



Association for Molecular Pathology v. United States Patent and Trademark Office & Myriad Genetics

133 S. Ct. 2107 (2013), 132 S. Ct. 1794
(2012), 689 F.3d 1303 (Fed. Cir. 2012)

653 F.3d 1329 (Fed. Cir. 2011)

702 F.Supp.2d 181 (S.D.N.Y. 2010)

669 F.Supp.2d 365 (S.D.N.Y. 2009)

Topics Covered: Patents

Outcome: Very Favorable

Issue

The issue in this case was whether human genes can be patented.

AMA Interest

The AMA believes that patents should not be used to hinder the development of improved medical treatment and technologies.

Case Summary

The American College of Medical Genetics, American Society for Clinical Pathology, College of American Pathologists, three other health care organizations, and several individuals sued the United States Patent and Trademark Office, Myriad Genetics, and the Directors of the University of Utah Research Foundation in the United States District Court for the Southern District of New York. The suit challenged the validity of the patents on the BRCA1 and BRCA2 genes, which

can be examined to determine whether a woman is at risk for breast and/or ovarian cancer. The suit asserted that the patent claims are overbroad and also in conflict with constitutionally and statutorily based policies that prohibit the patenting of natural phenomena and basic human knowledge and thought.

The defendants asserted that although the underlying genes are found in nature, the patents cover isolated and purified gene molecules, which do not exist in nature. The plaintiffs and the patentees cross-moved for summary judgment, and the Patent and Trademark Office moved for judgment on the pleadings.

The trial court found that seven of the patent claims relating to the BRCA1 and BRCA2 genes were unpatentable subject matter and therefore invalid. The court observed that substances derived from products of nature can be the basis for patent protection only if the patented substances are fundamentally new or markedly different from the natural products. While some organic compounds may be patentable if they simply represent an isolated and purified form of a naturally occurring chemical, DNA is distinctive. Unlike other organic chemicals, DNA carries genetic information. Since the chemicals covered by the BRCA1 and BRCA2 gene patents merely replicate, rather than change, the information transcribed in the naturally occurring genes, the patent claims do not concern a fundamentally new or markedly different product. However, the court dismissed the United States Patent and Trademark Office from the suit, based on the doctrine of "constitutional avoidance."

The patentees appealed to the United States Court of Appeals for the Federal Circuit, which specializes in hearing appeals of patent cases. The Federal Circuit then found that an isolated DNA sequence is markedly different from the same DNA sequence incorporated naturally within the genome. Because the covalent chemical bonds between the isolated sequence and the rest of the genome have been broken, the isolated DNA has different chemical properties from the naturally occurring DNA. Moreover, because accepted practice, including procedures set forth within the Patent Office regulations, deems isolated DNA to be patentable, any change in such practice would upset settled economic expectations and should come from Congress, rather than the courts. Accordingly, the Federal Circuit reversed the principal holding of the trial court – which had found isolated DNA to be inherently unpatentable subject matter. The Federal Circuit affirmed some of the less consequential trial court holdings. The Federal Circuit affirmed some of the less consequential trial court holdings.

Both sides petitioned the Supreme Court for *certiorari*. The Court granted these petitions and summarily remanded for further consideration in light of its recent decision in *Prometheus Laboratories v. Mayo Collaborative Services*. After reconsidering the case on remand, pursuant to the Supreme Court order, the Federal Circuit confirmed its earlier decision, including its determination that an isolated DNA sequence can potentially be patentable. The plaintiffs again appealed to the Supreme Court, with the certified question being: "Are human genes patentable?"

On June 13, 2013, by a unanimous decision, the Supreme Court reversed the Federal Circuit, holding that the mere isolation of a human gene does not make it patentable. Although the chemical bonding property of an isolated gene is different from the gene as incorporated within the complete genome, this small difference from the natural gene is too insignificant to make it patentable subject matter.

Litigation Center Involvement

The Litigation Center, along with the Medical Society of the State of New York and several other health care organizations, filed numerous *amicus curiae* briefs supporting the plaintiffs in the trial court, the Federal Circuit, and the Supreme Court.

United States District Court brief

United States Federal Circuit Court of Appeals brief

First United States Supreme Court brief

United States Federal Circuit Court of Appeals (remand from Supreme Court)

Second United States Supreme Court brief (petition for certiorari)

Third United States Supreme Court brief (merits)