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Batting Practice with DNA Patents at the U.S. Supreme Court

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The Supreme Court heard oral arguments today in *Association of Molecular Pathology vs. Myriad Genetics (Docket 12-398)* regarding the patent eligibility of isolated DNA sequences. More specifically, they probed both parties in search of the line demarcating the patent eligibility of recombinant DNA (rDNA), complementary DNA (cDNA) and isolated DNA sequences. The Supreme Court's decision in this case could impact not just the patentability of DNA sequences but also that of any composition derived from a naturally occurring product.

The Justices were concerned about the effect of broad patents on the DNA sequences and their possible preemptive effect. Justice Kagan questioned the patentability of an isolated DNA sequence, and whether one could have patented an isolated chromosome under the current "patent happy" United States Patent and Trademark Office. Several Justices sought to understand the extent of human manipulation required to make a product found in nature patent eligible. An oft-used analogy was a bat that does not exist in nature but is derived from a natural product – a tree. They sought to understand the point at which a composition of matter stops being a "product of nature" and becomes a product of human manipulation.

But the Justices' unease with the patent-eligibility of isolated DNA sequences appeared to be tempered by the understanding that making any DNA sequence patent-ineligible could have chilling effects on biotechnological innovations. Early in the arguments, Justices Kagan, Kennedy and Scalia pointedly asked about the incentives for a company, like Myriad, to spend millions of dollars to develop a product that lacked patent protection. They also sought to understand the difference in value of patents directed to isolated DNA sequences and those directed to cDNA. Moreover, they inquired whether there would be sufficient value in process and use patents if even cDNAs are held patent-ineligible. Justice Sotomayor observed that isolation of DNA sequences may not have value until applied to a particular use.

Stepping beyond the questions regarding patent law, scientific questions were raised about the distinctions among recombinant DNA, cDNA and isolated DNA. The Justices struggled with appropriate analogies: a baseball bat carved out of a limb, chocolate chip cookies, isolating compounds extracted from a plant in the Amazon forest, and removing a plant from the forest. A bat does not exist in nature but is a product of human manipulation of a natural product. Using this analogy, the Justices were questioning the nature of cDNA – whether creating cDNA was just snipping off the branches of the tree or just fashioning a bat from the branch. Justice Sotomayor, who started off asking the most scientific questions, drew a very simplistic analogy using a chocolate chip cookie made of natural ingredients like salt and flour. She questioned whether cDNA sequence was akin to the salt and flour or to the chocolate chip cookie.

Some Justices appeared receptive to the Solicitor General's position that patent-eligibility should start with cDNA sequences and not isolated DNA sequences. Justice Breyer noted that cDNA does not exist in nature, and does not contain uracil nor introns. If he were to take a super microscope, Justice Breyer noted, the cDNA sequence would look different from anything found in nature and have a different function. The Justices then probed the amount of manipulation necessary to make a product found in nature patent eligible.

As Justice Breyer indicated, patent law is filled with uneasy compromises. Although the Justices appeared uneasy about the patent eligibility of isolated DNA sequences, they recognized that cDNA is a result of human manipulation bringing it closer to patent eligibility. The Justices' concern regarding the effects of their decision on investments in biotechnology will likely temper any changes to the patent eligibility requirement they may make with their decision in this case.

These are simply impressions from the batting practice at the Supreme Court. Let's see what happens when the Justices step up to the plate and deliver their decision at the end of this term.