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Richard Gold (Canadian) is the BCE Chair in e-Governance at McGill University's Faculty of Law in Canada. He teaches in the area of intellectual property and technology. His research centres on the nexus between technology (particularly biotechnology), commerce and ethics. His publications include *Body Parts: Property Rights and the Ownership of Human Biological Materials* (published by Georgetown University Press) and numerous articles in legal and scientific journals examining the ethical and social effects of patent law and industry's use of patent with particular emphasis on health care.

Richard was recently Senior Advisor, Intellectual Property, to the Canadian Biotechnology Advisory Committee, is a Research Associate at the Health Law Institute at the University of Alberta, and is actively involved in judicial education at the international level on genetics in his capacity as Senior Fellow, Einstein Institute for Science, Health & the Courts (Washington DC).

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GENETIC INVENTIONS, INTELLECTUAL PROPERTY RIGHTS AND LICENSING PRACTICES

Possible Policy Responses: Tools to Achieve Balance between Ethics and Commerce

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Recent events have given substance to academic warnings that conflicts will arise between the award of gene patents and health policy. While many of these warnings have been exaggerated or uninformed, several are substantive. The most recent examples of conflict include challenges to Myriad Genetics' gene patents in Europe and in Canada and the NIH's attempts to gain access to patented stem-cell lines in the United States.

In this presentation, I will briefly outline health care policy goals (including cost containment, access, and choice) and point out some of the ways that patent law and business practices using patents may affect these goals. The bulk of my presentation will concentrate on the tools that governments have available to maximize the positive effects of patents on health care while minimizing patent law's potential negative effects. I will discuss some of the tools that follow during my presentation:

- excluding certain categories of innovation from the scope of patent law (a blunt instrument);
- raising the standards applied to determine whether a gene-based innovation ought to receive a patent;
- through a combination of patent office policy and judicial or quasi-judicial review (underway but slow and leaves unwanted uncertainty);
- alternatively, setting these standards by legislation (quicker but care must be taken to ensure sufficient flexibility remains);
- refining the scope of gene patents (differentiating between the physical structure of a gene and its information content);
- finding new ways to use the “ordre public or morality” clause (establishing a separate administrative structure to define which inventions cannot be patented for breach of ethical norms);
- clarifying experimental use exceptions in patent law;
- enforcing competition laws against anti-competitive effects of the mere ownership of gene patents;
- separating the right of financial return from the right of control (compulsory licensing);
- creating of specialised courts dealing with patent matters; and
- investigating the use of civil liability rules to hold patentees responsible for unethical conduct.