

Who Owns Your Genes?

Scott E. Walker

The focus for the front cover of *CJHP* in 2002 will be the Human Genome Project and advances in science, medicine, and technology related to this project.

While it is widely hoped that the human genome project¹ will assist us in treating genetic disease,² the race to map the human genome also has a financial incentive. Although the Human Genome Project was completed with public (US) money, some large genome-mapping groups have done their work with private funding and have actually patented the DNA fragments that they have mapped. These DNA fragments, called expressed sequence tags (EST), may be thousands of bases in length and may carry real genetic information. EST strands may code for a specific function, so if a scientist finds a useful application in a particular coded sequence and that application depends on the DNA sequence, the application will in effect be patented.

Although private firms believe that patenting is necessary to protect their work, it may also restrict innovation, as independent scientists will have no incentive to work on patented sequences. However, the ethical issues related to this topic — even the thought that there could be private ownership of a part of the human body — are incredible. Many groups have pointed out that since genomic information cannot be invented, it should not be considered patentable. Furthermore, since the first person to observe the hypothalamus was not granted title to it or any of its hormones, why should a scientist be given title to a base-pair sequence from any chromosome, just because he or she was the first to sequence that strand?

An example of the effect of patenting a sequence or gene on health care relates to breast cancer. In 1994, the *BRCA1* gene was identified as part of chromosome 17 and was sequenced.^{3,4} Subsequent studies have demonstrated that women with this mutation have a greater risk of breast cancer than those without it.⁵ As a result, a test was developed to detect the presence of the *BRCA1* gene. However, Utah-based Myriad Genetics has a patent that covers the *BRCA1* gene⁶ and is exercising the patent by insisting that any testing to detect the presence of the mutation must use its version of the test. The test kit sold by Myriad costs US\$2400, whereas many



The ras protein, made up of 189 individual amino acids, is crucial to all cells because it transmits regulatory signals that control cellular growth and differentiation. Graphic courtesy of US Department of Energy Human Genome Program (<http://www.ornl.gov/hgmis>).

laboratories can complete the test for one-third that amount.^{6,7} This situation has led a number of European countries to question the legitimacy of patenting the human genome.^{7,8}

References

1. Walker SE. The human genome project. *Can J Hosp Pharm* 2002;55:4,51.
2. Walker SE. Treating genetic disease. *Can J Hosp Pharm* 2002;55:96,100.
3. All about breast cancer genes. In: Ethical, legal and social issues in science [Web site]. Berkeley (CA): Lawrence Berkeley National Laboratory, University of California; 2002. Available at: <http://www.lbl.gov/Education/ELSI/Frames/cancer-genes-f.html> (accessed 2002 Aug 8).
4. Van Warren L. The *BRCA1* breast cancer gene [DNA drawing]. In: Cell World storyboards [Web site]. Warren Design Vision; 2000. Available at: <http://www.wdv.com/CellWorld/Storyboards/BRCA1/> (accessed 2002 Aug 8).
5. Lakhani SR, Van De Vijver MJ, Jacquemier J, Anderson TJ, Osin PP, McGuffog L, et al. The pathology of familial breast cancer: predictive value of immunohistochemical markers estrogen receptor, progesterone receptor, HER-2, and p53 in patients with mutations in *BRCA1* and *BRCA2*. *J Clin Oncol* 2002;20:2310-8.
6. Butler D, Goodman S. French researchers take a stand against cancer gene patent. *Nature* 2002;43:95-6.
7. Wadman M. Testing time for gene patent as Europe rebels. *Nature* 2001;413:443.
8. Kaiser J, Malakoff D, Balter M. Patent challenge grows. *Science* 2001 Oct 12;294:283.

Scott E. Walker, MScPhm, FCSHP, is Editor of *CJHP*.

