

Bioethics vs. The Market: Myriad Genetics, BRAC1-2 and Moralities in Conflict

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The March 2010 court ruling in which Myriad Genetics' (Myriad) patent on the BRAC1 and BRAC2 genes and the concomitant testing and analysis (BRACAnalysis) protocols were invalidated offers insight into the conflict between one moral (fiduciary) system based primarily upon stock valuations, dividends and the ability to attract venture capital, and another based primarily upon the imperatives of the physician-patient relationship.

Myriad was challenged on the legitimacy of a number of claims arising from their patents on the BRAC genes, which fell into two broad categories: (1) their claim to exclusive rights to test for genetic mutations associated with breast cancer (BRAC1) and ovarian cancer (BRAC2), which rights derive from (2) their ownership of the genes themselves, owing to their claim of having (a) identified them and (b) isolated them. The legal challenge brought by a class of plaintiffs including the American Civil Liberties Union (ACLU), researchers, physicians and patients argued against these claims, and against the principle of private ownership of human genes.

Myriad argued that a ruling against them would have a chilling effect on genomics research, especially in that investors would be reluctant to fund research without the expectation of a reasonable return on their investments, mainly in the form of exclusive intellectual property rights over a "predictive medicine product" that all women with the salient risk factors (and the appropriate financial resources) would be encouraged to use. The suit against their patents was an affront to their business model and the overall ability of the biotechnology industry to attract venture capital. The imperatives of treating illness were neither at nor near the top of their list of priorities, as Myriad stated them.

ACLU in challenging Myriad's patents argued in favor of access to the BRACAnalysis protocols, so that more women would have access to what is acknowledged to be a significant breakthrough in early diagnosis — and therefore a greater probability of successful treatment — of breast and ovarian cancer; and, further, that broader access by researchers and clinicians would lead to improvements in the protocols, including the availability of second opinions. ACLU, therefore, argued on behalf of women's health; and on behalf of the researchers, clinicians and genetic counselors whose ability to advance both the science and the healthcare was compromised by their exclusion from the current state of the art.

Even though biomedical research, pharmaceutical research and development, and the practice of medicine itself ("predictive" or otherwise) are extraordinarily expensive, is it possible that there exists a fundamental ethical incompatibility between certain types of intellectual property rights (Myriad's position as stated in court documents is that DNA is just another chemical compound) and healthcare delivery? The March 2010 ruling was overturned on appeal in August 2011, a result that pleased neither side. Thus, even though many of Myriad's patent claims have been restored the issues are far from settled. With approximately one-quarter of the human genome being claimed as intellectual property, the portent is that one hundred percent of human genes will eventually belong to research laboratories or biotechnology companies. But the still-unresolved state of the case might be considered an opportunity to evaluate the bioethics-market dichotomy on the ground of healthcare ethics rather than business ethics.