

## Strategies for Gene Patenting



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In light of the *Myriad Genetics*<sup>1</sup> decision, we propose updated strategies for gene patenting, as well as laying out a landscape of gene patenting from the perspective of down-stream enforcement. Until the courts resolve the gene patenting issue, the contents presented herein should be viewed merely as potential impacts and prospective strategies.

The landscape for patentable subject matter is not static. Technologies disfavored or favored by the courts and patent office one year are viewed differently the next. For example, five years ago, business method patents were broadly patentable and enforceable. However, the courts recently greatly restricted patentability and enforceability of business method patents, illustrating the fluidity of patentable subject matter from year to year.

Because of the long life of patents, including long application pendency periods, we recommend continued filing of gene patents until the Federal Circuit or the Supreme Court definitively weigh in against them. Obviously, *Myriad* must be factored into filing strategies for gene-related inventions. However, with the uncertainty surrounding *Myriad*, a business's best interest is to continue filing gene patents, at least at a baseline level, to ensure that no rights are forfeited if the Federal Circuit or Supreme Court reverses the *Myriad* decision.

### Impact of *Myriad* on Gene Patents

*Myriad* patents presented two types of claims: (1) gene composition claims, which consisted of isolated gene sequences naturally found in the human genome, and (2) methods of diagnostic use of the gene sequences (including complimentary sequences). Generally, the holding only applies to naturally occurring nucleotide sequences (including *via dicta*, cDNAs that are reverse transcribed from naturally occurring mRNAs) and diagnostic methods of using such sequences. The decision did not reach the merits of other methods utilizing genes, other gene compositions, or downstream products (e.g., proteins expressed by genes), and therefore doesn't preclude them.

### Reach of *Myriad*

A federal district court may opine in a relative vacuum, as was done here. But, *Myriad* is not binding except in the Southern District of New York. Because patents are a federal right, the Southern District of New York is a potential venue, provided jurisdiction can be established.

In other district courts, *Myriad* remains persuasive authority only and is not binding. However, these district courts could follow *Myriad's* reasoning. Likewise, the Federal Circuit could adopt the reasoning as well, although the decision appears to contradict current Federal Circuit case law. In its decision, the Southern District of New York failed to account for Federal Circuit precedent that expressly allows for gene patenting, namely in *Amgen v. Chugai*<sup>2</sup> and *Fiers v. Revel*<sup>3</sup>.

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<sup>1</sup>*Association for Molecular Pathology et al. v. United States Patent and Trademark et al.*, 2010 U.S. Dist. Lexis 30629 (S.D.N.Y. Mar. 29. 2010).

<sup>2</sup>*Amgen Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir. 1991).

<sup>3</sup>*Walter C. Fiers v. Michel Revel*, 984 F.2d 1164 (Fed. Cir. 1993).

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The Biotechnology Industry Organization concurs with our preliminary analysis of the decision, at least with respect to the patentability of genes:

As explained in the ruling yesterday, the District Court's determination is only a preliminary step in the legal process that does not affect how the U.S. Patent and Trademark Office (PTO) evaluates patent applications relating to DNA-based inventions.<sup>4</sup>

### Patent Strategies After *Myriad*

A number of potential patent strategies are likely still be viable for gene patents, assuming *Myriad* becomes the law of the land. For example:

- **Non-natural gene compositions.** Non-naturally occurring versions of genes, potentially even including use of genes from one organism in another organism (e.g., use of mouse genes in humans).
- **Use of gene methods.** Methods of using a non-naturally occurring gene or naturally occurring genes in ways not observed in nature.
- **Gene combination diagnostics.** Claiming use of multiple genes for use in diagnostic applications.
- **Natural gene compositions/methods of use.** After *Myriad*, naturally occurring genes have a penumbra of doubt over their continued viability. But they are still permissible under current Federal Circuit case law.

***Businesses should remember that current Federal Circuit precedent allowing gene patenting of isolated nucleotide sequences still controls.*** Nevertheless, in light of *Myriad*, gene patent applications should have a robust disclosure that will support many types of claims. Although claiming strategy will vary case-by-case, a number of potentially viable claiming strategies, including those detailed above, may exist for patenting of genes if *Myriad* becomes the law of the land.

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<sup>4</sup>[http://www.bio.org/news/pressreleases/newsitem.asp?id=2010\\_0330\\_02](http://www.bio.org/news/pressreleases/newsitem.asp?id=2010_0330_02), last accessed May 25, 2010.