Is DNA Still Patentable?

By: John J. Cunniff, Esq.

The recent decision in *Association for Molecular Pathology v. U.S. Patent and Trademark Office* (09 Civ. 4515, USDC SDNY, March 29, 2010, the "*AMP*" case below) has renewed debate regarding both the wisdom of allowing and the validity of patent claims directed to genetic sequences. In the *AMP* case, the plaintiffs challenged the validity of 15 claims in 7 patents directed to isolated DNA encoding the Breast Cancer Susceptibility Genes 1 and 2 (*BRCA1* and *BRCA2*, respectively) and to testing methods involving comparing an individual's genetic make up to a normal (or "wild type") gene. The extensive opinion (152 pages long) goes to great lengths to provide a basic summary of the biology of genetic information and various arguments made by the parties themselves and numerous parties joining either side as friends of the court (*amici curiae*). However, at its core, the case revolves around one fundamental question "Are isolated human genes and the comparison of their sequences patentable?"

For an invention to be patentable, it must, among other requirements, satisfy Section 101 of the U.S. patent laws, which states in part:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore …" (35 U.S.C. § 101).

It is well established that abstract ideas, laws of nature, mental processes, mathematical algorithms, and scientific principles fall outside the category of a patentable "process, machine, manufacture, or composition of matter." However, a particular practical application of such ideas, laws of nature, algorithms, etc., may satisfy Section 101 and a valid claim may be granted on such a practical application. For example, a newly discovered mineral would not be patentable as an item found in nature, but a particular use of such mineral to make an item, for example, might be.

Currently, the U.S. Patent and Trademark Office considers claims directed to isolated or purified DNA to be patentable because DNA is typically not found in nature isolated from a cell, its natural environment. While the court in *AMP* agreed with the patent owner that "isolated DNA" refers to "a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences," the court's holding, in effect, largely agreed with the plaintiffs' contention that DNA is primarily information, rather than "a real and tangible molecule, a chemical composition."

The court cited previous cases that indicated that for an invention involving a "product of nature" to be patentable, the product to be patented must be "markedly different" from the product of nature itself or must "possess a new or distinctive form, quality, or property". The court held that claimed isolated DNA was not "markedly different" from native DNA, insofar as both possess the same "unique qualities as a physical embodiment of information." In comparing isolated and native DNA, the court considered the differences to "merely (constitute) a difference in purity that cannot serve to establish subject matter patentability."

The court also considered the claims directed to methods of screening an individual's *BRCA1* and *BRCA2* genes to be invalid. For this holding, the court relied on the decision of the Court of Appeals for the Federal Circuit in *In re Bilski*, (545 F.3d 943 (Fed. Cir. 2008)). Under *Bilski*, a process is patentable under section 101 if it is tied to a particular machine or apparatus or it transforms a particular article into a different state or thing. One representative method claim recited "A method for detecting a germline alteration in a BRCA1 gene…which comprises analyzing a sequence of a BRCA1 gene or BRCA1 RNA from a human sample or analyzing a sequence of BRCA1 cDNA made from mRNA from said human sample…" The court rejected the patent owner's contention that a "transformation" was present in isolating the

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DNA sample to be tested from an individual. The steps of "analyzing" or "comparing" were considered to only be directed to "abstract mental processes." Therefore, the claims were invalid.

The decision in this case has been widely criticized in the biotechnology area. While the patent owner indicates that this decision will be appealed to the Federal Circuit (and it is difficult to see any decision not being ultimately appealed to the Supreme Court), it should be noted that not all of the patent claims directed to the isolated DNA molecules or methods were even subject to challenge at this time. Even if a decision adverse to the validity of the claims at issue here is ultimately upheld, it would not necessarily invalidate all claims to isolated DNA. Furthermore, the decision of the Federal Circuit in the *Bilski* case is currently on appeal to the Supreme Court and a decision there may have a dramatic effect on the holding here regarding the method claims. Additionally, while it may be unlikely to advance, a bill has been introduced in Congress (The Genomic Research and Accessibility Act) which would specifically prohibit the patenting of all genes, regardless of source.

It is clear that the debate over the patentability of DNA and genetic screening is far from over on a number of different fronts. Inventors in the biotechnology area as well as patent practitioners would be well advised to consider the arguments and holdings provided in the *AMP* case when presenting such claims.

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