

Gene Patents Threaten Health Care

Hamilton Spectator and Straight Goods – November 30, 2001

By Dr. Gordon Guyatt

People will not remember Mike Harris for being an aggressive advocate of public health care at the expense of private companies. Yet, in one crucial area, Harris stood up courageously, and wisely, to private interests.

Before his resignation, our Premier took on national leadership in a fight against private companies threatening public access to exciting advances in genetic diagnosis and therapy. It's an unusual role for the provincial government, which has advocated private delivery of health care services. Because of the huge benefits that may flow from genetic research, it is a crucial role.

Genes are the fundamental building blocks that determine who we are. Our genes control our physical appearance, much of our capabilities and limitations and our susceptibility to disease.

The last decade has seen a race to understand the structure of human genes. Both public research institutions and private companies have been part of the competition. Typically, the winner in a race to identify the structure of a specific gene places a patent on their discovery. If you have identified the sequence of nucleic acids, the genetic building blocks, and are the first to the patent office, that gene is yours.

But wait a minute. Just because you are first to understand the structure of a gene, does that mean you own it?

Some companies who have patented genes would like to think so. Take Myriad Genetic Laboratories Inc. of Salt Lake City, Utah, for instance. This company completed "sequencing" two genes, BRCA 1 and BRCA 2, that make women more susceptible to breast cancer. Their accomplishment allowed development of a diagnostic test that tells women with a family history of breast cancer whether they carry the gene.

The company now claims that their patent gives them exclusive rights to any diagnostic test, or any therapy, that uses the gene sequence. So, when Canadian provinces developed their own diagnostic tests for BRCA 1

and BRCA 2, Myriad demanded they stop. The company requires that all material be sent to them.

Which raises a problem. Myriad charges \$3850 for full screening, while Canadian laboratory costs for the same procedure are less than half that amount. Mike Harris has decided to defy Myriad, continue testing, and if necessary fight Myriad in court.

Understanding this issue, we need to consider why we have patent laws in the first place. If I make a discovery and the government prevents other people from using that discovery, I can make money by selling the discovery, or what it allows me to produce. With a monopoly, I can keep my prices high. This provides a strong incentive for individuals, and industry, to invest resources in research. Thus, patents contribute to innovation in our society.

But there is a down side. Those high prices may block access to the discovery, and its benefits. If patent laws are too restrictive, the losses in terms of public access outweigh the benefits of encouraging innovation. As Dr. Ron Carter, President of the Canadian College of Medical Geneticists, has pointed out, there are at least three lines of argument suggesting that Harris is right to fight Myriad. The first is the extravagance of the Myriad claim. It's as if the discoverer of x-rays were to say "no one else can use x-rays. Anyone who wants an x-ray has to come to me."

The second argument has to do with how much Myriad has contributed. A huge body of work, largely publicly funded or publicly supported, contributed to understanding the structure of genes, and how they function. Furthermore, many investigators contributed to the specific area of research looking at breast cancer susceptibility genes. Myriad's contribution was limited to the final step of completing the gene sequence.

The third argument has to do with the social consequences of letting Myriad, and other companies who complete gene sequences, have sole rights to all medical advances that flow from their contribution. The first, and most obvious adverse consequence is the threat to health care availability. Should wealthy Canadians be the only ones who can access the health benefits of gene research?

In addition, if we allow American companies a monopoly on gene testing and therapy, our local expertise in these areas will wither. No one outside of the companies will have the knowledge and understanding to determine if the tests or therapies are working the way they should. No one will be able to improve the performance of the tests or therapies.

Finally, if we don't challenge Myriad's monopoly, we will lose other benefits of local testing. Having the testing expertise locally allows coordination of the whole testing and counselling process. This means that we can avoid unnecessary testing, and make sure patients receive the best counselling most efficiently.

Other companies who have patented genes have recognized these arguments, and have been willing to compromise. For instance, they have negotiated modest royalties instead of demanding total control. If Myriad demanded some payment for each test that a Canadian province undertakes, it would continue to encourage innovation and keep the test affordable, while acknowledging Myriad's limited contribution to the process of understanding the gene structure.

Mike Harris, acting in an unaccustomed but extremely welcome role as an advocate of affordable, universal public health care, summarized the situation beautifully: "Our genetic heritage belongs to everyone. We must share the benefits fairly, and do what we can to make genetic tests and therapies affordable and accessible."