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INTELLECTUAL PROPERTY
ALERT

SUPREME COURT HANDS DOWN DECISION IN *MYRIAD* — MUCH ADO ABOUT NOTHING

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The United States Supreme Court ruled today that a naturally occurring isolated DNA is not patent eligible, but cDNA is patent eligible because it is not a product of nature. The Supreme Court also noted that this decision does not involve method claims, patents on new applications of knowledge about BRCA1 and BRCA2 genes, or the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. The Court held that genes and information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material. cDNA retains the naturally occurring exons of DNA, but is distinct from the DNA from which it is derived, because it is missing the introns. What about the situation where the genomic DNA does not have any introns? The Supreme Court discussed that situation where a "very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA."

The Court noted that claim 1 of the patent covers genomic DNA coding for the amino acid sequence of SEQ ID No. 2. Claim 2 is not impacted by the decision because the claim recites a limitation of an express nucleotide sequence obtained from cDNA. Claim 5, which depends from claim 1, recites "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 1." Claim 6, which depends from claim 2, recites "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 2." This poses an interesting dilemma for the Federal Circuit as to the fate of similar type claims to smaller DNA fragments. For example, if a DNA fragment covers a junction of two exons, the claim should represent patent eligible subject matter under §101.

How will this decision impact the Biotech industry? Currently, there are over 3,000 issued patents with claims directed to naturally occurring human DNA sequences. Those claims will not be asserted against third parties. All the major Biotech companies and Big Pharma have these types of patents. With this decision, the Biotech industry and patent practitioners now have a rule book in which to stake claims in patent eligible subject matter.

The initial reaction from investors sent the stock of Myriad Genetics, the company involved, higher.

As Mark Twain once said, "The reports of my death are greatly exaggerated."

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