

## Ask The Expert: Are Diagnostic Patents Dead?

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**Let's say I discovered, for example, that I can diagnose prostate cancer by detecting protein X in blood. I am the first person to make the correlation between this protein and prostate cancer. Can I patent this invention?**

Unfortunately, the invention you describe — without more — is considered to be the discovery of a natural principle that is not eligible for patent protection. You have discovered something that happens naturally without human ingenuity or intervention. The Supreme Court in *Mayo v. Prometheus* found that this type of discovery by itself is not eligible for patent protection.

**But I thought the Supreme Court's decision was called *Myriad*, and that it was related only to patenting DNA?**

The Supreme Court recently decided *AMP v. Myriad*, which related to patenting genes. However, other important cases, especially *Mayo v. Prometheus*, are having a significant impact on patents in personalized medicine and diagnostics. In *Prometheus*, the Supreme Court ruled that a natural correlation—in this case between a biomarker and the therapeutic efficacy of a drug—is a natural law that cannot be patented.

Also, keep in mind that although the *Myriad* case involved genes, the court's decision is not necessarily limited to genes. Other subject matter, like isolated natural proteins and compositions comprising combinations of natural products, are impacted by the Supreme Court's *Myriad* decision.

**What if I discover a new way of detecting protein X? For example, using a new antibody or a new method?**

This type of claim is likely patent eligible. The Supreme Court has made clear that “applications” of natural principles are patent eligible. Examples of “applications” of natural principles include methods for detecting the correlation and methods of treating patients who are identified by detecting the correlation.

**Great! So I can patent a method of detecting protein X; I just can't patent the correlation between protein X and cancer?**

Not so fast. A simply stated “method of detecting the protein in blood,” for example, will only be patent eligible if it includes elements or steps in addition to the natural principle that convert that natural principle into an “application” of that natural principle.

Although the case law is still unsettled as to what types of elements or steps are sufficient to convert a natural principle to an application of that principle, the guidance we have today suggests that to be patentable, the method must be demonstrably new—for example, employ a new antibody or recite a new method of detecting protein X.

**What guidance could we look for to help determine whether our invention can be patented?**

The U.S. Patent and Trademark Office (USPTO) in March issued guidance focused on these types of patent claims. The guidance explains how a claim involving a natural principle may be patent eligible if it goes beyond describing a natural phenomenon. But a considerable amount of confusion remains.

The Court of Appeals for the Federal Circuit is currently reviewing several district court decisions related to personalized medicine and diagnostics that should provide insight and guidance. For instance, the Federal Circuit will soon review *Ariosa v. Sequenom*. In this case, Judge Illston found that claims directed to non-invasive pre-natal detection methods were not eligible for patent protection, in part, because the claimed steps that were “in addition” to the natural principle were no more than well-understood, routine, or conventional activity already engaged in by the scientific community. In reviewing that decision, the Federal Circuit will be forced to provide some guidance as to the scope of the “additional steps” that may convert an otherwise patent ineligible natural law into patent eligible subject matter. Clarity is also likely to come as the USPTO has time to consider public comments on the USPTO’s March 4, 2014 guidance.

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