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Court Reviews Patentable Subject Matter In Biosciences

Decisions will affect medical diagnostic and personalized medicine fields

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Under U.S. law, inventors may obtain a patent for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof[.]" Since the Supreme Court's 1980 decision in *Diamond v. Chakrabarty* (447 U.S. 303), the U.S. Patent and Trademark Office (USPTO) has expanded the types of patentable subject matter to include biological materials such as nucleic acids and proteins, as well as methods of using these materials.

However, while the scope of patent-eligible subject matter is generally broad, the Supreme Court has also recognized that not everything is a patentable invention under the law. Notable exceptions to patentable subject matter include inventions that cover: (1) laws of nature; (2) physical phenomena; and (3) abstract ideas.

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These inventions have been deemed ineligible for patent protection. Unfortunately, the Supreme Court has done little to provide insight into the scope of these exceptions, much less articulate clear tests for patent-eligible subject matter.

For many years, U.S. patent policy has allowed biological molecules and genetic tests to be patented. Among other requirements, a patent-eligible DNA molecule must be manipulated and isolated through human intervention so as to have a different identity and a distinctive chemical form as compared to naturally occurring DNA. Similarly, diagnostic testing may also be patented, so long as the tests involve clear, tangible steps, chemical transformations or the use of a specific machine or device. However, the settled understanding that biological molecules and certain diagnostic tests are eligible for patenting was recently called into question in two cases that will have significant impact on the biotechnology industry in general and the personalized medicine area in particular.

In *Mayo Collaborative Services et al. v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court held that an invention directed to a diagnostic relationship between biological materials was, at its core, a naturally occurring law of nature and hence patent-ineligible. The patent at issue related to methods for determining the ideal dosage of thiopurine drugs for treatment of autoimmune diseases. The inventors discovered that the drug was most effective when the concentration of a particular metabolite in a blood sample fell within a narrow range.

The patent covered a diagnostic method in a series of steps: (1) administer the drug, (2) determine

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the level of the metabolite, and (3) if it falls outside of an optimal range for effectiveness, increase or decrease the dosage to return the level to the optimal range. In holding the invention ineligible for patent protection, the Court said that more than an observation of a relationship was necessary to transform the relationship into a patent-eligible application of a natural law.

It appears clear that diagnostic inventions relating to correlations between biological materials and an outcome will now require more for patent protection than merely a simple observation, application or use of those materials.

In *Association of Molecular Pathology v. Myriad Genetics Inc.*, the Supreme Court will decide whether Myriad's claims to isolated breast cancer genes are patent-eligible subject matter. *Myriad* holds patents on two genes which are associated with a heightened risk of breast cancer, and uses these genes to test a patient's cancer risk. The Association of Molecular Pathology challenged these patents because they believe that human genes are products of nature and thus unpatentable.

The U.S. Court of Appeals for the Federal Circuit previously upheld patentability, holding that Myriad's isolated DNA is a man-made composition that is different from naturally occurring DNA. The Supreme Court granted certiorari to determine whether Myriad's isolated DNA is properly patentable subject matter. The Court is scheduled to hear oral arguments on April 15, 2013, and a decision is expected by summer.

Three-Step Test

Both the *Prometheus* and *Myriad* decisions will significantly affect subject-matter eligibility for inventions in many areas, but particularly in medical diagnostics and personalized medicine. While it is unclear how the USPTO or the courts will apply the new standards, steps can be taken to address these changes.

The USPTO has issued guidelines outlining its approach to examination of method claims after *Prometheus*. The guidelines describe a three-step test for patent eligibility: (1) determine whether the claim is directed to a process; (2) determine whether the claim focuses on a natural principle; and (3) determine whether the claim includes additional elements or a combination of elements that integrate the natural principle into the invention such that the natural principle is practically applied.

With respect to step (3), an invention that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself. According to the guidelines, the analysis turns on whether the invention has added enough to show a practical application of the natural principle. In other words, the invention cannot cover the natural principle itself such that it is effectively standing alone. A bare statement of a naturally occurring correlation, albeit a newly discovered or narrowly defined correlation, would fail the inquiry.

Thus it appears clear that diagnostic inventions relating to correlations between biological materials and an outcome will now require more for patent protection than merely a simple observation, application or use of those materials. These guidelines should be taken into account when drafting patent applications in the medical diagnostic or personalized medicine fields.

Thoughtful approaches in the patent drafting process may also be helpful to address these new subject matter eligibility standards. For example, if a step in the invention relies upon an unconventional, novel, or nonobvious technique or reagent (for example, a novel detection agent), the claim could be argued to be a patent-eligible application of a law of nature. Similarly, an invention that includes an unconventional or nonobvious combination of known markers may be sufficient to reach patent-eligible status. Use of a "man-made" sample may also impart patent eligibility, for example, a combination of a marker and a biological sample that would not otherwise exist in nature. Thus, while the *Myriad* and *Prometheus* decisions may impose limits on what can be covered in personalized-medicine or diagnostic medical technologies, it may still be possible to protect much of these inventions through strategic claim drafting and application preparation. ■