Is Isolated DNA Patent Eligible Subject Matter? The Department of Justice Says, "No"

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To say merely that gene patenting is a controversial topic would be a gross understatement. In one camp, supporters of gene patenting believe it is absolutely necessary to drive innovation in biotechnology and to drive the development of new diagnostics and therapeutics in medicine. In the other camp, the opposition to gene patenting believes that genes are a product of nature, equivalent to a law of physics, and are strictly patent ineligible. The controversy is heated and ongoing.

Those who oppose gene patenting celebrated this spring when the District Court for the Southern District of New York, in a case captioned *Association for Molecular Pathology, et al. v. USPTO, et al.*, ruled that isolated DNA is not patent eligible subject matter. The ruling surprised many in the biotechnology community and effectively invalidated some of the patents held by Myriad Genetics, a codefendant in the case and provider of the BRAC*Analysis*® hereditary breast and ovarian cancer test.

Myriad Genetics and the University of Utah Research Foundation, the rights holders of the patents at issue, have appealed the case to the Court of Appeals for the Federal Circuit (CAFC). Because the district court's ruling could affect all pending and future gene patents if it is upheld, members of the biotech community have been following the case closely. In fact, members of the community submitted many *amicus curiae*, or "friend of the court," briefs to the CAFC on the issue of whether isolated DNA is patent eligible subject matter. These briefs are submitted on behalf of persons or organizations who are not a party to the case, but who nevertheless hope the court will review and consider their opinion when deciding the case and drafting the opinion.

The most interesting *amicus* brief in the case was filed by the Department of Justice (DOJ). In its brief, the DOJ claimed to support neither party to the case. Instead, the brief made a distinction between isolated DNA, which the DOJ believes should not be patent eligible, and human manipulated isolated DNA, which the DOJ believes should be patent eligible. Like the district court's earlier ruling, the DOJ's brief also surprised many in the biotech community.

The brief was surprising first because the government has long supported patenting isolated DNA. The earliest of the patents at issue, United States Patent 5,693,473, applied for on June 7, 1996 and issued December 2, 1997, contains claims to isolated DNA. Since that time, the United States Patent and Trademark Office (USPTO) has issued patents covering approximately 20% of human DNA. These patents, and others related to them, have been partially responsible for the growth of the biotech industry and the development of personalized medicine. The DOJ is aware that its brief is a departure from long-standing federal policy and, interestingly, no attorneys from the USPTO joined the DOJ's brief.

The brief was also surprising because its distinction between isolated DNA and human manipulated isolated DNA is somewhat unscientific. Many *amicus* briefs filed after the DOJ's brief correctly state that all DNA must be manipulated by humans to isolate and characterize it: isolated DNA is not merely cut off of a chromosome and read. Rather, DNA is manipulated by a series of laboratory techniques while it is isolated and when the process is complete, the isolated DNA exists in a form unlike those occurring naturally in our bodies. The briefs explain further that if all isolated DNA is human manipulated, then, all isolated DNA is patent eligible because the decades-old "product of human ingenuity having a distinctive name, character and use" test is satisfied.

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Although the question of whether gene patenting is not yet resolved, many in the biotech community hope it will be soon. Many other members of the community have submitted *amicus* briefs in an attempt to guide the CAFC's decision-making. Even more members hope the CAFC is not influenced by the DOJ's brief: if the CAFC followed the delineation suggested by DOJ and ruled isolated DNA patent ineligible, many in the community believe that other isolated biologics such as antibodies and therapeutic proteins could lose patent eligibility as well, and this loss would be a difficult challenge for many startups in the biotech community to overcome.

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