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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

Fed. Circ. Rules Myriad Can Patent Breast Cancer Genes

By **Roxanne Palmer**

Law360, New York (July 29, 2011) -- The Federal Circuit on Friday ruled that two breast cancer genes isolated by Myriad Genetics Inc. are patentable inventions in a precedential victory for the biotechnology industry, though the court also invalidated most of Myriad's related claims for diagnostic methods.

A New York federal judge had previously ruled that the DNA molecules isolated by Myriad fell within the realm of nonpatentable "products of nature" because the individual genes are not markedly different from the same DNA sequence found naturally.

But the appeals court said Myriad's BRCA1 and BRCA2 gene isolates fall within the realm of a human-made invention because they "are markedly different — have a distinctive chemical identity and nature — from molecules that exist in nature," Judge Alan D. Lourie wrote for the majority.

The majority's decision hinged on the fact that in order to isolate the two genes — which are associated with a higher risk for breast cancer — Myriad had to break the covalent chemical bonds anchoring them to the rest of the DNA molecule, producing a chemically altered product not normally found in nature.

In his dissent, Judge William C. Bryson objected to this reasoning, noting that while the ionic bonds in lithium compounds must be broken before they can be put to industrial uses, the majority has acknowledged that elemental lithium would not be patentable because "is the same element whether it is in the earth or isolated."

However, the majority said Judge Bryson was too quick to disparage the significance of a covalent bond in distinguishing different molecular structures and that covalent bonds in this case separate one chemical species from another.

Isolating a gene sequence is not analogous to purifying an element, refining a mineral, or physically removing a kidney from a body or a leaf from a tree, according to Judge Lourie.

“Elemental lithium is the same element whether it is in the earth or isolated; the diamond is the same lattice of carbon molecules, just with the earth removed; the kidney is the same kidney, the leaf the same leaf. Some may have a changed form, quality, or use when prepared in isolated or purified form, but we cannot tell on this record whether the changes are sufficiently distinctive to make the composition markedly different from the one that exists in nature,” Judge Lourie wrote.

Despite the fact that the genetic information in the isolated genes is the same as the information contained in the naturally occurring genes, the fact that the isolated DNA is distinct from its natural existence as a portion of a larger entity makes its informational content irrelevant, the opinion said.

However, the Federal Circuit ruled that all but one of Myriad's patent claims for methods of diagnosing breast cancer risk using the isolated genes were ineligible because they were based on abstract mental processes.

Myriad's claim for a method of comparing a patient's DNA sequence to isolated BRCA1 and BRCA2 sequences “recites nothing more than the abstract mental steps necessary to compare two different nucleotide sequences,” the majority said.

The appeals court did rule Myriad's claim for a method of screening potential cancer therapies by measuring cell growth rates is a patent-eligible process because growing and manipulating cell cultures constitutes a transformative action.

“We believe this decision is in the best interests of the agriculture, biotechnology and pharmaceutical industries, as well as the hundreds of millions of people whose lives are bettered by the products these industries develop based on the promise of strong patent protection,” Myriad CEO Peter Meldrum said on Friday.

Myriad's patents relating to BRCA1 and BRCA2 can still be challenged on other grounds such as obviousness, according to pharmaceutical patent lawyer Bruce Wexler of Paul Hastings LLP, who said the ruling would strengthen the biotechnology industry.

But American Civil Liberties Union attorney Chris Hansen, who argued the case for the plaintiffs, said the Federal Circuit's ruling would impede scientific research.

“Human DNA is not a manufactured invention, but a natural entity like air or water. To claim ownership of genetic information is to unnecessarily block the free exchange of ideas,” Hansen said on Friday.

Courtenay Brinckerhoff, vice chairwoman of Foley & Lardner LLP's pharmaceutical practice group, noted that the Federal Circuit's opinion seemed more concerned with the semantics of chemical bonds than with parsing case law or outlining policy.

“They're really digging into the science here,” Brinckerhoff told Law360 on Friday.

The ACLU filed suit in May 2009 on behalf of women's health groups and other medical organizations, challenging seven patents and 15 claims as invalid and unconstitutional. The case, which also named the U.S. Patent and Trademark Office as a defendant, was the first patent suit to claim a First Amendment violation.

The patents-in-suit are U.S. Patent Numbers 5,747,282; 5,837,492; 5,693,473; 5,709,999; 5,710,001; 5,753,441; and 6,033,857.

Judges Alan D. Lourie, Kimberly A. Moore and William C. Bryson sat on the panel for the Federal Circuit.

Myriad is represented by Brian M. Poissant, Gregory A. Castanias, Laura A. Coruzzi, Eileen Falvey, Sasha Mayergoyz and other attorneys from Jones Day.

The plaintiff-appellees are represented by Christopher Hansen and other attorneys with the American Civil Liberties Union.

The case is The Association of Molecular Pathology et al. v. USPTO et al., case number 2010-1406, in the U.S. Court of Appeals for the Federal Circuit.

--Additional reporting by Christopher Norton. Editing by John Quinn.