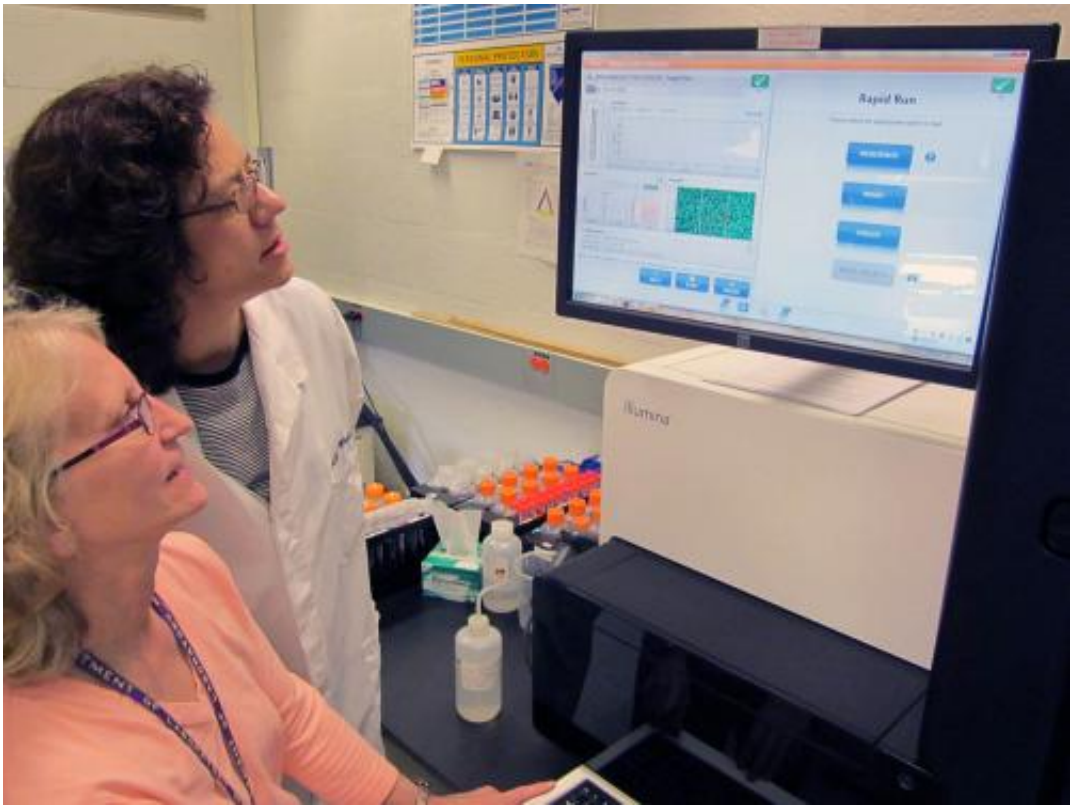
US Supreme Court decision to bar gene patents opens genetic test options

June 21 2013, by Leila Gray



Using a DNA sequencing instrument, medical technologists Karen Koehler (left) and Christina Smith (right) of the UW Department of Laboratory Medicine perform a BROCA panel for a patient to check for known disease-linked mutations in more than 40 genes.

The June 13 U.S. Supreme Court's unanimous decision to bar the patenting of naturally occurring genes opens up important clinical testing

options for a variety of diseases.

Several UW medical geneticists and laboratory medicine experts hailed the ruling's benefits for patients.

"We're thrilled," said Gail Jarvik, professor and head of the Division of Medical Genetics in the UW Department of Medicine. She explained that some patents on human genes restricted clinical care and research. Such patents posed an obstacle to developing and using multi-gene panels. These efficiently check mutations in scores of a patient's genes, not just one or two.

While the Supreme Court case focused on one company, Myriad Genetics Inc., that had patented two breast and ovarian cancer genes, BRCA1 and BRCA2, the ruling against gene patents has far greater medical implications.

According to Jonathan Tait, professor of laboratory medicine and director of the Clinical Molecular Genetics Laboratory at University of Washington Medical Center, "The Supreme Court decision is broadly beneficial to UW Medicine, going well beyond removing limits on testing for these two cancer risk genes."

"We'd like to be able to perform genomic tests that screen for all the mutations implicated in the medical question at hand," Jarvik said. "In our inherited colon cancer program, for example, we'd also want the ability to report genetic results that might be important to a patient or family even if the mutation is not related to the condition for which we are seeing them."

Cancer treatment decisions also increasingly require multi-gene test panels on diseased tissue, as the presence or absence of hundreds of gene mutations helps predict which therapies will and won't work. One of

these tests, UW-OncoPlex, was developed by a UW team led by Tomas Walsh, UW research associate professor of medicine in the Division of Medical Genetics, and Colin Pritchard, UW assistant professor of laboratory medicine. The test checks a cancer sample for mutations in 194 genes. The information can help improve the accuracy of diagnosis and the selection of proper therapy for solid tumors and blood cancers.

Along with the changes expected from the landmark court opinion, Myriad Genetics specifically was denied its previously exclusive right to isolate an individual's BRCA1 and BRCA2 genes.

A woman's odds of developing breast or ovarian cancer are greatly increased if she inherits a mutation in either of these tumor-suppressor genes.

The existence of the genes was first determined by a University of California Berkeley group led by Mary-Claire King, now a professor of medicine and genome sciences at the UW.

Myriad Genetics in Utah acquired several patents after establishing the genes' DNA sequence and exact location on the human genome. The company then designed medical tests to detect mutations in their patented genes.

Because of gene patents, the UW Department of Laboratory Medicine had to mask results on BRCA1 and BRCA2 in the cancer-risk gene panel conducted in the clinical labs at UW Medical Center and the Seattle Cancer Care Alliance. Samples from hundreds of patients a year, whose family history put them at risk for breast or ovarian cancer, had to be sent out for Myriad testing at a cost in excess of $4,000, despite the institutional expertise available here.

The UW's clinical laboratories had stopped performing their own

methods to test for mutations in BRCA1 and BRCA2 after receiving a patent infringement warning letter.

Following the Supreme Court ruling, the UW Department of Laboratory Medicine announced that it would provide clinical testing for mutations in the BRCA1 and BRCA2 genes as part of the BROCA Cancer Risk Panel. This lab test looks for mutations in more than 40 genes associated with breast, ovarian, colon, pancreatic, throat, kidney, and other cancers.

The BROCA panel emerged from UW genome research. Tait, who oversees UW Medical Center 's clinical genetics lab for patients, explained that BROCA testing, performed with next-generation DNA sequencing, detects all known classes of disease-causing mutations. Tomas Walsh, Mary-Claire King and other UW medical scientists first developed this technology to study hereditary risk of breast and ovarian cancer. They reported their methods in 2010.

"The Supreme Court decision is a victory for patients, their families, their physicians and common sense," King said. "A measure of its importance for our patients is that UW Lab Medicine now offers testing for BRCA1 and BRCA2 and all other known breast cancer genes. The test was open for clinical use less than 24 hours after the decision was announced."

Provided by University of Washington