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Diagnostic Method Patents In Doubt

USPTO OFFERS GUIDANCE ON CLAIMS RELATED TO NATURAL PRODUCTS, NATURAL LAWS

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Are diagnostic methods patentable? Until quite recently, the answer to this question would have been an unqualified "yes." But court decisions concerning subject matter eligibility for patenting have changed the answer to this question to a hesitant "maybe."

In 2013, the U.S. Supreme Court held that isolated, naturally occurring genomic DNA was a nonpatentable product of nature, even though isolating the DNA required breaking chemical bonds. *Association for Molecular Pathology v. Myriad Genetics,* 133 S. Ct. 2107, 2110 (2013). *Myriad* followed on the heels of another Supreme Court decision addressing the patent eligibility of a diagnostic method for determining whether a patient was receiving a safe and effective dosage of a drug by measuring the level of drug metabolite in the patient's blood. *Mayo Collaborative Services v. Prometheus Laboratories*, 132 S.Ct. 1289, 1291 (2012). The Supreme Court held the diagnostic method was not patentable because the patent claim had a natural law—the relationship between concentration of drug metabolite in the patient's blood and the likelihood that the dosage would prove either ineffective or harmful—at its core, and the additional steps in the claim were not enough to transform the unpatentable natural correlation into a patentable application of the natural law.

It worth noting that in *Myriad* the court addressed only the patentability of claims to a natural product, genomic DNA, while in *Prometheus* the court addressed only the patentability of a diagnostic method. More recently, a federal district court has combined the holdings of *Myriad* and *Prometheus* to reject claims for a diagnostic method that incorporated an unpatentable natural product, because the only additional steps in the process were routine and well-known. *Ariosa Diagnostics v. Sequenom*, C 11-06391 SI, 2013 WL 5863022, at *8 (N.D. Calif. Oct. 13, 2013).

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Sequenom's patent claims a method of noninvasive prenatal genetic testing in which paternally inherited DNA of fetal origin, known as cell-free fetal DNA (cffDNA), in a maternal blood sample is isolated, amplified and detected. The district court held that the diagnostic methods of the testing process was not patent eligible because the cffDNA was not patentable and the additional steps recited in the claims that included isolating, amplifying and detecting the nonpatentable cffDNA applied "well-understood, routine, and conventional activity to the natural phenomenon" and therefore do not add enough to the natural phenomena of cffDNA to meet the requirements for patent eligibility.

Most diagnostic methods include detection of naturally occurring biological molecules. Commonly detected biological molecules include naturally occurring DNA sequences, proteins, hormones and other naturally occurring biological compounds. After *Myriad*, none of these biological molecules can be regarded as patent eligible.

According to *Sequenom*, the combination of *Myriad* and *Prometheus* severely limits patentability of diagnostic methods which hinge on the detection of a biological molecule even if discovery of the biological molecule was considered "groundbreaking, in-

novative, and brilliant." To be patent eligible a diagnostic method must contain other elements, or combinations of elements, sometimes called "an inventive concept," to ensure that the patent is more than a patent to a natural law or naturally occurring product.

Three-Step Process

While the case law on patent-eligible subject matter continues to evolve, the U.S. Patent and Trademark Office (USPTO) issued guidance to its examiners on March 4, instructing them on determining patentability of claims related to natural products and natural laws.

The new guidelines are in view of the U.S. Supreme Court decisions in *Myriad* and *Prometheus*. On March 19, the USPTO followed up with an extensive PowerPoint presentation for examiners that includes additional examples of patent-eligible and patent-ineligible claims. The new guidelines focus on "judicial exceptions," a concept that was articulated in *Prometheus*. There, the court stated that § 101 contains an implicit exception: laws of nature, natural phenomena and abstract ideas are not patentable. The new guidelines further define the term "judicial example," and provide examples of patentable and nonpatentable subject matter based on *Myriad, Prometheus* and earlier rulings. Although the court's holding in *Myriad* was confined to DNA, the new USPTO guidelines include examiner rules for determining the patent eligibility of other natural products, including isolated proteins.

The new guidelines instruct the examiners to use a three-step process to determine whether a claim contains patent-eligible subject matter under 35 U.S.C. § 101. In step one, the examiner determines whether the claim is directed to one of the four § 101 statutory categories, i.e., a process, machine, manufacture or composition of matter. In step two, the examiner determines whether the claim recites or involves a judicial exception to patentability. The new guidelines explicitly state that judicial exceptions include natural laws and principles, natural phenomena, and/or natural products, including chemicals derived from natural sources, nucleic acids, organisms, proteins and peptides, and that if there is any doubt whether the claim contains a judicial exception, the examiner must proceed to step three. In step three, the examiner determines whether the claim as a whole recites something significantly different from the judicial exception.

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The USPTO guidelines list factors (a)-(f) that weigh toward patent eligibility and factors (g)-(i) that weigh against it. To weigh toward patentability, the claim needs to take the natural product or law and add something more, possibly additional steps or elements involved in using the natural product or law, or in the case of a natural product, additional features that make the product different from what is in nature. The guidelines also state that broad claims which preclude all use of the natural product or law by others will weigh against patentability.

In one USPTO example, a claim recites a process of diagnosing a disease by contacting a patient's blood with a novel diagnostic antibody XYZ and performing flow cytometry to detect binding to protein ABC. In the USPTO analysis, this claim is patent eligible because of its requirement for the novel antibody XYZ and using the particular detection technique, flow cytometry. Under this analysis, the requirements make the claim significantly different from the natural principle and do not foreclose others from using the natural principle in other ways. Thus, the claim is patentable. Presumably, if the claim had been for diagnosis by detection of ABC by any means, or detection by a conventional method, the claim would not have added something "significantly different" and would not be patentable.

While the new USPTO guidance does not make all patents involving natural laws and products ineligible, it does require a narrowing of claims for use of any natural law or product, no matter how much effort and ingenuity was required to discover it, and this represents a change from USPTO policy prior to *Prometheus*. For diagnostic methods, it means broad claims that used to be patentable are no longer eligible. As a result, an inventor of a diagnostic method may find they can obtain some claims, but the required narrowness provides little protection for their invention. ■

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