

Ontario defies US firm's genetic patent, continues cancer screening

The Ontario government is challenging the right of a Utah-based genetics company to stop Canadian laboratories from performing predictive genetic testing for 2 breast cancer genes for which the US company holds patents.

Lawyers for Myriad Genetics asserted the Salt Lake City firm's patent rights to the genetic-sequencing tests for the *BRCA1* and *BRCA2* genes in "cease and desist" letters sent to the Ontario and British Columbia governments last year. Publicly funded laboratories in the 2 provinces, along with those in Quebec and Alberta, were using the tests that screen for hereditary breast and ovarian cancer.

Myriad claims the testing violates its patent. The company told the provinces to send their samples to Utah, where Myriad would perform the tests for about US\$3850; in Ontario the test costs, on average, about Can\$1150. After assessing the legal, ethical and financial implications of Myriad's claim, the province decided that the precedent they would set by agreeing to Myriad's request was insupportable, said Gord Haugh, a health ministry spokesperson.

"Basically, Ontario was being told which test it could fund and where and how the test could be performed," Health Minister Tony Clement said last fall. "Implicitly, this is also about who controls and stores genetic data."

Ontario will continue financing predictive genetic testing for ovarian and breast cancer through its 7 regional genetics centres, he added. "It's our position that payment to hospitals for the provision of these services does not constitute infringement of any valid claim of Myriad's patent." Earlier, the British Columbia Ministry of Health followed legal advice and decided to stop providing testing (*CMAJ* 2001;165[6]:812).

Haugh says the province is now pushing Ottawa to re-examine its patent laws, most of which have not been updated since the 1800s. "These patents have been granted under the laws that exist. We're questioning whether they should have been granted."

Courts in both Canada and the US have ruled that genes can be patented as long as the company or individual applying for the patent can demonstrate some

use for the gene, such as genetic testing, says Toronto psychiatrist Miriam Shuchman, who teaches ethics at the State University of New York in Buffalo. But "this is not the same as a drug that you went into the laboratory and devised. You could make the argument that people have a right to have at least access to something found in their own bodies."

The court of public opinion may ultimately decide these issues, adds Shuchman. "The fact that the patent courts went ahead and made this decision doesn't mean it can't be modified."

Across Canada, BC has temporarily suspended funding for the test, but will provide counselling services if patients pay for it themselves. Quebec has agreed to Myriad's request and is sending samples to Utah. Alberta is quietly continuing to finance the predictive screening, funded through the Alberta Cancer Genetics Program. The other Canadian provinces are not currently offering the tests.

A spokesman for Myriad declined to discuss Ontario's decision. "This is a difficult time to discuss the issue," said spokesperson Bill Hockett. "It's really [a question of] whether Canada is going to uphold biotechnology patents."

For Janet Dikland, a Kingston, Ont., breast cancer survivor, relieving her

daughter's anxiety was the most important factor in being tested. When Dikland tested negative for the 2 genes, her daughter knew neither she nor her mother were likely among the 6% or 7% of women who have a hereditary predisposition to the disease. "She was very relieved," Dikland says.

Although Dikland could have afforded genetic testing if Ontario hadn't provided it, she says it should not be patented, especially since Myriad was building on years of publicly funded research.

"We've already paid for it," agrees Dr. Ron Carter, president of the Canadian College of Medical Geneticists. He says the college has been warning for years that the gene-patenting issue is critical to the future of medicare. "This is not a discussion about 1 test and 1 pair of genes. There are literally hundreds of genes that have been patented and hundreds more to come. It means that for many of the other diseases we test for and hundreds to come, there could be significant limitations on how we provide laboratory tests, who does it, how much they cost and how it's done."

Although Myriad is aware of Ontario's decision, the province has not yet been notified of any further legal action, says Haugh. — *Laura Eggertson, Ottawa*

Health Canada introduces online reporting of radiation exposure

Managers of a new Health Canada project hope a move online will improve turnaround times for the country's dosimetry services. National Dosimetry Services (NDS), operated by Health Canada's Radiation Protection Bureau (RPB), measures Canadians' occupational exposure to ionizing radiation using various dosimeters. For the past 50 years, NDS has sent exposure reports to clients and to the National Dose Registry. The new online system is expected to speed their delivery and provide feedback from clients.

Dr. Dietlind Gardell, who was formerly with the RPB and is now associate executive director of the Centre for Emergency Preparedness and Response, says online reporting to physicians, dentists and other professionals exposed to radiation will improve the management of radiation risks. "It also assures instant information about any radiation sources that exceed permissible levels and that questions about workplace health can be answered more efficiently."

Previously, reporting of occupational radiation exposure was usually done by telephone, fax or regular mail, and Gardell says this slowed service delivery. The new project has been labelled a "pathfinder" by Treasury Board because it has been chosen to help Health Canada map out how it can use interactive electronic communication securely. Additional information is available from Gardell (Dietlind_Gardell@hc-sc.gc.ca) or on the Web (www.gol-ged.gc.ca). — *CMAJ*