



## Issue: Legislation to Patent Genes

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**CAP Position:** Draft legislation to amend Section 101 of the Patent Act, if enacted, would permit patenting of human genes and naturally occurring associations between genes and disease. The proposal would eliminate the judicially created exceptions to patent eligibility, thereby overturning the *Mayo*, *Myriad*, and *Alice* decisions. Gene sequences and pathogenic variants would no longer be protected from patent eligibility as ‘products of natural phenomena’. The CAP is opposed to this section of the draft legislation as the negative consequences include additional barriers and decreased access to lifesaving genomic tests, loss of access to confirmatory testing, and substantially increased costs of implicated diagnostic testing.

**Background:** Clinical laboratory genomics is a rapidly growing field with numerous critical implications for patient care. Pathologists and other health providers are obligated to oppose legislation that would restrict patient access to these crucial diagnostic services. Gene patents pose a serious threat to patient care, medical advancement, and medical education. Allowing commercial entities to patent genes impedes the provision of genetic-based clinical testing and patient care through exclusive license agreements, excessive licensing fees, and restrictive licensing conditions.

These negative consequences are not conjecture. Prior to the Supreme Court’s *Myriad* decision, a woman could find out if she carried a mutated *BRCA1* or *BRCA2* gene only from a test provided by *Myriad* at a cost of more than \$3,000. The Court’s 2013 decision created academic and commercial freedom for other companies and researchers to create novel tests and conduct research on the previously patented genes. Now there are tests for *BRCA1*, *BRCA2*, and a litany of other pathologically significant genes for as little as \$249.

The proposed legislation also cripples patient self-directed care, blocking their ability to seek second opinions on genetic or other clinical tests and interpretations. An independent second opinion on test-results protected by a gene patent would be unattainable, because no laboratory would be able to develop such a test for confirmatory testing purposes.

Finally, as ‘products of natural phenomena’, gene sequence data is fundamental to the understanding of numerous diseases and should remain exempt from patent eligibility. No commercial entity should have ‘exclusive ownership of a disease’ through license agreements on gene-based tests. This practice has previously been used to prevent physicians and clinical laboratories from performing genetic tests as diagnostic medical procedures. In addition to *BRCA*, prior examples where testing has been halted due to patent enforcement include Alzheimer disease, Canavan disease, and Charcot-Marie-Tooth disease.

Restricting patient’s ability to evaluate and understand their own genetic makeup is the ultimate depersonalization of medicine and should be opposed.