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COUNSEL COMMENTARY

IP: Supreme Court hears oral argument on whether isolated DNA is a product of nature

THE HISTORY AND IMPLICATIONS OF THE UPCOMING *AMP. V. MYRIAD GENETICS* DECISION

On April 15, the Supreme Court heard oral argument in the highly anticipated *Association for Molecular Pathology v. Myriad Genetics* case. The question before the court was: "Are human genes patentable?" During the argument, the court's primary focus was on the issue of what is considered a product of nature and how much human intervention is required to transform a product of nature into a patent-eligible composition.

Background

Patents are granted only for patent-eligible subject matter, such as a new and useful process, machine, manufacture or composition of matter. Previously, the Supreme Court has ruled that subject matter that is not eligible for patenting includes abstract ideas, natural phenomena and laws of nature.

Myriad Genetics and inventors from the University of Utah were the first to isolate the BRCA1 and BRCA2 DNA sequences and discovered that certain mutations in the BRCA genes are associated with higher incidences of breast and ovarian cancer. Myriad developed a diagnostic test for mutations in BRCA1 and BRCA2 to identify patients at risk of these cancers. Myriad obtained patents covering the isolated BRCA1 and BRCA2 DNA sequences, as well as the BRCA cDNA sequences (a continuous DNA strand of spliced-together genes) and methods of use of the isolated DNA in a diagnostic test.

AMP and other entities filed suit against Myriad in the Southern District of New York, asserting that the isolated DNA patented by Myriad does not alter the information of the natural gene product and therefore is not patent-eligible subject matter. The district court held that Myriad's claims to isolated DNA were directed to a product of nature and therefore were not patent-eligible. Myriad appealed.

In 2011, the Federal Circuit held that Myriad's isolated DNA was patent-eligible, but that screening method claims directed to comparison of *BRCA* DNA sequences were ineligible subject matter. On appeal, the Supreme Court granted *certiorari*, ordering the Federal Circuit to re-hear the case in light of its recent decision in *Mayo v. Prometheus*, related to patent eligibility of method claims involving laws of nature. The Federal Circuit again held in 2012 that isolated DNA and cDNA are patent eligible subject matter, supporting decades of Patent Office practice. The Supreme Court ultimately granted *certiorari* on the appeal of this decision, asking "are genes patentable?"

Highlights from Oral Argument

AMP argued that the Myriad patents gave it a monopoly over a product of nature, keeping others from using the genetic information and carrying out

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research. Myriad argued that the *BRCA* genes would not have been isolated and sequenced were it not for intervention by humans. AMP agreed that human intervention was required to isolate the gene, but that the information provided by the gene in Myriad's patents did not provide any information beyond that found in nature, and that it therefore was ineligible for patenting. Myriad also argued that cDNA is not a product of nature as it does not occur naturally in the human body but is strictly a laboratory invention.

A representative for the U.S. Solicitor General was also present at oral argument to provide the government's views on the question. The Solicitor General argued that isolated genomic DNA was an unpatentable product of nature, but argued that cDNA was man-made and patent-eligible subject matter.

Questions From the Bench

During oral argument the Supreme Court tried to analogize isolated DNA to a more everyday, common composition.

Justice Sonia Sotomayor compared isolated genes to the ingredients in a batch of chocolate chip cookies, stating "I can't imagine getting a patent simply on the basic items of salt, flour and eggs, simply because I've created a new use or a new product from those ingredients." Justice Samuel Alito compared the isolated gene to a plant isolated from the Amazon. Many of the justices followed this line of reasoning, agreeing that while it might take effort and ingenuity to "isolate" the plant from the Amazon, the plant is still a natural product.

The justices also often referenced that while a natural composition itself may not be patentable, an entity could get a patent on the new use of the composition or method of isolating it, such that the patentee still has a protected invention without protection for the isolated DNA itself.

The Solicitor General alluded to a previous court remark, stating that "what the Court is in a position to do is to apply the general principles of law … and then if there needs to be a particular different set of rules for the biotech industry, Congress can provide that different set of rules." Interestingly, the justices also questioned counsel on the possible impact of any decision on the incentive for companies to innovate. While AMP's counsel indicated that research and innovation would come due to the desire for recognition and reward, and taxpayers would fund the necessary research if companies did not, the justices expressed skepticism to this line of argument.

Possible Outcome and Implications

Some in the field believe the court will rule that isolated genomic DNA is unpatentable but cDNA is manmade and therefore patentable subject matter. The question on many practitioners' minds is: If isolated DNA is unpatentable, then what will be the impact on "gene patents" currently in force, applications claiming isolated DNA and on patent protection for other categories of compositions of matter?

While the U.S. Patent and Trademark Office (PTO) has issued only a handful of patents claiming isolated DNA for human genes in the last several years, isolated DNA patents are still relevant to researchers studying other genomes, such as bacterial, viral, plant or other mammalian DNA. A ruling that isolated DNA is unpatentable could have a significant impact on innovators that have invested in the isolation and use of these DNA sequences, as well as innovators claiming that fragments of isolated DNA are useful as therapeutics to treat disease.

If the Supreme Court holds that Myriad's isolated genomic DNA is an unpatentable product of nature, such a decision could raise questions about what other innovations with biological origins could be considered products of nature and not patent-eligible, worrying many in the industry. The court seemed to consider the possible impact on the industry, but how that will play, if at all, into its decision is unknown at this time.

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Finally, the Solicitor General's oral argument alluded to the fact that if the biotechnology industry requires separate patent rules for its technology to be eligible for patenting, then it is up to Congress to implement these rules. This also sends a chill into the air for patent practitioners. The thought that each industry is given its own set of patent rules would add a new layer of complication to a process that already faces a fair number of complexities.

The decision in *AMP v. Myriad* is expected in June, and an entire industry holds its breath awaiting the outcome.

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