

Medical Technology Patents Affected by U.S. Supreme Court

By Christopher Ramsey, PhD



Several recent decisions by the U.S. Supreme Court affect the extent to which two important classes of medical technology inventions are patentable: those inventions that involve (1) natural products or (2) natural processes. By themselves, natural products and processes have never qualified as patentable subject matter, while isolated natural products and practical applications of natural process have been patentable. Many patented blockbuster drugs and medical treatment methods are derived from natural products or the body's natural processes.

The well-publicized gene patent debate concerns patents on isolated human genes and methods of using them to detect a person's genetic disposition to diseases such as breast cancer. In *Association for Molecular Pathology v. Myriad Genetics*, 133 S.Ct. 2107 (2013), the Supreme Court recently decided that isolated human genes cannot be patented because isolating genes from their natural environment is not an act of invention.

The United States Patent and Trademark Office (USPTO), the government agency responsible for examining patent applications, applies the Myriad gene patent case to all natural products, such as proteins and other naturally occurring molecules. For now, people will not be able to patent natural products in the U.S. merely by identifying a use for them and isolating them from nature. Instead, for natural products to qualify as patentable subject matter, the isolated natural products will need to be combined with other materials or modified so that they are not just isolated copies of their natural selves.

In *Mayo v. Prometheus*, 132 S.Ct. 1289 (2012), the Supreme Court decided that a diagnostic method for determining the best dose of the drug thiopurine for a given patient was not patentable subject matter. The method involved the steps of: (a) administering a drug that produced a particular metabolite in the patient's body and (b) determining the amount of metabolite the patient produced. The amount corresponded to the dose of thiopurine the patient needed.

Prior to the Mayo decision, this method would have been patentable subject matter because the "administering" and "determining" steps were not part of the body's natural metabolic processes – they required human involvement. The Supreme Court concluded, however, such steps were just routine physician activities. Accordingly, after Mayo, a method involving a natural process cannot be patented just by practically applying the natural process using routinely-performed steps.

These Supreme Court decisions do not signify the end of patenting naturally-derived products or practical applications of natural process, although they will adversely affect certain patents that issued prior to the date of these decisions. For the patents that will be adversely affected, the problem will often be a matter of how those patents define their respective inven-


tions. Their fate, in other words, will lie as a matter of wordsmithing, but not be based on the overall subject matter the patents describe.

Inventions involving naturally-derived products or natural processes are still patentable, but the Supreme Court has made it more difficult. Patent practitioners must artfully draft patents to ensure that inventions are precisely defined to fit within these new boundaries of what is patentable subject matter.

Christopher M. Ramsey, Ph.D. practices intellectual property law and is a registered patent attorney at Gray-Robinson, P.A. in Orlando, FL. He advises clients on patent, trademark, and copyright issues. Chris is a Ph.D. chemist. His research is published in more than twenty peer reviewed articles. For additional information, Chris can be reached at 407-244-5686; christopher.ramsey@gray-robinson.com; or by visiting www.gray-robinson.com. ■

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