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Do the Courts Really Understand DNA?

Part of the patent attorney's job is to ensure that judges comprehend the science

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To promote the Progress of ... useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their respective ... Discoveries." This statement in our Constitution makes science the basis of our patent law. As such, it is important for the courts (and the lawyers that argue before the courts) to understand not only the law that they are applying, but the science that is being protected by that law. Of course, this is easier said than done in light of the pace at which technology is advancing.

The recent decision by the Supreme Court in *Association for Molecular Pathology v. Myriad Genetics*, and the legal history that led to the decision, highlight the importance of knowing and understanding what is being protected. Central to this article is the court's understanding of exactly what constituted "isolated DNA," since patents now claiming isolated DNA may no longer be patent eligible or claims reciting "isolated DNA" or similar terms may be invalid.

The Supreme Court has been criticized for whether it understood the science behind its decision in *Myriad*, but these criticisms have been primarily based on minor mistakes regarding the court's wording of the science — at one point the court refers to pre-mRNA as "pre-RNA" and refers to cDNA as "composite DNA," when cDNA refers to complimentary DNA. Those errors by the court appear more typographical in nature. What is addressed here is whether the substantive understanding of isolated DNA was strong enough to make such an impactful decision. For several reasons, both scientifically and under the law, this author concludes that it was not.

The most striking aspects of the Supreme Court's decision, regarding how well the justices understood the science, came from Justice Scalia's concurrence. In an interesting and short concurrence with the majority's opinion, which held that isolated DNA sequences are not patentable, Justice Scalia stated that "I am unable to affirm those details [of molecular biology] on my own knowledge or even my own belief." Yet, he affirmed the majority's opinion based on the "opinions below and the expert briefs presented here." This illustrates the point that the court's understanding of the science is critical to its application of the law to protect that science.

The notion that molecular biology is a tough subject to understand was not lost on the district court when it stated that "[t]wo complicated areas of science and law are involved: molecular biology and patent law." In this context, the District Court for the Southern District of New York decided whether isolated human genes were patentable. Ultimately, the district court decided that they were not. In so deciding, the district court acknowledged the practice of seeking patents on isolated DNA based on the reasoning that purification of DNA from cells renders it patentable because it is transformed into something distinctly different in character

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from what is found in cells. However, the district court characterized this as a "lawyer's trick" that attempts to circumvent the prohibitions on the direct patenting of DNA.

Citing to Supreme Court precedent that included *Funk Brothers Seed Co. v. Kalo Inoculant Co*., 333 U.S. 127 (1948), and *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), the district court concluded that "DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA [i.e., the physical embodiment of biological information] as it exists in the body nor the information it encodes," and held the claims invalid under 35 U.S.C. 101. The district court invalidated the Myriad patents because the claimed isolated DNA was not markedly different from natural or native DNA. since the nucleotide sequence (i.e., the order of the ACGT nucleotides) of an isolated segment of DNA is the same, and thus information encoded therein is the same regardless of whether it is natural or isolated.

On appeal from the district court's opinion, the U.S. Court of Appeals for the Federal Circuit also focused on the issue of the patent eligibility of isolated DNA sequences. Specifically, the Federal Circuit addressed whether the claims to isolated BRCA DNA met the threshold test for patent-eligible subject matter under 35 U.S.C. § 101, in light of various Supreme Court holdings. The Federal Circuit compared native DNA, one physical composition of matter, with isolated DNA, another physical composition of matter, and not the sequences or information encoded within isolated and native DNA.

Because the Federal Circuit viewed the distinction between isolated and genomic DNA quite differently than the district court, it held that isolated DNA sequences were patent-eligible subject matter. As the court stated in its reasoning:

> One distinction, therefore, between products of nature and human-made invention for purposes of § 101 turns on a change in the claimed composition's identity compared with what exists in nature. Specifically, the Supreme Court has drawn a line between compositions that, even if arrayed in useful combinations or harnessed to exploit newly discovered properties, have similar characteristics as in nature, and compositions that human intervention has given "markedly different," or "distinctive," characteristics. *Id*. (citing *Hartranft*, 121 U.S. at 615); *see also Am. Fruit Growers v. Brogdex Co*., 283 U.S. 1, 11 (1931).

Applying this test to the isolated DNAs in the *Myriad* case, the Federal Circuit held that the challenged claims were drawn to patent-eligible subject matter because the claims cover molecules that are markedly different — have a distinctive chemical structure and identity — from those found in nature.

On the issue of isolated DNA, the Supreme Court sided with the District Court and relied on its decision in *Funk Brothers*. The Supreme Court in *Funk Brothers* held that combining different naturally occurring bacteria in a composition without altering the bacteria from the way it existed in nature was not patentable. That was different from the situation in *Chakrabarty*, where the bacteria were genetically altered and did not exist in nature. The Supreme Court held that isolated DNA were also not patent eligible because "separating that gene from its surrounding genetic material is not an act of invention" and, therefore, "genes and the information they encode are not patent eligible under §101 simply because they have been isolated from the surrounding genetic material."

All three courts looked at the outer bounds of the law on patent eligibility when applying it to the field of molecular genetics and came up with two different views on isolated DNA. One view, held by the Supreme Court and the district court, was that DNA is a naturally occurring unit of information regardless of whether it is in a native form or an isolated form. In the other view, the Federal Circuit looked at it as a physical object or matter of composition, where the physical and chemical attributes of the native form are vastly different from the physical and chemical attributes of the isolated form. In other words, the courts examined the issue as patenting that which exists in nature unaltered by human ingenuity, versus patenting that which does not exist in nature because it was altered by human ingenuity.

A quick search of the U.S. Patent and Trademark Office database shows there are approximately 3,000 patents that claim some form of "isolated DNA." Thousands of other patents use similar phrases such as "isolated nucleic acid." In light of the Supreme Court's decision, these several thousand patents are likely invalid, or at least their validity is now in question. This is only one measure of the impact that the court's decision has had on patents in the biotechnology industry. But the impact it will have on the industry as a whole is yet to be seen.

Because the court's decision will likely have such a wide impact, it is important to ask if the way in which "isolated DNA" was defined or understood by the Supreme Court is correct. If the court misunderstood the science, then the result would be incorrect and with grave consequences.

According to the Federal Circuit, isolated DNA could mean that is excised or amplified from the native DNA. But the Supreme Court, in its opinion, makes little mention of how DNA is isolated. This point seemed immaterial to the Supreme Court. But this is peculiar in light of the Supreme Court's holding that cDNA is patentable. cDNA consists of DNA that has been created by reverse transcribing mRNA back to DNA using viral enzyme known as reverse transcriptase. mRNA is a direct transcript of native DNA, but lacks intervening sequences known as introns. cDNA is a transcript of the RNA. cDNA is an intron-free molecule, which is not naturally occurring, and thus patentable according to the Supreme Court. The Supreme Court recognized that the sequence within cDNA may be dictated by nature, but argued that the lab technician unquestionably creates something new when introns are removed from a DNA sequence to make cDNA. But the lab technician does not remove the introns, nature does when it creates the mRNA. True, cDNA does not exist in nature, but using this logic, neither does isolated DNA. A lab technician would have to use molecular tools similar to reverse transcriptase, such as restriction enzymes or DNA polymerases, to create isolated DNA from the native DNA resulting in a molecule that does not exist in nature. Applying the tests in *Funk Brothers* and *Chakrabarty*, isolated DNA is like taking something in nature (e.g., bacteria) and changing it into something

that does not appear in nature.

If the ability of the bacteria in *Funk Brothers* to fix nitrogen in nature were compared to the patented composition, there would be no change in the bacteria's ability to fix nitrogen. However, if we took an isolated piece of DNA and put it back into a cell, it would not function the way native DNA would, since it is essentially man-made.

In reality, natural DNA consists of proteins and chemical modifications (e.g., methylation) in addition to just the pure GATC nucleotide sequence that encodes "life." The opinions of the district court and Supreme Court failed to recognize a critical difference between native DNA and isolated DNA — that the proteins or other cellular materials associated with DNA as it exists in nature have a tremendous impact on the character and function of that DNA sequence and what it is able to encode. Looking at native and isolated DNA in this manner, isolated DNA is nothing like native DNA, just as the bacteria in *Chakrabarty* were altered to be nothing like the same bacteria that existed in nature.

At the end of the day, we are left with what our high court has decided. Those of us who practice in patent law should look to this Supreme Court decision as a reminder that our jobs are not only to ensure that the law is applied properly, but that the science is relayed and understood properly by the court. ■