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Isolated Human DNA Molecules are Patent Eligible, Cancer Screening Methods are Not

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The United States Court of Appeals for the Federal Circuit on July 29, 2011 held in a split decision that isolated BRCA 1/2 DNA molecules patented and used by Myriad Genetics Inc. for diagnosing increased breast and ovarian cancer risk are patentable[1]. The Court also found that claims on methods of using the DNA to screen for cancer therapeutics were also patent eligible but held that diagnostic claims directed to "analyzing" and "comparing" DNA sequences are not.

The Court concluded that the isolated DNA molecules are eligible for patent protection under 35 U.S.C. §101 and rejected the plaintiff's arguments that the isolated DNA molecules were naturally occurring material. Referring to the Supreme Court precedent of *Diamond v. Chakrabarty*, the majority noted that the distinction between a product of nature and a human-made intervention for purposes of §101 turns on a change in the claimed composition's identity compared with to what exists in nature. Applying this test to the isolated DNA in this case, the Court concluded that "*the challenged claims are drawn to patentable subject matter because the claims cover molecules that are markedly different — have distinctive chemical identity and nature — from molecules that exists in nature*".

The Court also rejected the U.S. government's position and its proposed "magic microscope" test where a DNA molecule would not be eligible to patent protection if it could be visualized in the human body through and imaginary "magic microscope". The Court indicated that that approach misunderstands the difference between science and innovation and fails to take into account the existence of molecules as separate chemical entities. "*The ability to visualize a DNA molecule through a microscope, or by any other means, when it is bonded to other genetic material, is worlds apart from possessing an isolated DNA molecule that is in hand and usable*". Such an approach would "*discourage innovation*" because "*[v]isualization does not cleave and isolate the particular DNA; that is the act of human invention*" according to the Court.

The Court also refused to change the longstanding practice of the PTO who has been issuing patents on DNA molecules for almost 30 years: "*If the law is to be changed, and DNA inventions excluded from the broad scope of §101 contrary to the settled expectation of the inventing community, the decision must come not from the courts, but from Congress*".

In the second step of its analysis, the Court considered the method claims reciting a method of screening by "comparing" or "analysing" BCRA sequences from a tumor sample to detect genetic mutations associated with a predisposition to cancer. The Court concluded that these claims fail to satisfy the machine-or-transformation test set by the Supreme Court in *Bilski* and that they fell outside the scope of the §101 because they claim only abstract mental processes.

On the other hand, the method of screening potential cancer therapeutics was found patentable because the claim includes transformative steps of "growing" host cells, "determining" the growth rate of the cells and "comparing" the growth rate.

Comment: The biotechnology and biopharmaceutical industry will welcome this much anticipated decision since it removes overhang over the thousands of patents claiming "*isolated DNA*" issued so far by the USPTO. However, the decision raises some issues with respect to patents covering diagnostic-related methods because they may be seen as merely claiming abstract mental processes. To ensure that patents directed to diagnostic methods satisfy the machine-or-transformation test, the claims should recite some form of manipulation like extraction, collection of a bodily sample or affirmative steps for obtaining a sequence to be analysed.

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[1] *Association for Molecular Pathology* v. *U.S. Patent and Trademark Office*, Fed. Cir., No. 2010-1406, July 29, 2011.

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