# Patents and (Ag)Biotechnology

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Most, if not all, countries that have a patent system provide some type of protection for (ag) biotech inventions.

- Transgenic Plants and/or Seeds
  (e.g., United States, Europe, Australia)

- Transformed Plant Cells
(add e.g., Canada, China and India (sometimes))

- Recombinant DNA, Transformed DNA Molecules, Promoters, Vectors, Optimized Transit Peptides
(add the rest of the world!)

The United States Patent code states that to be eligible for a patent in the United States, an invention must be:

- Directed to Patentable Subject Matter (Process, Machine, Manufacture, or Composition of Matter (or Improvement Thereof) (Section 101)
- Novel (Section 102);
- Useful (Sections 101 and 112); and
- Nonobvious (Section 103).

The US Patent Code also requires the patentee to describe the invention in a manner sufficient to enable one of skill in the art to reproduce the patented invention (Section 112).

Patent claims directed to genes and/or a DNA sequence encoding a particular protein are generally treated as compositions of matter.

Courts and the USPTO at times attempted to limit this broad language or create "exclusions" to otherwise patent-eligible subject matter.

In 1980, in the landmark case of *Diamond v. Chakrabarty,* the US Supreme Court cleared up much of this confusion, holding that the patent statute should be given an expansive reading, stating that patent-eligible subject matter includes "anything under the sun that is made by man."

Following *Chakrabarty,* many patents issued on "isolated and purified" DNA sequences and proteins, even if the DNA sequence or protein existed in nature, albeit in an impure state, or not isolated.

**UNTIL JUNE 13, 2013!**

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## *Association for Molecular Pathology v. Myriad Genetics ("MYRIAD")*

In MYRIAD, the main question was whether DNA sequences that had been isolated (removed and separated from its natural environment) from the body were patentable.

District Court Holding – Patent Invalid because drawn to non-patentable subject matter.

Court of Appeals for the Federal Circuit – Reversed in part, holding that those claims directed to isolated DNA which did not exist alone in nature were patentable.

US Supreme Court – Reversed the Federal Circuit, ruling that "A naturally occurring DNA segment is a product of nature and not patent eligible **merely because it has been isolated,"** [emphasis added] invalidating MYRIAD's patents on the BRCA1 and BRCA2 genes. However, the Court also held that **synthesized** DNA sequences, not occurring in nature, can still be eligible for patent protection.

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# Update on MYRIAD

Several companies entered the market and began BRCA1 and BRCA2 diagnostic testing.

MYRIAD has sued several of these companies for patent infringement, including Quest Diagnostics, Gene DX, Ambry and Counsyl.

MYRIAD's case against one of these companies, Gene DX alleges infringement of sixteen different MYRIAD patents.

Gene DX has requested Inter Partes Review before the USPTO, challenging 11 of the MYRIAD patents. To be continued….

## *Mayo Collaborative Services v. Prometheus Labs, Inc. ("MAYO")*

In MAYO, the question was whether the patent claims added enough substance to what a doctor already could observe from simply applying the laws of nature.

The claims in question in MAYO were directed to a two step method of "optimizing therapeutic efficacy" for treatment of a gastrointestinal disorder.

Essentially, the claims required the doctor to 1) administer one drug (a thiopurine); and 2) determine the level of a metabolite of the drug in the bloodstream of the patient, and thereby decide whether or not to increase or decrease the dosage of the drug.

After a couple of trips to the Federal Circuit, the US Supreme Court applied a 4 step test and determined that the claimed method was not sufficient to transform unpatentable natural correlations (i.e., laws of nature) into patentable applications of those regularities.

# Impact of MYRIAD and MAYO

On March 4, 2014, The USPTO issued final guidelines to its Patent Examiners to assist them in determining what subject matter involving laws of nature, natural phenomena and natural products is patent eligible.

The guidelines are not law and not binding of federal courts!

The guidelines lay out a three part test for Examiners to follow when determining patent eligibility of claimed subject matter.

**Step One:** Is the claim directed to one of the four statutory categories of patent eligible subject matter (i.e., a process, machine, manufacture, or composition of matter)? If NO, the subject matter is not eligible for patenting. If YES, the Examiner is to go to Step Two.

## Impact of MYRIAD and MAYO (cont.)

**Step Two:** Is the claim directed to a "judicial exception" to the four statutory categories (i.e., is it directed to subject matter the courts have carved out of the statutory categories and deemed patent ineligible for public policy reasons, such as an abstract idea, a law of nature / natural phenomenon, or a natural product)? If NO, the claim is directed to patent eligible subject matter. If YES/maybe, the Examiner is to go to Step Three.

**Step Three:** Does the claim as a whole recite something "significantly different" than a judicial exception (i.e., significantly different than an abstract idea, law of nature or natural product)? If NO, the subject matter is not eligible for patenting. If YES, the claim is directed to patent eligible subject matter.