

### ***“Biotech business plans and patenting of human genes”***

For a number of years the US Patent and Trademark Office (PTO) has issued patents on human genes and mutations. During that time the biotech industry has blossomed. In 2008, more than \$30 billion was invested in biotech R&D in the US. The estimated cost of bringing a single biotech therapeutic to market exceeds \$1.2 billion. To what extent does the US biotech industry depend upon ‘gene patents’? Do gene patents support or hinder biotech R&D? To what extent do biotech business plans, funding and strategies rely on the validity and value of these patents?

In May 2009, the ACLU initiated litigation against the PTO, Myriad Genetics and University of Utah, challenging the legality of patenting genes, naturally occurring mutations, methods of looking for natural mutations and the correlation of mutations with tendencies. The ACLU claims the PTO should not have issued patents to Myriad or the university on the BRCA1 and BRAC2 genes and challenges Myriad’s use of those patents to exclude others from testing for BRCA1 and BRAC2 mutations for correlation with an increased risk of breast and ovarian cancers. What does the ACLU identify as the legal basis for invalidating gene patents? What are the immediate and longer term implications of the ACLU’s challenge for biotech research institutions and businesses?