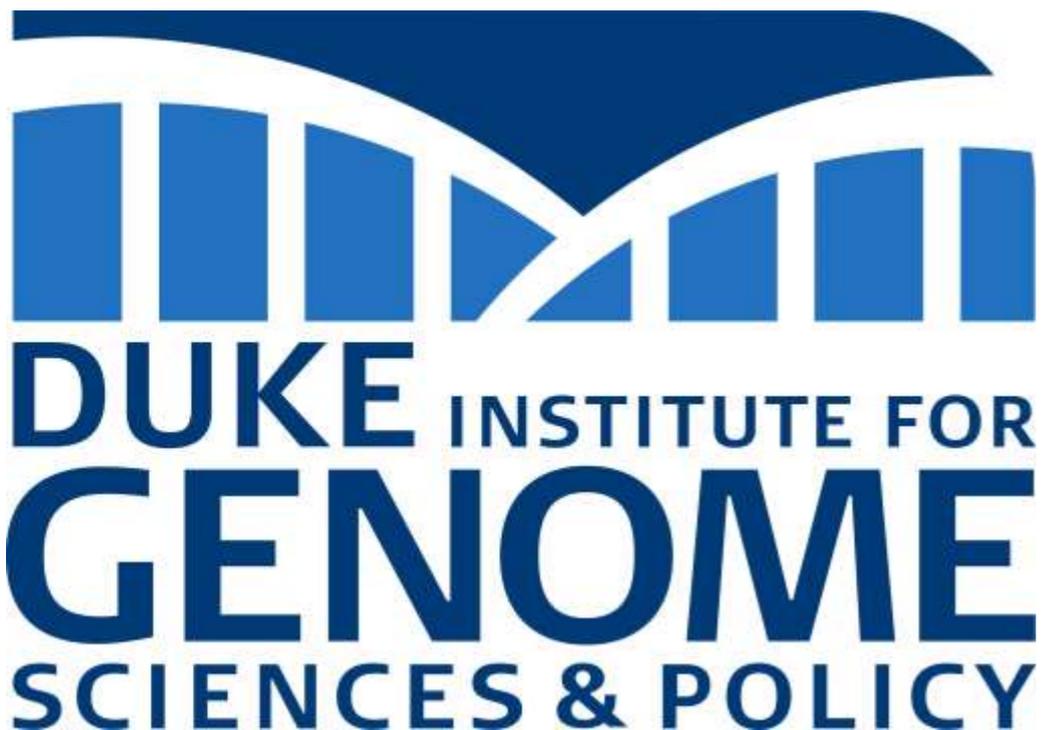


The Myriad Case: So many issues, so little time!

International Society for Philosophy, History and
Social Sciences of Biology

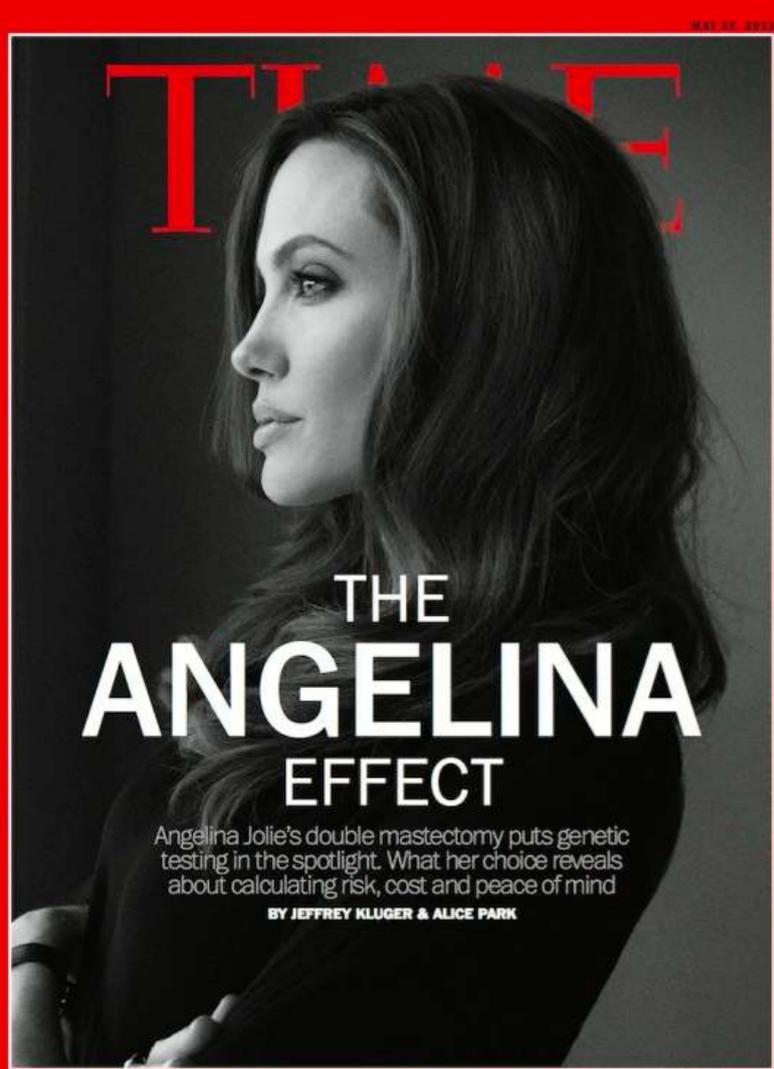
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Disclosure

- I remain on the Jeanne Lenzer/Shannon Brownlee list of health professionals who do not consult or accept funding from pharma/biotech/device companies:
Naming names: is there an (unbiased) doctor in the house? BMJ 2008; 337 doi: 10.1136/bmj.a930 (Published 23 July 2008)
List maintained by HealthNewsReview.org
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The Myriad Case: Great Case, wrong lessons

- Suit happened not because advocates worry about monopoly, but because they were concerned about who makes medical decisions
 - Price an issue, but not the main issue
 - Dislike of business practices, not of patents *per se*
 - Line of attack = patents

The Myriad Cases: The Neverending story

- Supreme Court decision that cDNA is patentable and gDNA is not
- Myriad sues Ambry and Gene to Gene
 - If I discover mutations in a gene associated with inherited cancer risk, can I block competitors from doing PCR on the mutated gene (even if BRCA1/2 are just two among many genes being assessed)?
 - Myriad has pledged not to sue for academic nonprofit research use or verification testing

The other issue: trade secrets

- Myriad's proprietary database drawing on ~1 million tests
- Leveraged on sole-provider status in US
- Does not expire with patents
- Myriad claiming 2% variants of unknown significance (VUS) compared to 30% for Euro competitors

The long tail of mutation

- Most common mutations are usually discovered first
- Patents and IP established on first discovery
- Two decades and >1 million tests later, we are still finding mutations in *BRCA* genes
- *BRCA1/2* have been joined by ~20 other genes in conferring risk for breast/ovarian cancer

Different cases

- AMP v Myriad was public interest case
- Current cases are more conventional conflicts among competitors

Merton's CUDOS

- Communal (shared)
- Universal
- Disinterested
- Original
- Skeptical

Restatements of independent verification in genomics

- **Cech report** (*Sharing Publication-Related Data and Materials*) 2002, National Research Council
- **Omics report** (*Evolution of Translational Omics*) 2012, Institute of Medicine
- **Precision Medicine** report (*Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease*) 2012, Institute of Medicine