

UNIVERSITY OF UTAH RESEARCH FOUNDATION v. AMBRY GENETICS CORPORATION, Appeal Nos. 2014-1361, 1366 (Fed. Cir. December 17, 2014). Before Dyk, Prost, and Clevenger. Appealed from D. Utah (Judge Shelby).

Background:

University of Utah Research Foundation ("Patentee") discovered the locations and sequences of BRCA1 and BRCA2, mutations of which are linked to hereditary ovarian and breast cancers. Patentee obtained patents having claims directed to various aspects of testing for alterations to the BRCA genes, including claims directed to: DNA primers used to generate BRCA using a polymerase chain reaction ("PCR"); and methods of screening for alterations of BRCA by using PCR or a hybridizing gene probe.

Ambry Genetics Corporation sold allegedly infringing medical kits that tested for the presence of the same BRCA alterations. Patentee brought suit against Ambry for patent infringement and sought a preliminary injunction. The District Court denied the motion for preliminary injunction, holding that Patentee was unlikely to succeed on the merits because the asserted claims were likely drawn to patent-ineligible subject matter. Patentee appealed.

Issue/Holding:

(1) Are claims directed to DNA primers patent-eligible subject matter? (2) Are claims directed to methods of screening for an alteration of a gene patent-eligible subject matter? No to (1) and (2), affirmed and remanded.

Discussion:

Regarding issue (1), the Federal Circuit held that DNA primers were not patent-eligible subject matter because they were a natural phenomenon. The Federal Circuit applied *Association for Molecular Pathology v. Myriad*, which held that isolated DNA was an ineligible natural phenomenon, but that synthetic cDNA was patent eligible because it was not naturally occurring. The Federal Circuit analogized the DNA primers to isolated DNA rather than cDNA, because the DNA primers are identical to sequences of DNA that normally exist in the human body.

Regarding issue (2), the Federal Circuit held that the screening method claims were not patent-eligible subject matter because they were directed to abstract ideas. The Federal Circuit applied the two-part test from *Alice Corp. v. CLS Bank Int'l*, which asks (1) whether a claim is directed to a patent-ineligible abstract idea and (2) if so, whether the claim's non-abstract elements "transform" the abstract idea into a patent-eligible application. The Federal Circuit held that the claim elements directed to screening for BRCA alterations by comparing a patient's BRCA gene to a normal gene were directed to an abstract idea, because they are nothing more than comparing BRCA sequences and determining the presence of alterations. The Federal Circuit then held that the claim elements directed to using PCR or a hybridizing gene probe to make the BRCA comparisons failed to transform the abstract idea into a patent-eligible application, because using PCR or hybridizing gene probes was nothing more than well understood, routine, and conventional activity that any scientist engaged in obtaining the sequence of a gene would rely on. The Federal Circuit hinted that if the claims had been limited to screening for specific alterations to BRCA, they may have been considered patent-eligible under the *Alice* test.