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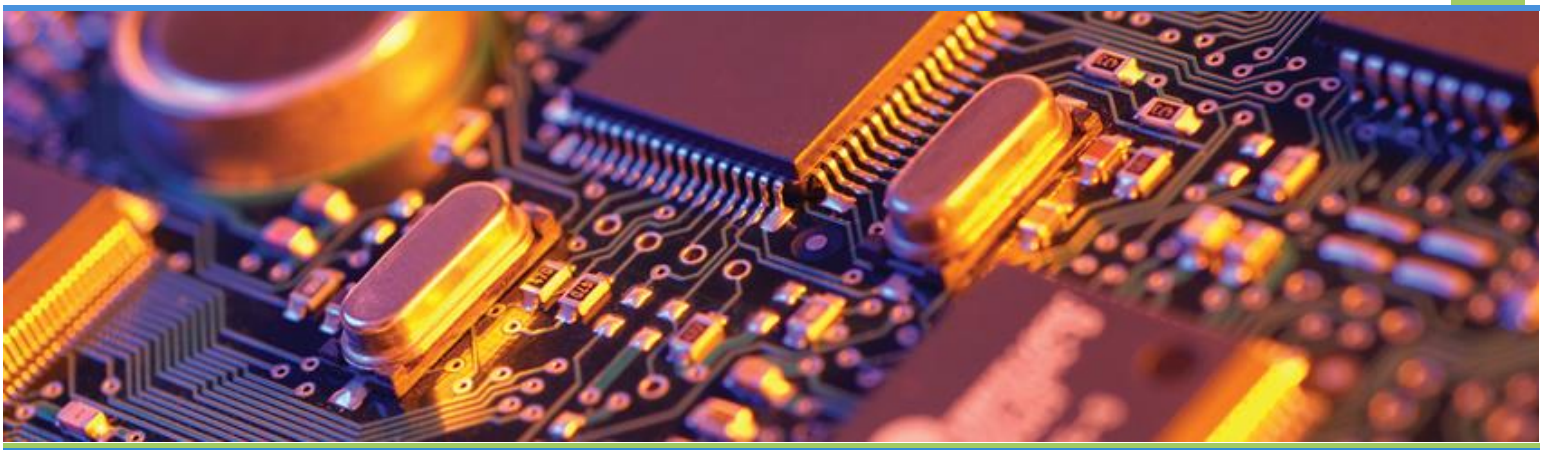

Intellectual Property & Technology | Alert

May 2016

USPTO Issues Subject Matter Eligibility Update with Examples for Life Sciences

Following the recent Supreme Court decisions in *Alice Corp*., *Myriad*, and *Mayo* which invalidated an array of claims under 35 U.S.C. § 101, patent subject matter eligibility has become a closely watched and debated issue. In its most recent attempt to decipher these decisions and apply them in patent examination, on May 4, 2016, the U.S. Patent and Trademark Office ("USPTO") issued a Subject Matter Eligibility Update ("May 2016 Update," link available here) May 4, 2016. The May 2016 Update provides a memorandum to the Patent Examining Corps on best practices in formulating a subject matter eligibility rejection and evaluating the applicant's response (link available here), along with additional subject matter eligibility examples in the life sciences area (link available here).

The Memorandum

In formulating a § 101 rejection, examiners should, according to the memorandum:

> (1) identify the judicial exception (*i.e.,* abstract idea, law of nature, or natural product) by referring to what is recited (*i.e.,* set forth or described) in the claim and explain why it is considered an exception;
>
> (2) identify any additional elements (specifically point to claim features/limitations/steps) recited in the claim beyond the identified judicial exception; and
>
> (3) 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 provides hints as to how applicants can effectively respond to a § 101 rejection. One option is to amend the claim to provide additional elements so that when these elements are considered individually or in combination, the claim as a whole amounts to significantly more than the judicial exception. Applicant can also present

persuasive arguments or evidence as to why the rejection is in error. For example, an applicant may challenge the identification of an abstract idea if the original rejection did not identify a binding court decision in which a similar abstract idea was found. Then the burden shifts back to the examiner to point to a case and explain what the corresponding abstract idea is. Applicant 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. Finally, while applicant may argue the claim does not preempt all applications of the judicial exception, the memorandum notes that the absence of complete preemption does not demonstrate that a claim is eligible.

Life Sciences Examples

As an initial matter, the memorandum at page 5 cautions the examiners not to use any examples recited as a basis for an eligibility rejection. It is acceptable for applicants, however, to cite an example in support of an argument for eligibility. As such, the published examples should be helpful in forming amendment and/or response strategies.

A total of six examples, 27 claims in the life sciences field are provided in the May 2016 Update, of which 22 claims are explained to be eligible. These include:

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

The general thrust of these examples is that for a nature-based product, it must have "markedly different characteristics" such as in structure, form, function, activity, or chemical or physical property than its naturally occurring counterpart. For claims directed to abstract idea or law of nature, a limitation that is not well-understood, routine and conventional would be sufficient to transform the claim into a patent-eligible application. Examples of such limitations include using a porcine antibody to detect a human protein to the extent it was not routinely or conventionally done; using a novel antibody; administering a specific drug for a new indication; a combination of additional elements that adds meaningful limits on the use of the exception; a specific microscopy detection method that was not routinely or conventionally used in the field; and a specific PCR method that was previously used by only a few scientists (as opposed to being routinely and conventionally used in the field as a whole).

Notably, in Example No. 29 pertaining to diagnosis and treatment method claims, *Mayo v. Prometheus* is cited to for providing "recited steps of administering a drug to a patient and determining the resultant level of 6-thioguanine in the patient 'are not themselves natural laws.'" Accordingly, a method claim having two steps, obtaining a sample and detecting the presence of a biomarker using its antibody, is found not directed to an exception, and is eligible. In contrast, when a third step of diagnosing a disease based on the present of the biomarker is added, the claim now "describes a correlation or relationship between the presence of [the biomarker]… and the presence of [the disease]," according to Example No. 29, and thus, is directed to at least one judicial exception, namely law of nature and/or abstract idea. Based on this example, one viable way of protecting biomarker inventions would seem to focus the claims on detection, not diagnosis.

Again citing to *Mayo v. Prometheus*, Example No. 29 confirms that a treatment method claim having a step of administering antibodies to a patient does not recite or describe any recognized judicial exception. Furthermore, by appending a specific administering step (even if routine and conventional) to an otherwise ineligible (albeit new) diagnostic method claim, "[t]he totality of these steps… integrate the exception into the diagnostic and treatment process, and amount to more than merely diagnosing a patient… and instructing a doctor to generically 'treat it.'… The claim is eligible." As such, treatment method claims might generally survive eligibility scrutiny in the USPTO, and offer another avenue for protecting diagnostic method claims.

Conclusion

The May 2016 Update provides some much-needed guidance for examiners and applicants on how to formulate, understand, and respond to § 101 rejections, particularly for those in the life sciences field. In addition to the memorandum and examples, the May 2016 Update also includes an index of all 33 USPTO eligibility examples (link available here), and a summary of subject matter eligibility court decisions (link available here). These provide a quick reference tool.

As a final observation, the June 2015 Federal Circuit decision in *Ariosa v. Sequenom*, finding prenatal diagnostic method claims patent ineligible as law of nature lacking an "inventive concept," has caused overwhelming concerns in both the life sciences and patent law communities. Indeed, in response to Sequenom's March 21 petition for *certiorari* seeking Supreme Court review, a total of 22 *amicus* briefs have been filed, unanimously supporting the grant of *certiorari*. Until a decision by the Court, the USPTO guidelines will serve as a practical road map for both the Patent Examining Corps and patent applicants to navigate the contours of subject matter eligibility.

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