

in the news

Science and Technology



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The Future of Patentable DNA: A Myriad of Possibilities

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Association for Molecular Pathology et al. v. Myriad Genetics, Inc., et al.

Summary

On Thursday, June 13, 2013, the Supreme Court held that a patent claim directed to “an isolated DNA molecule” was not patent eligible under 35 U.S.C. §101 solely because the DNA molecule had been “isolated” from the rest of the genome. The Court found, however, that a cDNA (complementary DNA) molecule may be patent eligible, because a cDNA molecule is “not found in nature.” This conclusion assumes

that a cDNA molecule is different from the genomic sequence because it lacks intron sequences.¹

This holding potentially impacts claims directed to prokaryotic nucleic acid sequences, short segments of eukaryotic nucleic acid, regulatory regions and/or promoters, isolated proteins, antibodies, naturally occurring mutations such as SNPs, regulatory RNA sequences, such as siRNA, RNAi, shRNA, etc., and arrays.

¹ Genomic DNA comprises both introns (non-coding regions of DNA) and exons (coding regions). In vivo, genomic DNA is transcribed to RNA and processed to remove the introns. The complementary DNA to the processed RNA molecule is referred to as cDNA, and due to the lack of introns, the cDNA molecule is not the same as the genomic sequence.



As a result, we strongly recommend reviewing your patent estate to determine the potential impact of the Myriad decision and, if necessary, to devise new claim strategies. If a claim in your estate is directed to a sequence that may be found in a cell or organism, the claim may be invalid as directed to an unpatentable product of nature.

For issued patents, we recommend analyzing the benefit of a reissue application to potentially redraft any claims that may be held invalid. For new or presently pending claims, we recommend redrafting the claims to encompass a sequence element that is not found in a cell or organism.

In addition to evaluating your own estate, it may be beneficial to use the Myriad decision offensively against competitors. Please contact a member of the Science and Technology practice for more details.

Case Analysis

The present case (*Association for Molecular Pathology et al. v. Myriad Genetics, Inc, et al.*) stems from Myriad's research and patents surrounding the BRCA1 and BRCA2 sequences. Specific variants, or mutations, of these sequences are associated with a significantly increased risk of breast and ovarian cancer in afflicted women. Myriad built a patent estate around this discovery, including claims to the isolated BRCA1 and BRCA2 sequences. These patents² were challenged under §101 of the Patent Act, with the challengers alleging that "isolated" sequences are not patent eligible because despite the fact that the sequences are no longer within the human body, they are still products of nature.

The Supreme Court has "long held that [Section 101 of the Patent Act] contains an important implicit exception

[:] Laws of Nature, natural phenomena, and abstract ideas are not patentable" (slip opinion pg. 11).

Prior to Thursday's Supreme Court decision, it was widely understood that a claim directed to "an isolated DNA molecule" was patentable by virtue of the fact that the DNA molecule had been separated from the natural environment and was in a form that was no longer found in nature. Hence, it was not a "natural product."

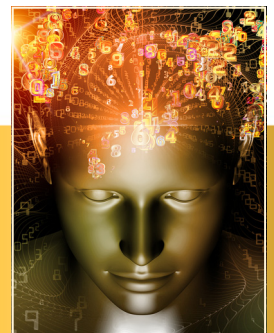
Thursday, however, the Supreme Court found that merely "isolating" a DNA molecule was not sufficient to render the molecule patent eligible. The Court explains that

"[t]he location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes" (slip opinion pg. 12).

The Court continued, saying that in this case "Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention" (slip opinion pg. 12).

In contrast, the Court reasoned that eukaryotic cDNA may be patent eligible. cDNA, or complementary

² The patents at issue include claims 1, 2, 5, 6, and 7 of US Patent 5,747,282, claim 1 of US Patent 5,693,473, and claims 1, 6, and 7 of US Patent 5,837,492.





DNA, is a nucleic acid sequence that is complementary to the mRNA for a particular gene. Eukaryotic cDNA sequence lacks introns derived from the genomic sequence, and therefore, is not a sequence that would be “found in nature,” but rather, is lab created. Hence, the Court found that cDNA was patent eligible under §101 because it is not a “product of nature.”

The Supreme Court addressed arguments that the Court should find “isolated” sequences patent eligible due to reliance on the Patent Office’s history of allowing such claims by indicating that such reliance concerns “are better directed to Congress.”

Implications

- Prokaryotic Nucleic Acid Sequences

Prokaryotic chromosomes do not comprise introns. Therefore, it would appear that bacterial nucleic acid sequences, by themselves, are no longer patent eligible, as there is not a way to produce a cDNA molecule that is “not found in nature.” Even if a court found that a cDNA molecule derived from a prokaryotic organism was eligible under §101 by virtue of being lab manipulated, it would seem that such a sequence would minimally be subject to challenge under §103 for obviousness in light of the genomic sequence.

It may, however, be possible to claim a prokaryotic sequence that is operably linked to a different promoter, or that is fused with a different genetic segment, so as to create a sequence “not found in nature.” In this manner, vectors may be patent eligible.

- Short Segments of Eukaryotic DNA

As short segments of eukaryotic DNA may not cross an intron/exon boundary, it appears that they would also no longer be patent eligible, because similar to prokaryotic sequences, there is not a way to produce a cDNA molecule that is “not found in nature.” This would impact claims directed to, for example, 15 contiguous nucleotides of a

particular genetic sequence. It may also impact claims to probes, and claims to single nucleotide polymorphisms (SNPs).

- Promoters/Regulatory regions

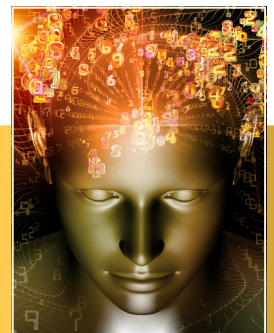
The Court’s decision only seemed to address coding regions of the genome. Non-coding regions, such as promoters, enhancers, repressors, etc. were not mentioned. However, as none of these sequences, on their own, can be manipulated in a manner analogous to the creation of cDNA it would appear that these sequences are no longer patent eligible either.

It may, however, be possible to create “new” regulatory “regions” that combine a promoter and regulatory sequences in an order or manner not found in nature.

- Isolated Proteins

The Court’s decision did not directly address the patent eligibility of isolated protein sequences. Following the Court’s logic, however, it would appear that a claim directed to an “isolated” protein, and nothing more, may no longer be patent eligible as such a protein may “be found in nature.”

It would appear that fusion proteins, or other manipulated proteins may still be patent eligible by virtue of the fact that they are “not found in nature.”





- Antibodies

An antibody is a specific type of protein. Generically speaking, researchers will use the innate ability of an organism to develop antibodies against a particular target antigen, and then isolate the antibody or antibody-producing cell from the organism. It is not clear how such isolation techniques will be addressed under the Myriad decision.

It may, however, be possible to claim a hybridoma, as the hybridoma is a cell fusion that is not found in nature. It may also be possible to claim chimeric antibodies, humanized antibodies, or single chain antibodies, for instance, as those antibodies are not sequences typically “found in nature.”

- Mutations

The Court specifically mentions that it is not making a decision on the application of §101 to genetic sequences that have been altered. It would appear, though, that claims to mutations that are found in nature, even if not “wild-type” would be patent ineligible.

Mutations that fuse two heterologous sequences, or that mutate a sequence to something that has not yet been seen in nature, however, would still seem to be patent eligible.

- Regulatory RNA sequences

A great deal of research has focused on small RNA molecules that regulate transcription in a cell – these include RNAi, siRNA, and shRNA. The status of claims to these sequences is not immediately clear, and will most likely have to be determined on a case by case basis with the test being whether the sequences would be “found in nature” or whether they are artificial lab constructs.

- Genetically modified organisms

Genetically modified organisms still appear to be patent eligible. These organisms, as explained by the Court, do not appear in nature. And the Court seemed to endorse the *Chakrabarty* decision as still being good law.

Suggestions

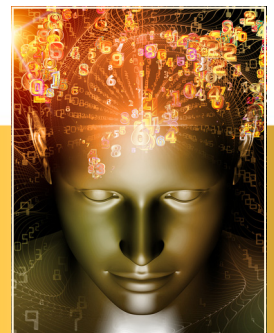
In light of the June 13th decision, we strongly recommend reviewing your patent estate to determine which claims may be impacted by this decision.

Issued Patents:

If claims in an issued patent are directed to unpatentable sequences, we recommend analyzing the patent to determine if a reissue application will be helpful. If the application is within two years of issuance, this procedure may be of great significance in maintaining patent validity. If the patent has been issued for more than two years, a reissue may still offer a solution if the claim is narrowed. This may, for instance, be possible by adding a limitation to the claim that is not found in nature.

New or Presently Pending Applications:

For presently pending applications, we recommend analyzing the specification for potential claim elements that are not found in nature, but that are not





unnecessarily restricting. For instance, it may be possible to claim a vector comprising the nucleic acid sequence, without specifically indicating any other components of the vector.³

For new applications, we recommend defining terms in the specification to exclude sequences found in nature. For instance, in reference to antibodies, the term

“chimeric” may be defined as “at least one amino acid change from the wild-type sequence.” This definition indicates the claimed sequence is not found in nature, while not being excessively restricting. All such amendments, however, should also be viewed in light of potential written description/enablement, novelty, and obviousness issues. ■

For More Information

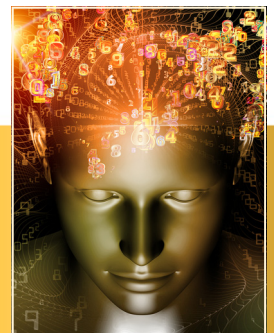
If you would like a more detailed analysis of your specific claims, please contact us. In addition, we expect that the US Patent and Trademark Office will soon issue Examiner guidelines that reflect the changes brought by the Myriad decision. Similarly, lower court decisions in the coming months will also elucidate the scope of the Myriad decision. We are monitoring such cases and will keep you informed of new developments.



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³ It is not clear, however, how the courts or the Patent Office will view the obviousness of such claims.





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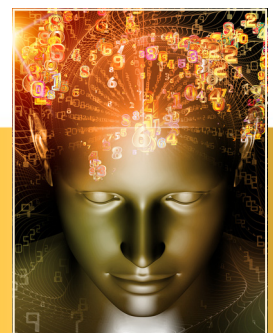
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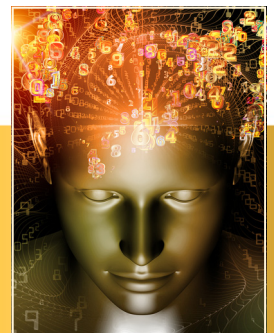
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