Patent Law Update: Association for Molecular Pathology v. USPTO

August 1, 2011

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Federal Circuit Holds Claims to Isolated DNA and to Methods of Using Isolated DNA to Screen for Cancer Patent-eligible

On July 29, 2011, the Federal Circuit handed down the hotly-anticipated decision in *Association for Molecular Pathology v. USPTO*, Fed. Cir., No. 2010-1406, 7/29/2011. In a 2-1 decision, the Panel held that isolated DNA molecules are eligible for patent protection under 35 U.S.C. § 101.

The substantive dispute amongst the parties is whether claims to isolated DNA impermissibly encompass a product of nature. Myriad argued that isolated DNA is patent eligible because it is "a nonnaturally occurring composition of matter" with "a distinctive name, character, and use." The plaintiffs responded that the isolated DNA molecules encompass products of nature because they are not "markedly different" from the natural product. In other words, the question before the court was whether the differences between isolated DNA and naturally occurring DNA is sufficient to confer patent-eligibility.

The three judge panel struggled to find common ground. Judge Lourie, writing for the majority, held that claims to isolated DNA are patent-eligible. In his view, isolated DNA is "markedly different" from DNA in the human body because the covalent bonds have been cleaved to isolate the DNA from the native DNA molecule. Notably, Judge Lourie did not differentiate between different types of DNA and applied this reasoning to find both isolated DNA similar to the DNA in the chromosome and cDNAs patent-eligible. Judges Bryson (dissenting-in-part) and Moore (concurring-in-part), however, drew distinctions between the two categories of DNA and whether—and why—they are patent-eligible.

Isolated DNA versus cDNAs

In her concurring opinion, Judge Moore divided DNA claims into two categories and applied different reasoning to find each category patent-eligible. The first category was directed to isolated sequences that are identical to naturally occurring sequences and included the isolated full length sequence and fragments of those which are found on the chromosome. Judge Moore's second category was cDNAs, which lack introns and are complementary to naturally occurring RNA. Judge Moore found that the chemical differences between cDNA versus RNA or continuous DNA on the chromosome were "markedly different" and thus claims to cDNAs were patentable.

Short Fragments versus Long Fragments

Judge Moore did not, however, extend this reasoning to "DNA sequences that have the same pattern of DNA bases as a natural gene, in whole or in part." Instead, Judge Moore further differentiated between short DNA fragments and longer strands that included most, or all, of the gene. The former type she found patentable as having uses and applications, such as primers, that were different from the DNA found in nature. For the latter type, however, Judge Moore based patent-eligibility on the settled expectations of stake-holders that such claims have always been patent-eligible. Notably, Judge Moore strongly suggested she may have held otherwise in the absence of settled expectations, particularly because of a paucity of uses for such DNAs that are different from the gene as it appears on the chromosome.

Judge Bryson concurred with the patentability of the cDNA claims on the basis that the cDNA lacks introns and can be used in cells to express proteins, but dissented from the court's holding that Myriad's claims to the BRCA gene and gene fragments were patent-eligible. Judge Bryson protested that "[t]he structural differences between the claimed 'isolated' genes and the corresponding portion of the native genes are irrelevant to the claim limitations, to the functioning of the genes, and to their utility in their isolated form." Notably, in contrast to Judge Lourie, Judge Bryson found that breaking covalent bonds alone was insufficient to confer patent-eligibility, particularly in view of the fact that breaking other bonds, such as ionic bonds during

isolation of lithium, would not confer patent-eligibility on the isolated lithium. Finally, Judge Bryson opined that claims to fragments of DNA having at least 15 nucleotides are not patent-eligible because they are overbroad, indicating the underlying policy concern that genes are claims to natural products and should be limited in scope.

Important practice tips for drafting diagnostic method claims

The Court's analysis of the methods claims used a straightforward application of the "machine-or-transformation" test. Almost all Myriad's method claims recited "comparing" or "analyzing" sequences but not any prior steps indicating how the sequences were obtained. Without such a step, the Court held that claims recited only the abstract mental steps required to compare two nucleotide sequences, and were thus not valid. In contrast, Myriad's claim for screening for potential therapeutics included two steps sufficient to confer patent eligibility. The claims recited "growing" transformed cells, which supports eligibility by the "transformative step involving the manipulation of the cells and their growth medium." That the "determining" step "necessarily involv[ed] physical manipulation of the cells" further supported patent eligibility. The Court's opinion thus reinforces a key take-home for both litigators and patent-prosecutors regarding diagnostic method claims: Make sure you have "determining" and transformative steps recited in the claim to avoid claiming only "abstract mental processes."

It may not be over yet

A threshold issue before the Court was whether the plaintiffs had standing to sue for declaratory judgment. . The American Civil Liberties Union, which had organized and brought the case to district court, had listed a plethora of researchers and medical organizations as plaintiffs and it was unclear at oral argument whether any plaintiff had suffered a sufficient legal injury such that the court had power to hear the case. In the opinion, the Court found standing for only a single physician who had stated an intent to imminently begin testing for breast cancer mutations using the Myriad approach. Counsel submitted a letter to the Court, dated just two days before the opinion issued, informing the Court that this physician will be soon leaving the employment of the research institution where he was to have conducted the testing, and accepted employment at an organization that does not and is not equipped to conduct genetic testing. It will be interesting to see whether the Court vacates or reconsiders its decision on standing in light of this development.

On the merits, the panel agreed that claims to cDNAs are patent-eligible, allowing most stakeholders in the biotech space to breathe more easily. But the differences in their reasoning and the distinctions between different types of isolated DNA suggest we haven't seen the last of this case or the issues it raises. Indeed, the thoroughly-developed reasoning in each of three opinions may suggest the Court anticipates the case will be reheard *en banc* and may possibly make its way to the Supreme Court.

Please click here to view the Federal Circuit decision.

Posted: August 1, 2011