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Gene Patents at Risk in Information Age
Recent Court Decisions Could Affect Patentability of Isolated Sequences and Dx

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Gene patents have been issued in the United States for decades, however, a decision from the Southern District of New York in March 2011 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 require less and less the decade patented in earlier eras.

A recent opinion from the U.S. Patent and Trademark Office et al., an opinion that it is a race of health, policy, and patent law, Judge Sweet issued a broad holding invalidating Myriad Genetics’ patents on the BRCA1 and BRCA2 genes 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 most predictably might have contributed to narrow interpretations based on novelty or obviousness). But while such reasoning under 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 implausible. “[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 § 101 novelty and/or § 102 [obviousness] challenge has no bearing on the present inquiry.”

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 in June 2010. Bilski’s patent application in question recognized the changing nature of innovation, the Supreme Court addressed the changing nature of innovations in the Information Age, 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 manipulation of digital signals.”

The Supreme Court, however, left open the details or implementation of its decision: “[T]he Court today is not commenting on the patentability of any particular invention, but rather holding that any of the above-mentioned technologies from the Information Age should not be patentable.

Implications for Ingenuity

Many who believe strongly in patents as incentives for innovation, particularly critical in fields such as the biotechnology industry, will see this as a step backwards. Some see this as a victory for patient advocates and for the right to access to life-saving innovations. Others see it as a setback for biotechnology firms, which have spent millions developing new treatments and diagnostics.

As recounted by the court plaintiffs in Molecular Pathology, the sequence is not necessary to create incentives for initial discoveries or for the development of commercial applications, including diagnostic tests,” while patent-holder Myriad clearly disagrees, stating that “patents on isolated DNA are necessary for progress in research and advance clinical development to the benefit of patients.”

This is perhaps the crux of the debate. Although the incentives provided by strong patent protection are typically seen as necessary to spur innovation, there is also concern that overly strict patenting could stifle progress and limit access to life-saving treatments.