lead to a reduction in deaths from cardiovascular disease.

Given the available evidence, the fortification of foods with folic acid is justifiable. It is an effective and inexpensive way to ensure adequate folate levels in all prospective mothers and maximizes the effect of folic acid in preventing NTDs. Finally, the advantage of avoiding or minimizing the number of pregnancy terminations in the second trimester because of these anomalies should not be underestimated.

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Gene patents and the standard of care

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Although many have debated the ethics of patenting human genes over the past 2 decades, recent controversies surrounding the effect of gene patents on genetic tests for breast and ovarian cancer have brought that debate to a head.[1] In the absence of changes in Canada's patent laws, physicians will face a variety of legal and ethical dilemmas regarding the ordering of appropriate genetic tests for their patients.

A DNA sequence patent provides its holder with a great deal of power to control how anyone — including a physician and his or her patient — uses the "patented" sequence. Since all genetic tests require the reproduction of the patient's target gene, gene patents can create a number of access problems. First, the patent permits patent holders to charge a premium for access to the service. Second, patent holders can require that physicians wishing to order genetic tests for their patients have the test done by the patent holder or one of its licensees. The patent holder may impose additional conditions, such as the requirement that the test be conducted at a specific location. In the case of the *BRCA1* and *BRCA2* genes, a mutation of which increases a woman's predisposition to breast and ovarian cancer, Myriad Genetics, the patent holder, requires anyone wishing genetic testing to send their sample to Myriad in Salt Lake City to be analyzed by a method determined by Myriad at a cost of about US$2500. A comparable test provided by Genetic Diagnostic Laboratories in Ontario, licensed by the Ontario Ministry of Health and Long-Term Care, costs Can$1150.

These limitations pose several problems for physicians. First, the implied or real threats of patent infringement may delay or block the development, validation and implementation of diagnostic tests by Canadian laboratories.[2–4] Second, the method mandated by the patent holder for conducting the test may not be the most appropriate for the patient. Third, the high price charged by patent holders for genetic tests may cause provincial health care systems to refuse to insure these tests. A recent report issued by the Ontario Ministry of Health and Long-Term Care concluded that genetic tests will increase the cost burden on the health care system, at least in the short term.[5] Fourth, the high costs of tests not covered by provincial health insurance plans may render these tests unaffordable and thus unavailable to many patients. Fifth, sending patient samples out of Canada to a company not subject to Canadian laws and regulations may cause ethical concerns over quality control and confidentiality.

It is the availability of tests that perhaps is of greatest con-

cern to physicians. The conventional wisdom states that patents are necessary in order to stimulate innovation and the development of useful technologies,[6,7] particularly in the context of biotechnology.[8] This wisdom is based on the assumption that the monopoly control that comes with the granting of a patent will serve as an incentive to innovation and private sector investment. Although recently published studies have questioned the validity of these assumptions — for example, work by Merz and colleagues[9,10] suggests that patents may not be necessary for the development of diagnostic tests and can actually delay implementation — gene patents remain central to the current commercialization process of gene technology.

As highlighted by the Myriad controversy, patents may also have a profound impact on access. In Canada most genetic diagnostic laboratories are situated in hospitals and are subject to the constraints of hospital budgets. Under our health care system the potential costs of royalties, which in the extreme can double the cost of testing, cannot be passed on to the patient and therefore put an economic burden on the hospital or regional health authority. Canadian laboratories currently offer DNA testing for about 120 genetic diseases, compared with the more than 600 tests available in the United States. This is rapidly creating a Canadian standard of care with respect to genetic testing that is substantially below that of the United States. Not only do physicians and their patients face frustration over not having access to the appropriate test, but physicians may find themselves in a potentially difficult legal situation. A physician has a duty to advise his or her patient that a clinically useful test has been developed, but if the physician cannot order the test, he or she may not be able to provide successful disease management for the patient.[11]

The situation is more complicated if an alternative genetic test is available outside of Canada. Again using the *BRCA1* and *BRCA2* gene test as an example, the relevant patents over that gene in Europe are or are likely soon to be in abeyance as a tribunal rules whether the patents are valid. Until the tribunal makes its decision, which may take years, Myriad has no right to prevent others from providing genetic tests for the genes in Europe. In this situation, just as rural physicians have an obligation to tell patients about beneficial diagnostic services that are available only in larger centres, Canadian physicians may be under a legal duty to advise their patients of the availability of the alternative *BRCA* gene test in Europe and to inform them about how to get that test.[12,13]

Although the problems posed by gene patents are not unique to Canada, other countries have been more aggressive in addressing them. France, for example, has recently introduced legislation that would permit the country's minister of health to grant compulsory licences to provide a genetic test in return for a reasonable royalty in order to protect public health.[14] This measure, being contemplated by other countries, would not only reduce the cost of genetic tests but would ensure that patients have access to the most appropriate test available. In the United States, a member of the House of Representatives has introduced a bill that would prevent patent holders from suing physicians for administering a genetic test.[15]

There seems little doubt that gene patents will remain an important part of the innovation process. However, Canada needs to contemplate a way to ensure that clinically useful genetic tests become available to Canadians as soon as they are validated. As the examples in France and the United States illustrate, there are several options available to Canada to attain this goal, including the amendment of the Patent Act to introduce limited compulsory licensing and an exclusion of liability for medical practitioners providing medical services, such as genetic tests. Until the federal government amends the Patent Act, physicians will be caught in the middle, being forced on occasion to recommend a diagnostic procedure unavailable in Canada.

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