

April 1, 2011

# Gene Patents at Risk in Information Age

Recent Court Decisions Could Affect Patentability of Isolated Sequences and Dx

James Morando and Julie Wahlstrand

**G**ene patents have been issued in the United States for decades, however, a decision from the Southern District of New York in March 2010 put them on the chopping block of patentable subject matter.

The decision comes in the middle of a growing debate over the boundaries of patentable subject matter in what the U.S. Supreme Court recently dubbed the "Information Age," where inventions pertaining to information in its various forms resemble less and less the devices patented in earlier eras.

In *Association for Molecular Pathology et al., v. U.S. Patent and Trademark Office et al.*, an opinion that is a mix of health policy and patent law, Judge Sweet issued a broad holding invalidating Myriad Genetics' patents on the BRCA1 and BRCA2 genetic mutations and related diagnostic tests, determining that these inventions did not qualify as patentable subject matter. The court invalidated the patents and granted summary judgment for plaintiffs: the ACLU and a group of physicians, patients, and researchers. The case is now on appeal to the Federal Circuit.

After decades of patenting genes, why now remove them from the realm of patentable subject matter? Isolating DNA sequences and engineering genetic diagnostics may have become, at least in the abstract, a more routine laboratory exercise in recent decades (which more predictably might have contributed to narrower invalidations based on novelty or obviousness). But while such reasoning may implicitly underlie the court's opinion, it was not the basis for its published decision.

Instead, the court chose to more broadly and categorically remove these innovations from patent eligibility altogether, finding earlier decisions on gene patents inapplicable: "[I]n the absence of a § 101 [patentable subject matter] challenge to patent validity, the fact that courts have previously upheld the validity of patents directed to biological products in response to § 102 [novelty] and/or § 103 [obviousness] challenges has no bearing on the present inquiry."

If upheld, this decision has potentially far-reaching implications for the two basic types of patents that were at issue in the case: isolated gene sequences and genetic diagnostics.

## Composition of Matter Patents

Specifically, the court invalidated patents on isolated DNA containing all or part of the BRCA1 and BRCA2 gene sequences, finding that the isolated sequences were not "markedly different" from a product of nature and had not been physically transformed into something sufficiently, fundamentally different. The court drew a distinction between the BRCA patents and those in *Diamond v. Chakrabarty*, where the Supreme Court

upheld patentability of a human DNA sequence placed into a bacterial plasmid, as there the DNA sequence was manipulated and "transformed," not merely isolated.

Should Judge Sweet's holding stand, remaining questions regarding what constitutes sufficient "transformation" will create substantial uncertainty for the PTO, the courts, and anyone seeking biotechnology patents.

The court's holding is also in tension with long-standing opinions upholding patents on extracted and purified natural substances, such as adrenaline. (See *Parke-Davis & Co. v. H.K. Mulford and Co.*)

Judge Sweet ruled that DNA should be treated differently than other isolated or purified chemical compounds based largely on the conceptualization of DNA as information. Judge Sweet noting that "DNA represents the physical embodiment of biological information," and that "DNA's existence in an 'isolated' form alters neither this fundamental quality of DNA as it exists in the body nor the information it encodes."

He went on to state, "This informational quality is unique among the chemical compounds found in our bodies, and it would be erroneous to view DNA as 'no different' than other chemicals previously the subject of patents." Therefore, although genetic material is in fact a chemical compound, under Judge Sweet's opinion it is not patentable because nucleotide sequences carry genetic information.

The Department of Justice (DOJ) recently weighed in, submitting an amicus brief to the Federal Circuit in late October, 2010, arguing that isolated DNA sequences should not be patentable. The DOJ offered consolation that new and useful methods utilizing genetic information (such as therapies and diagnostics) may still be patented, subject to the prohibition against patenting abstract ideas. However, the DOJ's opinion that therapies and diagnostics should remain patentable offers little comfort, as patentability of genetic diagnostics is also under scrutiny in *Molecular Pathology*.

## Method Patents on Diagnostic Tests

Judge Sweet also invalidated, on the basis of patentable subject matter, a method patent for the diagnostic test used to screen for BRCA1 and BRCA2 mutations by using isolated DNA as a comparison. He found that the process of "analyzing" or "comparing" was not sufficiently transformative and ruled that the "claimed comparisons of DNA sequences are abstract mental processes" not constituting patentable subject matter.

Judge Sweet relied largely on the machine-or-transformation test of *In re Bilski*, which was recently rejected by the Supreme Court on June 28, 2010 in *Bilski et al. v. Kappos* in an opinion recognizing the changing nature of innovation. The Supreme Court addressed the changing nature of innovations in the Information Age,



James Morando (jmorando@fbm.com) is a partner, and Julie Wahlstrand is an associate at Farella Braun & Martel. Web: www.fbm.com.

noting that "the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals" (emphasis added).

The Supreme Court, however, left open the details for implementation of its decision:

"[T]he Court today is not commenting on the patentability of any particular invention, let alone holding that any of the above-mentioned technologies from the Information Age should or should not receive patent protection....In disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit's development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text."

As the Supreme Court reiterated the limits to patentable subject matter previously set forth (precluding "laws of nature, physical phenomena, and abstract ideas"), it remains to be seen whether Judge Sweet's invalidation of the diagnostic method patents as "abstract mental processes" will stand on appeal.

## Implications for Ingenuity

Many who believe strongly in patents as incentives for innovation, particularly critical in fields such as the biotechnology industry where life-saving innovations come only after significant investment in research and development, hope that careful consideration will be given to the effect that precluding these patent categories could have on motivating future discoveries.

As recounted by the court, plaintiffs in *Molecular Pathology* asserted that "gene patents are not necessary to create incentives for initial discoveries or the development of commercial applications, including diagnostic tests," while patent-holder Myriad clearly disagreed, stating that "patents on isolated DNA, including the patents-in-suit, actually promote research and advance clinical development to the benefit of patients."

This is perhaps the central debate. Although the incentives provided by a strong patent system are admittedly difficult to quantify (given that we have no "control" in the intellectual property experiment to know what a world without patents would look like), if Judge Sweet's decision stands it may cast doubt on the future of ingenuity in the biotechnology industry. In the meantime, biotech companies must wait to see what becomes of patents in the "Information Age." **GEN**