SQUIRE SANDERS

US Supreme Court Holds That Isolated Human DNA is Not Patent Eligible Subject Matter Under Section 101

US Supreme Court's decision in *Association for Molecular Pathology, et al. v. Myriad Genetics, Inc., et al.* attempts a compromise by unanimously holding that an isolated DNA segment is not patent eligible subject matter while cDNA is patent eligible because, unlike isolated DNA segments, cDNA is not a product of nature. The Court does not, however, consider whether patents on cDNA are valid.

On June 13, 2012 the US Supreme Court reversed in part a ruling of the US Court of Appeals for the Federal Circuit, which had held that both isolated DNA and cDNA were patent eligible subject matter under §101 of the Patent Act. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (June 13, 2013).

The Court addressed (1) whether a naturally occurring segment of DNA is eligible for patenting "by virtue of its isolation from the rest of the human genome"; and (2) whether synthetically created DNA known as complementary DNA (cDNA), "which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins," was patent eligible. *Id.* at **6. The Court found the latter to be patent eligible while the former was held to not be patent eligible because it was a product of nature.

Patent eligibility has been somewhat of a hot topic lately, and has led to some confusion, with the Supreme Court seeming to conflate patentable subject matter and patent validity. Patentable subject matter includes "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof." 35 USC §101. A long held exception to the foregoing is that laws of nature, natural phenomena, and abstract ideas are not patentable. *Id.* at **21. Here, one of the questions was whether an isolated segment of DNA was a new and useful composition of matter since it did not exist in nature in isolated form.

By way of background, a short biology primer to explain the ruling: DNA consists of sequences of nucleotides that code for amino acids. The body uses these amino acids to build proteins. However, some of the DNA nucleotides do not fall into a sequence that codes for amino acids, these are called "introns." The nucleotides that do code for amino acids are called "exons." In order to create proteins, the DNA double helix unwinds, one of the two strands is translated into ribonucleic acid (RNA) creating an inverse image of the DNA strand from which it was created. All introns are then removed from the RNA strand, creating the messenger RNA (mRNA). The mRNA is the script by which the body assembles the specific sequence of amino acids to create proteins. The mRNA can then be reverse transcribed (or technologies that locate exons from a DNA sequence can be employed) to create synthetic DNA, or complementary DNA (cDNA), which is DNA with the introns removed.

Myriad Genetics Inc. identified the exact location of certain genes (known as BRCA1 and BRACA2) on chromosomes 17 and 13, which have 80 million and 114 million nucleotides respectively. The mutations in these genes can dramatically increase an individual's risk of developing breast and ovarian cancer. *Id.* at **10. Accordingly, Myriad claimed "the exclusive right to isolate an individual's BRACA1 and BRACA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome." Myriad's patents further claimed exclusive right to synthetically created BRCA cDNA." *Id.*at **14.

The Court focused on its holding in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980) where it ruled that "[p]roducts of nature are not created, and manifestations…of nature [are] free to all men and reserved

exclusively to none" (internal quotations omitted). The Court held that "[i]n 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." *Id.* at **23. The Court went on to state that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the §101 inquiry." *Id.* Accordingly, the Court concluded that "Myriad found the location of the BRCA genes, but that discovery, by itself, does not render the BRCA genes 'new…composition[s] of matter.'" *Id*. at **24-25.

The Court further held that because "cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring," the cDNA is not a product of nature and is therefore patent eligible under §101. *Id.* at **30. The Court rejected petitioners' argument that since the nucleotide sequence of cDNA is dictated by nature (i.e., the mRNA), the cDNA should not be considered patent eligible.

Although the Court held cDNA to be *eligible* for a patent under §101, this does not necessarily mean that patents on cDNA are valid. The Court specifically noted that it expressed no opinion as to whether cDNA satisfies the other statutory requirements of patentability, such as those under Sections 102 (novelty), 103 (nonobviousness) and 112 (written description) of the Patent Act. One potential challenge to a patent on the BRCA cDNA might come from §103, which states that a "patent for a claimed invention may not be obtained if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art." 35 USC §103. This nonobviousness requirement attempts to avoid patents for trivial changes to prior art (or things in the public domain).

There is some support that laws of nature and abstract ideas should be considered prior art and would thus color any nonobviousness analysis. In *Parker v. Flook*, the Supreme Court held that "[r]espondent's process is unpatentable…not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention." *Parker v. Flook*, 437 U.S. 584, 592 (1978). This same idea was recognized in Judges Linn and O'Malley's dissenting opinion in *CLS Bank Int'l v. Alice Corp.* in which they noted that the prior art would include the abstract idea itself*. CLS Bank Int'l v. Alice Corp. Pty*, 2013 U.S. App. LEXIS 9493 (Fed. Cir. May 10, 2013).

Although treating laws of nature and abstract ideas as though they were part of the prior art has been recognized only in §101 (patentable subject matter) cases, the Federal Circuit recently acknowledged that this consideration better fits as part of a validity analysis. See *Ultramercial, Inc. v. Hulu, LLC*, 2013 U.S. App. LEXIS 12715, *31 (Fed. Cir. June 21, 2013). The *Ultramercial* court noted that this consideration requires an "understanding of what existed in the ken of those skilled in the art during the relevant time frame" and thus was more a principle of patent validity rather than eligibility. *Id.* at *31-32. The court further recognized that "because a new combination of old steps is patentable [subject matter], as is a new process using an old machine or composition, subject matter eligibility must exist even if it was obvious to use the old steps with the new machine or composition." *Id.* at 32-33.

Accordingly, even where a patent claims eligible subject matter, practitioners might argue that abstract ideas, naturally occurring materials or natural laws should be treated the same as prior art in a nonobviousness analysis.

Contact

Amanpreet Kaur
T +1 650 843 3216
amanpreet.kaur@squiresanders.com

Rahul Pathak
T +1 650 843 3304
rahul.pathak@squiresanders.com