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United States Weighs in on *Myriad Genetics* Case

On Friday, October 29, 2010, the United States submitted an *amicus curiae* brief in the *Myriad Genetics, Inc.* case. (*The Association for Molecular Pathology, et al. v. Myriad Genetics, Inc.*, Federal Circuit Case No. 2010-1406.) Myriad Genetics holds several patents covering genomic materials relating to the human Breast Cancer Susceptibility Genes 1 and 2. A group of several health organizations and researchers brought suit seeking to have the patent claims declared invalid. The District Court held that 15 challenged claims from seven patents were invalid under 35 U.S.C. §101 because the challenged composition claims were allegedly directed to unpatentable products of nature and the challenged method claims were allegedly directed to unpatentable abstract ideas. That decision is on appeal.

In its *amicus* brief the United States clarifies its position as to whether (1) human engineered DNA molecules, such as cDNAs, are patent-eligible subject matter under 35 U.S.C. §101; and (2) isolated but otherwise unmodified genomic DNA is patent-eligible subject matter under 35 U.S.C. §101. The United States has taken the position that human engineered DNA molecules are eligible for patent protection (assuming the other requirements of Title 35 are met), but that isolated but unmodified genomic DNA is not eligible for patent protection because it is an article of nature.

According to the United States, human engineered DNA is patent-eligible subject matter, because those "molecules generally do not occur in nature, but are instead the synthetic results of scientists' manipulation of the natural laws of genetics. … cDNAs, for example, are synthetic molecules engineered by scientists to incorporate, in a single contiguous DNA segment, only the exons (i.e., protein-coding sequences) of a naturally occurring gene, and exclude the intervening introns and other regulatory regions that normally separate the exons in genomic DNA." (Br. at 15.) In contrast, the United States contends that isolated DNA segments are unpatentable because "the isolated DNA segment *itself* remains, in structure and function, what it was in the human body." (Br. at 21 (emphasis in the original).)

If the Federal Circuit adopts the United States' position, or if the PTO applies this position to new and pending patent applications, precise wording of claim language will become imperative. Claims that cover both synthetic DNA and isolated but unaltered genomic DNA may be invalid under Section 101 and are likely to also face anticipation and obviousness challenges based upon the underlying genomic DNA segments. Moreover, claims that are directed to cDNA segments that are not greater than naturally occurring exons (*i.e.*, do not exclude intervening introns or regulatory regions) are likely to be unpatentable without some disclaimer of scope in the specification or prosecution history. Indeed, many claims that identify specific isolated DNA or polypeptide sequences may need to be reviewed and carefully written (or re-written) to avoid

claiming naturally occurring sequences.

Rather than wait until a ruling is reached, it is suggested that patentees review their pending applications and soon-to-be-filed applications with counsel. The United States' *amicus* brief may carry significant weight with the Federal Circuit. In its brief, the United States noted that the extent to which basic discoveries in genetics may be patented is a question of great importance to the national economy, to medical science, and to the public health. And that the issues involved in such patenting implicate the expertise and responsibilities of the Patent and Trademark Office (PTO), the National Institutes of Health (NIH), the Antitrust Division of the Department of Justice, the Centers for Disease Control and Prevention, the Office of Science and Technology Policy, and the National Economic Council, among others. Notably, the Federal Government's position will arguably cause the PTO some embarrassment because the PTO has granted all the patents at issue, and will arguably cost NIH monetarily because the NIH is a co-owner of four of the patents in suit. Under the circumstances, the Federal Circuit may view the United States as a neutral arbitrar of the public interest. Moreover, the PTO may adopt the United States' position regardless of a decision by the Federal Circuit.

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