



Intellectual Property Alert:

District Court Rules Against Patenting Human Genes

By: Sarah A. Kagan

The ACLU filed a broad constitutional challenge to the patentability of gene sequences. While winning its declaratory judgment action at the U.S. District Court of Southern District of New York, the ACLU did not obtain the constitutional review it sought. Rather, the court decided that Myriad's fifteen claims in seven patents relating to the *BRCA1* and *BRCA2* genes and prognostic methods were invalid under patent statute 35 U.S.C. §101. Under the doctrine of constitutional avoidance, the court dismissed without prejudice the ACLU claims of constitutional violations.

The court instead focused on whether the claimed isolated DNA falls within the product-of-nature exception to §101, whether the claimed prognostic methods comply with the *Bilski* machine-or-transformation test, and whether the claimed drug screening methods were more than a scientific principle. The Myriad claims at issue were of three types: (a) isolated DNA encoding *BRCA1* or *BRCA2* polypeptide; (b) method of detecting germline mutations in *BRCA1* or *BRCA2*; and (c) drug testing.

The court construed the "isolated DNA" of the product claims as meaning a segment of DNA nucleotides existing separate from other cellular components normally associated with native DNA, including proteins and other DNA sequences. While the court explicitly stated that "genes" are segments of DNA incorporated into chromosomes, it is not clear whether the isolated DNA encoding *BRCA1* encompasses DNA segments in chromosomes.

Rather than relying on the expansive Supreme Court readings of patentable subject matter described in *Diamond v. Chakrabarty* (1980), the ACLU court relied on the earlier and more restrictive descriptions in *Parker v. Flook* (1978) and *Gottschalk v. Benson* (1972). "The rule that the discovery of a law of nature cannot be patented rests, not on the notion that natural phenomena are not processes, but rather on the more fundamental understanding that they are not the kind of 'discovery' that the statute was enacted to protect." *Parker*, 437 US 584, 593 (1978). The court also relied heavily on *Funk Bros. Seed Co.* (1948), an even earlier Supreme Court decision relating to mixtures of naturally-occurring seeds, as well as *American Fruit Growers* (1931). In the latter decision, the Court acknowledged that the claimed borax-treated, mold-resistant fruit were not found in nature, but nonetheless held that unless they acquired a new or distinctive form, quality or property compared to the naturally occurring article, they

were not patentable subject matter: “Manufacture implies a change, but every change is not manufacture, and yet every change in an article is the result of treatment, labor, and manipulation. But something more is necessary....There must be transformation; a new and different article must emerge having a distinctive name, character, or use.” In *Funk Bros.* the Court had similarly required a higher standard than merely being non-naturally occurring. While the patent holder had created a mixture by selecting and testing for certain beneficial properties, the Court concluded that the inventor himself “did not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable.” These older cases carved out a special niche for biological inventions, creating a higher but inchoate standard for inventions derived from or embodying living matter.

The ACLU court carves an even more special niche for nucleic acids. It holds that they are dual functioning, *i.e.*, they are both physical objects and they encode information. Even if the recited nucleic acid is physically different, if it encodes the same information then it has not been transformed to be “markedly different.” Thus Myriad’s claimed isolated DNA molecules are considered to be “unpatentable products of nature,” despite the fact that they do not exist as such in nature.

With regard to the prognostic method claims, the court held that they encompassed merely abstract, mental steps. The methods did not meet the *Bilski* machine-or-transformation test. The methods recited “analyzing” a sequence of a gene or RNA or cDNA or “comparing” one sequence to another. The court construed the sequences to be abstract strings of symbols rather than chemical components. Even if the court were to consider as part of the method the transformations involved in determining a nucleotide sequence, it explained, the transformations would not impart patentability, because they would be considered mere “data-gathering.”

Finally, the court considered the methods of testing for therapeutic agents that inhibit the growth of cells transformed with an altered *BRCA1* gene. Even though the court conceded that transformations may be involved in the methods, the court found the methods excluded from patentability because the claimed process “is, in fact, the scientific method itself.” The court saw the method as trying to capture “a basic scientific principle: that a slower rate of cell growth in the presence of a compound indicates that the compound may be a cancer therapeutic.”

The ACLU court did not hold that gene patents are unconstitutional. However, it held particular claims to isolated nucleic acids, particular claims to methods of performing a genetic test, and particular claims to methods of performing drug screening did not constitute patentable subject matter. However, each of these holdings is likely to be appealed to the Court of Appeals for the Federal Circuit. The Court of Appeals is more agile with both the patent laws and biotechnology. Even if it affirms the rulings of these particular claims as invalid under § 101, it is likely that it will do so on far more narrow grounds.

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