

It is not ethically
justifiable for
researchers essay



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The completion of the Human Genome Project has resulted in the identification of thousands of genes that are associated to specific medical disorders.

The discovery of novel genes specific to a medical condition has also resulted in the creation and design of specific analytical tests that are now routinely employed in the clinical research laboratories which facilitate rapid diagnosis of medical conditions. These specific clinical assays, now commonly called genetic tests, follow a unique molecular principle that each specific gene is encoded by a string of deoxyribonucleotide (DNA) sequences, of which any modifications in the size and composition of these sequences would result in a medical disorder. The development of several genetic tests has facilitated individuals and families that are in need of knowing whether a specific disease is hereditary or common in their family history. Hence this revolutionary breakthrough has resulted in a new approach to medical treatment that transforms the bench-side or laboratory experimentation to the bedside or patient application.

Concomitantly, the generation of the human genome sequence data has also has also resulted in the filing of thousands of patents that aim to claim property rights on specific genes. The application of patents is strongly linked to commercialization of a genetic test because once an assay has been validated of its efficiency and reliability, the technology may be adapted by other hospitals and research centers. The system of patenting is a form of intervention that is subsidized by the government to promote innovation and to encourage scientists, researchers and inventors to monopolize the technological assay that they have designed. As a result, the

patenting and commercialization of these genetic tests has influenced patent holders to exploit the end-consumers of their inventions, which is technically the patients that request for genetic testing (Reynolds and Stoianoff, 2003). Through the patent system, the scientists and inventors who are associated with the specific gene and genetic test control the use and employment of these genetic tests and therefore, not all healthcare facilities and other clinical research centers could provide the specific genetic test unless they pay for propriety fees for the use of the diagnostic assay.

This results in the payment of high prices for a specific diagnostic genetic test and since there are no competing companies that provide the same diagnostic test due to patent and property rights restrictions, the prices may be extremely high. It is therefore not ethical to claim property rights on genes because the public may not maximize the use of specific genetic diagnostic tests because of these commercialized settings. A good case example is that of the gene patent of Myriad Genetics, Inc. in partnership with Genetic Technologies of Australia.

Myriad Genetics was granted property rights over the gene BRCA1 (breast carcinoma 1) and BRCA2 (breast carcinoma 2), which are genes linked to a higher susceptibility to familial breast and ovarian cancers (Rimmer, 2003). The BRCA1/BRCA2 patent awarded to Myriad Genetics indicates that they should only provide their genetic test to a restricted number of genetic laboratories in a few regions around the world, namely Myriad Genetics in Salt Lake City, Utah, United States. This patent thus encouraged the monopolization of genetic testing for breast cancer and restricts other clinics and laboratories to put up their own genetic assays for breast and ovarian

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cancer. The controlled availability and access to the BRCA1/BRCA2 genetic test is thus restricted and undermines the fundamental goal of the Human Genome Project which is to transform bench or laboratory work to bedside tools for molecular diagnostics. Economically, the patent and property rights of a gene may result in the two- to three-fold increase in the price of genetic tests because the budget of the genetic assay is based on a private hospital's or a pharmaceutical company's research laboratory and the lowered or subsidized prizes of government health agencies are not realized due to the restrictions of the patent. In addition, further assessment, improvement and modification of the genetic test may not be performed by other clinical laboratories because the property rights also encompass the restriction that only the patentee may have the right to further study and investigate that particular gene (Bounpheng et al.

, 2003). Hence, there may be a great possibility that there may be a simpler, faster and even cheaper genetic test for BRCA1 but this may never be discovered because only Myriad Genetics may performed any subsequent studies and investigation on the genetic test and its conditions.

Unfortunately, should Myriad Genetics not opt to review and improve their patented BRCA1/BRCA2 genetic test, the rest of the world have no choice but to depend on the current form of breast and ovarian cancer genetic test. Several countries have voiced out their concern over the property rights of scientists and researchers over specific genes and the associated genetic tests (Andrews, 2002).

For example, the Medical Research Council of Australia and the National Institutes of Health of the United States have recommended that genetic

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testing be made accessible to individuals that are determined to require the BRCA1/BRCA2 genetic test in order to alleviate patient care. In addition, these countries are currently reviewing the systems of patenting and property rights in order for the public to receive as much benefits possible.

References Andrews L (2002): Genes and patent policy: Rethinking intellectual property rights. *Nat. Rev. Genet.*

3: 803-808. Bounpheng M, McGrath S, Macias D (2003): Rapid inexpensive scanning for all possible BRCA1 and BRCA2 gene sequence variants in a single assay: Implications for genetic testing. *J. Med.*

Genet. 40: e33. Reynolds R, Stoianoff N (2003): Intellectual property text and essential cases. Sydney: Federation Press. Rimmer M (2003): *Myriad Genetics: Patent law and genetic testing.*

Eur. Intellect. Prop. Rev. 25: 20-33. Exam questions 1.

Which genetic test served as a case study for gene patents? a) prostate cancer b) lung cancer c) breast cancer d) bone cancer 2. Which international scientific project resulted in the identification of thousands of genes that are related to specific medical disorders? a) Human Genetic Project b) Human Genome Project c) Human Genome Sequence d) Human Gene Project.