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Myriad Conflicts with Real World Molecular Biology

By Michael H. Anderson, Ph.D.
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In a unanimous opinion, on June 13, the Supreme Court drew a sharp line between isolated DNA (not patentable subject matter) and cDNA (patentable subject matter). *See Association for Molecular Pathology v. Myriad Genetics,* 2013 DJDAR 7484 (2013). In so doing, the court affirmed in part and reversed in part the Federal Circuit's decision regarding the subject matter eligibility of Myriad's composition claims. Continuing a trend of narrowing Section 101 patentable subject matter, the decision addressed two distinct issues: (1) the patentability of naturally occurring isolated DNA, and (2) the patentability of synthetically created DNA known as cDNA (a version of DNA that only includes protein-coding exons). Unfortunately, the Supreme Court's finding that cDNA is patentable, while isolated DNA is not, conflicts with real world molecular biology.

Isolated DNA

The Supreme Court has long recognized three exceptions to subject matter eligibility: laws of nature, natural phenomena and abstract ideas. As in previous patentable subject matter cases, the court first analyzed what Myriad had accomplished. "Myriad's principle contribution was uncovering the precise genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13."

The question the court faced is whether the discovery of the location and genetic sequence of BRCA1 and BRCA2 rendered those genes patentable. The court held 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." The court distinguished Myriad's claims to isolated DNA sequences from those found to be patentable in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In *Diamond,* the composition claims to engineered bacterial DNA were patentable because they did not cover a naturally occurring composition of matter, but rather "a product of human ingenuity having a distinctive name, character [and] use" and which had "markedly different characteristics from any [DNA sequences] found in nature." Also relying on *Funk Brothers Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948), the court held that Myriad's claims "fell squarely within the law of nature exception." Although the court pointed out that isolation of DNA from the cell severs chemical bonds, it found that this isolation was not enough to render the DNA patent eligible.

The court adopted an information-centric view of DNA in reaching its conclusion, noting that Myriad's claims are not expressed in terms of chemical composition, but rather focus on the

genetic information encoded in the DNA sequences. In other words, Myriad's claims to natural isolated DNA did not change the informational content of the sequences in any way.

cDNA

The Supreme Court took a different position with regard to cDNA. The decision noted that "cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA." Because cDNA is "an exons-only molecule," the court found that it is distinct from natural DNA, and is therefore, not a product of nature. In contrast to purifying unprocessed genomic DNA, "the lab technician unquestionably creates something new when cDNA is made." Noting a possible exception to this rule, the court suggested that very short sequences of cDNA may not be patent eligible because they "have no intervening introns to remove when creating cDNA." Thus, under some circumstances, a short cDNA sequence may not be patent eligible subject matter because it is indistinguishable from "natural DNA."

As the decision emphasizes that DNA must be modified from its natural state, patentees may argue that expression vectors, processed RNA, and covalently labeled DNA molecules represent patent eligible subject matter. While the court did not directly address biological molecules such as antibodies and therapeutic proteins, claims directed to these compositions are likely to be affected by the decision as well.

Satisfaction of the new Section 101 criteria appears to be critically dependent on the degree to which DNA is modified from its natural state. Unfortunately, the lack of specific guidance with respect to this issue may call many pharmaceutical patents into question. In fact, the court has hinted that cDNA will have difficulty surviving challenges to other statutory criteria (*e.g.,* Sections 102 and 103). "We express no opinion whether cDNA satisfies the other statutory requirements of patentability." *See, e.g.*, Sections 102, 103, and 112; Brief for United States as Amicus Curiae 19, n.5.

While the spirit behind the judicial exclusions outlined in this case is correct, a reasonable application of the human intervention standard enunciated by *Chakrabarty* likely would have resulted in a more balanced result that comports with real world molecular biology. In any case, there seems to be a wide open question as to whether one could simply take a sequence of unprocessed natural DNA and create a cDNA gene to obtain patentable subject matter. We will have to see how the Courts and the Patent Office address this question, especially with respect to Section 103 obviousness determinations.

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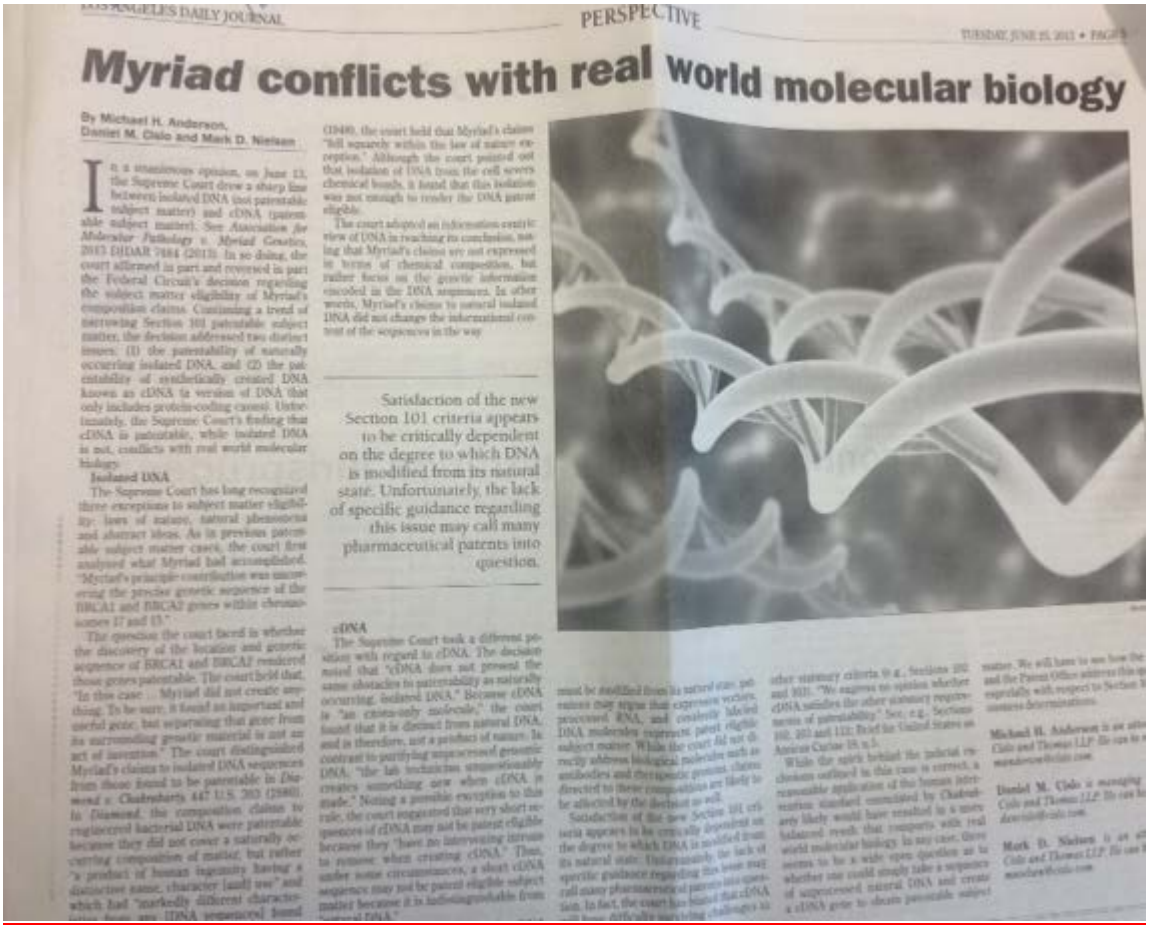

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