointment, comprises naturally occurring components (such as water and oil), when the components are assembled into the carrier form, the carrier has changed structural and physical characteristics that distinguish it from the closest counterpart in nature.

Claim 1 recites a vaccine comprising *live attenuated* Pigeon flu virus. Claim 2 recites a vaccine comprising *inactivated* Pigeon flu virus. Because both the live attenuated virus and the inactivated virus have markedly different characteristics from what exists in nature, these claims are *not* directed to a "product of nature" exception. Thus, both claims 1 and 2 are subject matter eligible.

Claims 3 and 4 both recite a mixture of Peptide F and a pharmaceutically acceptable carrier. In the case of claim 3, the carrier may be water, whereas for claim 4, the carrier is specified as a cream, emulsion, gel, liposome, nanoparticle, or ointment. As such, these claims are directed to a nature-based product that must be compared to its closest naturally occurring counterpart to determine if it has markedly different characteristics than the counterpart. For claim 3, there is no indication that mixing a peptide and water changes the structure, function, or other properties of the peptide or water. Thus, claim 3 is *not* subject matter eligible. In contrast, for claim 4, the recited carrier changes structural and physical characteristics that distinguish it from the closest counterpart in nature. Thus, claim 4 is subject matter eligible.

Example 29: Diagnosing and Treating Julitis. New example 29 "diagnosing and treating julitis" illustrates the application of the significantly more analysis to diagnostic and treatment claims using a hypothetical disease (julitis).

The hypothetical patent applicant discovered the presence of a protein known as "JUL-1" in a patient that can be used as a marker for the disease. The application discloses detection of the marker "JUL-1" by routine and conventional methods such as by immunoassays.
Seven exemplary claims are provided by the USPTO, and they are reproduced below:

1. 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.

2. 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.

3. 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.

4. 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.

5. 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.

6. 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.

7. A method of treating a patient with julitis, the method comprising administering an effective amount of anti-TNF antibodies to a patient suffering from julitis.

The example notes that applicant discloses detecting JUL-1 using anti-JUL-1 antibodies that may be naturally occurring (e.g., a human anti-JUL-1 antibody isolated from a patient known to have julitis), or non-naturally occurring (e.g., a porcine anti-JUL-1 antibody created by injecting pigs with JUL-1, or a specific monoclonal antibody named "mAb-D33" that was created by applicant). The example also notes that prior to applicant's invention, the use of porcine antibodies in veterinary therapeutics was known to most scientists in the field, but these antibodies were not routinely or conventionally used to detect human proteins such as JUL-1.

The example further notes that prior to applicant's invention, julitis was conventionally treated with anti-TNF antibodies, but for unknown reasons, some patients did not respond well to this conventional treatment. Applicant has successfully treated julitis patients (even those who are non-responsive to anti-TNF antibodies) with topical vitamin D, which had not previously been used to treat julitis.

Claim 1 recites two steps, obtaining a sample and detecting the presence of JUL-1 using an antibody. Because this claim is *not* directed to an exception, it is subject matter eligible. *Compare with Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015).

Claim 2 adds a third diagnosing step that "describes a correlation or relationship between the presence of JUL-1 in a patient's plasma and the presence of julitis in the patient," and thus, according to the USPTO, is directed to a judicial exception. The first two steps (recited in claim 1) are found to be conventional and routine and do not add something beyond the judicial exception. Thus, this claim is *not* subject matter eligible.

Claim 3 is also directed to a judicial exception because it recites a third diagnosing step. However, the use of the porcine antibody (which was not routinely used to detect human JUL-1 protein) adds an unconventional step such that the claim amounts to "significantly more" than the exception. Thus, this claim is subject matter eligible.

Similarly, claim 4 requires the use of the antibody mAb-D33 (which was not routinely used to detect human JUL-1 protein). Thus, this claim is also subject matter eligible.

Claims 5–7 recite nature-based product limitations (vitamin D, anti-TNF antibodies) but also recite administering steps, which are found to add "something more" to the claims. Thus, these claims are subject matter eligible.

Conclusion

The May 2016 Update provides additional guidance for examiners and applicants on how to formulate, understand, and respond to § 101 rejections, and it provides additional specific eligibility examples for those in the life sciences field, including for claims to vaccines and claims to methods of diagnosis or treatment.

Lawyer Contacts

For further information, please contact your principal Firm representative or one of the lawyers listed below. General email messages may be sent using our "Contact Us" form, which can be found at www.jonesday.com/contactus/.

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