SUMMARY DOCUMENT

A Summary of Principal Ideas arising from Research Papers not addressed in the Biotechnological Intellectual Property and the Patenting of Higher Life Forms Consultation Document 2001

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The views expressed in this document are those of the individual authors and not necessarily those of CBAC or its members.

Cat. No. C21-32/1-2001-1
ISBN 0-662-65675-X
53355B

PRINTED IN CANADA
IMPRIMÉ AU CANADA

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INTRODUCTION

This document is intended to serve as a supplement to the consultation document titled "Biotechnological Intellectual Property and the Patenting of Higher Life Forms." It outlines the majority of the research studies commissioned by the Canadian Biotechnology Advisory Committee (CBAC) in preparation for the spring 2001 consultations on intellectual property and the patenting of higher life forms. This summary is presented here to illustrate the complexity of the issues and the range of topics involved. In combination with the main consultation document, the reports in this summary paint a fuller picture of the issue of biotechnological intellectual property and the patenting of higher life forms. While CBAC may not make recommendations to government at this time concerning the matters delineated in this summary, readers are welcome to submit comments on them to CBAC at the contact points listed at the beginning of this document.

The Canadian Biotechnology Advisory Committee (CBAC) is an independent expert advisory committee created to assist the Government of Canada in formulating public policy on a broad range of biotechnology subjects. It is currently conducting a special project and preparing advice for the Government of Canada on biotechnological intellectual property and the patenting of higher life forms. In spring 2001, it will hold consultations on this subject.

In laying the groundwork for these consultations and other work ahead, CBAC commissioned an extensive series of research papers covering a broad range of topics pertaining to intellectual property and the patenting of higher life forms. Based on these documents and on information garnered from preliminary discussions with biotechnology stakeholders, CBAC targeted four key issues for consultation. These issues[1] are presented in the consultation document *Biotechnological Intellectual Property and the Patenting of Higher Life Forms*.

This summary outlines some of the research studies that extend beyond the scope of the four key issues but that contain interesting information relevant to intellectual property and the patenting of higher life forms that Canadians may wish to peruse. The reports on which this summary is based constitute significant groundwork on important matters that CBAC may wish to investigate more closely during its citizen engagement phase. They also help to lay a solid platform for CBAC's ongoing work as it continues to examine biotechnology-related matters and the views of Canadians following its report.

This summary does not attempt to provide a balanced examination of the issues introduced. Rather, the discussion set out in this summary presents the views and opinions of the authors of the commissioned studies or the participants in the stakeholder discussions. These reports do not necessarily provide a full discussion of all aspects of the issue. It is therefore important to note that the views expressed in the following pages reflect only those of the individual authors and not necessarily those of CBAC or its members. This summary also does not attempt to provide all of the details contained in the research studies, although it does present enough information to inform readers of the scope of the individual papers, which they can then access from CBAC's Web site.

The topics discussed on the following pages are open to public comment. Readers are welcome to submit their views to CBAC at the contact points listed at the beginning of this document. Readers may also use these contact points to obtain more information on CBAC, the consultations, the research papers and other aspects of CBAC's work.

[1] The four key issues are: What should and should not be patented? What are the mechanisms of governance available for change? How should social and ethical issues be addressed? International obligations and competitiveness.

OVERVIEW

DEFINITIONS

Biotechnology: Biotechnology is defined in various ways depending on the context in which the term is used. CBAC defines *biotechnology* as a body of technical knowledge about living organisms or their constituent parts, and defines *applied biotechnology* as those aspects of biotechnology that are used to make products and drive processes that serve social, scientific or economic purposes. The *Canadian Environmental Protection Act*[2] defines biotechnology as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms."

Patent: A patent is the right to exclude all others from making, constructing, using and selling an invention for a period of 20 years from the date an application for the patent was first filed.[3] Simply having a patent does not permit the patent holder to use the invention; he or she may do so only if there are no conflicting property rights or any laws or regulations preventing use of the invention. The patent also allows the holder to assign a whole or partial interest in the invention to another. Patents are granted on a country-by-country basis. Canadian patents are provided under the *Patent Act*.

Higher life form: The term "higher life form" has no technical meaning within the law. In common parlance, it includes plants and animals[4] other than single-celled organisms. In its deliberations on biotechnological intellectual property, CBAC uses the term "higher life form" to encompass whole plants and animals (including non-human primates), and parts of an animal or plant, such as an organ, tissue, cell and genetic material.[5] The broad scope of this definition of higher life forms means that one must almost always specify which of the many higher life forms one is referring to in discussing particular issues.

CANADA'S PATENT SYSTEM: TODAY AND YESTERDAY

Today's Patent System

The Canadian Intellectual Property Office (CIPO) grants patents in Canada and administers the country's patent laws. Patents are one of several intellectual property schemes (others include copyright, trade-mark, trade secret and plant breeders' rights). A patent gives the inventor and/or the sponsors of the work the right to prevent others from making, using or commercially exploiting their inventions in Canada for a period of 20 years from the filing date of the patent application. By international agreement, the person or company applying for a patent in Canada may also apply for patents for the same invention in other countries. Nevertheless, patents are granted on a country-by-country basis.

For the purposes of patent law (which contains its own definitions, which may or may not accord with popular usage), an invention is a product or process that is new, non-obvious and useful. An invention is new if it has not been disclosed prior to the filing date of its patent application (subject to a grace period in some countries[6]). An invention is non-obvious if it is not apparent (without the disclosure contained in the patent application) to a person skilled in the art or science to which it relates. An invention is useful if it has a realistic and substantial industrial application.

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[2] *Canadian Environmental Protection Act*, 1999, s. 3.

[3] Patents filed on or after October 1, 1989, receive a 20-year term of patent protection starting from the *filing* date (s. 44, *Patent Act*).

[4] Even though human beings are animals, most lawyers do not generally believe that a whole human being is patentable.

[5] Although not included in the definition of "higher life forms," processes that make use of higher life forms to manufacture something or to provide a service are also potentially patentable. It is important to note that some processes using plants and animals involve nothing more than allowing nature to do its work while others involve substantial human intervention.

[6] While national laws differ on the nature and extent of the grace period, Canada's *Patent Act* provides a one-year grace period to disclosures made by the inventor or someone else who obtained knowledge from the inventor, directly or indirectly (s. 28.2(1), *Patent Act*).

Canada's patent system aims to benefit both inventors and society. The economic rewards that can flow from a patent are thought to spur people and companies to invest time and money in new areas of scientific research. This, in turn, introduces innovations to the public more quickly. Also, because the application must include information about the nature, construction and anticipated use of the invention and because this information becomes publicly available 18 months from the filing date of the patent application, the patent enriches society's collective knowledge.

Patent applications are examined by technically qualified examiners for statutory compliance, particularly in terms of the novelty, non-obviousness and utility criteria. If a patent is refused, the applicant may request a review by the Commissioner of Patents. If the Commissioner rejects the application, it can be appealed to the Federal Court of Canada and, with permission, eventually to the Supreme Court of Canada.

A 1990 study found that some 17 percent of Canadian firms and 45 percent of top research and development performers were involved in court proceedings involving intellectual property rights during a three-year period. Some 40 percent of firms using intellectual property were involved with, threatened with, or had considered intellectual property-related legal action.[7]

Canada, like most countries, excludes certain categories of inventions from patent protection for policy reasons. Currently, only scientific principles and abstract theorem are explicitly excluded from patent coverage. Canadian courts have, however, also determined that methods of medical use cannot be patented. There is current uncertainty over whether patents can be granted over plants and animals and, if so, to what extent. Canadian courts have also determined that certain activity does not infringe a patent if it is conducted for experimental use. The scope of this defence is unclear, particularly with respect to biotechnology patents.

A Brief History of Canada's Patent System[8]

Before Confederation, several provinces had their own patent legislation. Early legislation favoured local residents and did not allow foreigners to obtain patents. Laws were designed to encourage local industry, and a patent could be obtained on imported foreign technology without actually having invented it.

The federal government received exclusive legislative patenting authority in the *British North America Act, 1867*. Canada's first patent act took effect in 1869. By the end of the century, foreigners were eligible to obtain patents and statutory authority was in place to allow the hiring of patent examiners.

Several amendments were enacted around the turn of the century, including a provision making applications secret during their pendency. The first major 20th-century revision of the *Patent Act* was in 1923 when measures were passed to allow Canada to join the *Paris Convention*, provide priority rights for corresponding foreign applications, introduce restrictive claiming provisions for foods and medicines, and provide compulsory licensing virtually as a right for the local manufacture of foods or medicines.

The 1935 *Patent Act* reduced the term of a patent from 18 to 17 years and, during 1935–54, the Act was amended several times to protect the rights of inventors during World War II and to provide a procedure for handling applications relating to national defence and atomic energy. The *Patent Act* also underwent numerous amendments from the 1950s to 2000 in response to government studies and international agreements, and to improve administration through technical and non-controversial amendments.

For almost 30 years, starting in the late 1950s, the government undertook several initiatives to examine the patent system from an economic perspective.[9]

[7] *A Brief History of the Canadian Patent System*, by Vic Duy.

[8] Unless otherwise indicated, the following section on the history of Canada's patent system and the historical highlights of the patenting of life forms in Canada is derived from *A Brief History of the Canadian Patent System*, by Vic Duy.

[9] Among these studies were the Royal Commission on Patents, Copyright and Industrial Design (1959), several reports concerning patented medicines, the Economic Council of Canada's 1971 *Report on Intellectual and Industrial Property*, and the Working Paper on Patent Law Revision (1976).

Together, these reports suggested a series of basic changes to the procedure for obtaining a patent and, although none was implemented immediately, several later became law. One of these changes involved amending the prohibition on the granting of patents over illicit subject matter to prohibit those that would be offensive to the *Criminal Code*.

In 1986, the federal government introduced Bill C-22, which amended the Act's compulsory licensing provisions, made fundamental changes to the procedure for obtaining and maintaining a patent, and included a provision that allowed Canada to join the Patent Cooperation Treaty.[10]

In 1990, the Science Council of Canada produced a discussion paper in response to concerns about the impact of trade-related intellectual property issues on industrial competitiveness.[11] It conducted a survey of high-technology and research and development companies that revealed that almost 80 percent of respondents had been involved in intellectual property activity over a three-year period. However, it also revealed a limited knowledge and understanding of intellectual property and its implications. Of particular interest was the finding that almost 40 percent of biotechnology firms indicated they were severely hindered by the lack of plant breeders' rights[12] and patents over biotechnological inventions. Within the biotechnology sector, 67 percent of firms were dissatisfied with the available protection in Canada.

In 1993, Canada again amended the Act. One of the amendments completely eliminated the provision dealing with illicit objects.

From the late 1980s to the early 1990s, Canada negotiated and signed three binding trade-related agreements that required amendments to its intellectual property legislation: the North America Free Trade Agreement (NAFTA); the World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs);[13] and the WTO Understanding on Rules and Procedures Governing the Settlement of Disputes (WTO Dispute Settlement).[14] NAFTA and TRIPs require harmony among nations in patenting technology, while the WTO Dispute Settlement allows member nations to challenge other members' domestic laws insofar as they are inconsistent with any WTO agreement including TRIPs.[15] Under NAFTA in 1994, in order to comply with international obligations, the rarely used prohibition on patenting inventions with an illicit object was deleted from the *Patent Act*.

Patenting of Life Forms in Canada: Historical Highlights

Decisions on the patentability of life forms, both in Canada and elsewhere, have evolved largely as a result of court or patent office rulings rather than by legislative enactments.

- A 1982 decision by the Canadian Commissioner of Patents ruled that claims in an application by Abitibi Co. for a yeast culture were patentable.[16] The application dealt with the production of a large mass of micro-organisms, such that the mass as a whole possessed uniform characteristics and properties.

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[10] Canada joined the treaty in 1990. The treaty sets out an international procedure designed to eliminate duplication among member states, and specifically benefits those applicants who seek to patent an invention in several countries. It provides for the filing of an international application that is searched, published and examined at the international level. However, the treaty has no provisions to grant a patent; that authority remains with each member state and is subject to the laws of each state.

[11] During its existence, the Science Council of Canada produced several papers touching on or dealing directly with intellectual property.

[12] The exclusive right to commercialize and breed a plant variety.

[13] *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, done at Marrakech, Morocco, 15 April 1994, Annex 1C: Agreement on Trade-Related Aspects of Intellectual Property Rights, 15 April 1994.

[14] *Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations*, done at Marrakech, Morocco, 15 April 1994, Annex II: Understanding on Rules and Procedures Governing the Settlement of Disputes, 15 April 1994.

[15] For further details regarding these international agreements, see the "International Perspectives" section of this report.

[16] *Re Application for Patent of Abitibi Co.* (1982), 82 C.P.R. (2d) 8.

- An application by Pioneer Hi-Bred for a patent on a new variety of soybean was the first plant patent case to reach the Supreme Court of Canada.[17] The Commissioner of Patents had refused the claims over the soybean on the grounds of non-statutory subject matter. The refusal was appealed and, in 1989, the Supreme Court affirmed the lower courts' decisions on the basis that the disclosure did not meet the statutory requirement, but the Court did not directly pronounce on the patentability of higher life forms.
- In 1990, Canada enacted the *Plant Breeders' Rights Act* (PBRA) and one year later ratified the 1978 text of The International Union for the Protection of New Varieties of Plants Convention (UPOV). This Convention contains an international consensus on the grant and scope of plant variety rights. The PBRA is designed to stimulate the Canadian plant-breeding industry and provide wider access to foreign plant varieties. It provides protection for new varieties of plants, whether bred sexually or asexually. The UPOV Convention was significantly amended in 1991 to both extend the scope of protection that countries could provide under plant variety legislation and to permit the grant of patents over plants. The government introduced Bill C-80 in 1999 in order to amend the PBRA so that it would conform to the new 1991 UPOV Convention. These amendments would have allowed Canada to join the new UPOV Convention. The bill died on the Order Paper.
- On August 3, 2000, the Federal Court of Appeal[18] concluded that a patent ought to be granted to Harvard University for the invention of a mouse that had been genetically engineered to be susceptible to cancer (the Onco-mouse).[19] The Court ruled that the wording of Canada's *Patent Act*, as it currently stands, permits the patentability of genetically altered non-human mammals for use in carcinogenicity studies. On October 2, 2000, the Attorney-General of Canada filed an application seeking leave to appeal the decision to the Supreme Court of Canada. The Supreme Court of Canada has not yet decided whether to grant this leave and hear the appeal.
- Canada has taken several steps in recent years to improve the effectiveness of the patent system and enhance service to the public. These include consolidating the administration of intellectual property statutes, including the *Patent Act*, under the new Canadian Intellectual Property Office; computerizing operations and making the technical information contained in patents available on the Internet; hiring more patent examiners; and launching an information program for businesses and the public.

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[17] *Pioneer Hi-Bred* v. *Commissioner of Patents* (1989), 25 C.P.R. (3d) 257.

[18] *President and Fellows of Harvard College* v. *Canada (Commissioner of Patents)*, August 3, 2000, A-334-09 (F.C.A.).

[19] The United States, Europe and Japan had already granted patents on the Onco-mouse prior to the Federal Court of Appeal hearing in Canada.

PROTECTION OF BIOTECHNOLOGICAL PROPERTY WITHOUT PATENTING[20]

Some non-governmental organizations question whether great effort should be placed on applying patent law to higher life forms because of various concerns raised. Such concerns include the fact that the patent system is becoming overburdened as technology continues to advance and the possibility that, rather than simply promoting innovation, patents might hinder competition, stifle innovation, marginalize public research and violate certain basic human rights. They argue that industry need not rely entirely on the benefits of the patent system because there are alternative routes that may protect the same interests, in some cases, possibly more effectively. The main complaints by some sectors of industry, as summarized by the Rural Advancement Foundation International, are that patents are practically unreliable, politically unpredictable and technologically untrustworthy and complicated.

It has been suggested that there are a number of mechanisms that the biotechnology industry has been exploring to supplement or replace reliance on intellectual property rights and patenting in particular as the "vehicles of choice" in establishing technological supremacy in specific markets. These alternatives include the following mechanisms.

Biological monopolies: So-called "Terminator" and other sterility or trait-control technologies make it difficult or impossible for customers to replicate the biological material without help from the inventor. By incorporating these technologies into their products, industry can prevent others from copying their inventions. Some of the new technological strategies are designed to prevent genetically modified products from "infecting" conventional crops. Researchers have recently announced a "safe sex seed" that would lead to a genetic modification of maize in order to resist foreign genes.

Biosensors: These include satellite and other DNA detectors that will be able to identify marker genes or sequences at any point in the life cycle of a product. This would allow industry to detect unauthorized growing of patented plants.

Contracts: Contract law and trade secrets can be used to protect inventions. These are often easier to enforce than patents over higher life forms. For example, the developer of a genetically engineered plant might impose certain restrictions on seed purchasers to prevent resale or reuse of the seed. Subject to anti-competition concerns, these rights would be enforceable whether or not patent protection existed. Because these arrangements are private, the public knows less about them and does not benefit from the disclosure that patents afford.

Mergers: Reliance on patent monopolies could be reduced through a reduction in the number of competitors to only a handful of large enterprises through mergers and acquisition.

In the main consultation document, CBAC has invited the public to comment on social and ethical issues arising from patenting higher life forms. Clearly, additional, if not more significant, issues arise from these alternative forms of protection and would require examination in a different context outside of the current CBAC consultations.

[20] The following notes derive from *The Impetus for and Potential of Alternative Mechanisms for the Protection of Biotechnology Innovations*, by Rural Advancement Foundation International (RAFI).

PATENTING ANIMALS[21]

Several issues have been expressed by various groups and individuals concerning the patenting of animals, some of which cut across all higher life forms while others are peculiar to animals. For example, one broad concern expressed by some people is that granting patents on higher life forms could impede further developments that might benefit society.[22] Other issues include the potential negative effects on the Canadian livestock industry, the safety and ethics of xenotransplantation,[23] stem-cell research, the relative safety and risk of transgenic animals to health and the environment, and mechanisms for reporting any adverse consequences on animals.

Box 1

Some 1.5 million animals are used in Canada for scientific research, regulatory testing and teaching. This represents a 25-percent decline over the past decade from 2 million. While mice, fish, rats and chickens make up 87 percent of animals used in research, testing and teaching, the proportion of farm animals (swine, chickens, cattle, sheep) is increasing. The number of transgenic animals created and used for these purposes is also rising, up by an estimated 73 percent in Canada from 1997 to 1998, compared with 29 percent in the U.K. and 20 percent in the U.S.

Additional problems that some have associated with patenting genetically modified animals are the potential for increased animal suffering, the possibility of devaluing or commodifying life, the potential to infuse commercial imperatives into the organization and priorities of academic research, the possible compromising of animal welfare through xenotransplantation, and the potential commercial production of genetically modified donor animals.[24]

INNOVATION IN THE LIVESTOCK INDUSTRY[25]

The livestock industry has contributed significantly to the Canadian agricultural economy. There is a long tradition in Canadian agriculture of controlled mating of livestock by humans for the improvement of the stock. This form of "engineering" has been used to isolate and perpetuate through generations the most desirable (i.e. profitable) characteristics of animals, usually by enhancing productivity.

Canada has strong livestock improvement programs in place, which at one time were funded by the federal and provincial governments operating in concert. The responsibility has since shifted to industry groups. Livestock genetic improvement programs have focussed on the accurate collection of animal-based information and pedigree data to track traits affecting the profitability of livestock. These data are accumulated and analysed

[21] Unless otherwise indicated, the section on patenting animals is based on *The Use of Animals in Scientific Research and as Sources of Bioengineered Products*, by Dr. Clément Gauthier and Dr. Gilly Griffin, Canadian Council on Animal Care ("CCAC Use") and *Alternatives to the Use of Animals for Research, Testing and as Sources of Bioengineered Products*, by Dr. Gilly Griffin and Dr. Clément Gauthier, Canadian Council on Animal Care ("CCAC Alternatives").

[22] See, for example, M.A. Heller & R.S. Eisenberg, "Can Patents Deter Innovation? The Anticommons in Biomedical Research" (1998) 280 Science 698. Various mechanisms are available to address such matters. The European Patent Convention's Article 53(b) and TRIPs' Article 27(3)(b), for instance, exempt plants and animals from patentability. In Canada, while the *Plant Breeders' Rights Act* protects plant varieties, no intellectual property regime protects animal varieties (see main consultation document for discussion of animal varieties exemption).

[23] Xenotransplantation is the transplantation of cells and organs from one species into another. In order to avoid or reduce immunological rejection, these cells and organs are usually genetically engineered.

[24] *Patenting of Biotechnological Innovations Concerning Animals and Human Beings*, by Ted Schrecker, Consultant, Ted Schrecker Research and Consulting; and Alex Wellington, Department of Philosophy, Ryerson Polytechnic University.

[25] The section on innovation in the livestock industry is based on *Innovation in the Livestock Industry*, by R.A. Kemp, RAK Genetic Consulting Ltd.

to estimate an animal's true genetic value, known in the industry as "Estimated Breeding Value." Improved animals are selected to be bred and, through artificial insemination and other methods, improved genetic material is disseminated. There is some tension between this form of engineering and natural selection whereby the fittest animals survive, reproduce and create generations of rigorous stock, without any necessary correlation with industrial productive potential.

In Canada, there is a system of livestock registration under the *Animal Pedigree Act*. Animal pedigree associations, also known as breed associations, are groups of breeders working collectively to make improvements in a breed of livestock. Under the *Animal Pedigree Act*, breed associations have the exclusive authority to represent breeders of livestock pedigrees that have been identified as being unique, distinguishable and valuable. The *Animal Pedigree Act* seeks to certify the genetic purity of an animal that is sold and to promote breed improvement through the breed association.

Biotechnology has advanced controlled mating by several steps. The identification of individual genes allows for the selection of certain traits and control over which of these traits may be expressed in animal populations and at what frequency.

Patent protection of genetic technology may have the desired effect of encouraging innovation in the livestock industry, but may also limit access to technology and genetic material. There is concern that the development of a system of intellectual property rights governing the genetic resources of livestock could affect access to and exchange of genetic resources by limiting the use of technology that is required to make genetic improvement. The restriction on the exchange of genetic information caused by the exclusivity conferred by patenting could reduce the size of livestock populations. In smaller populations, the available genetic variation is decreased, in turn decreasing the achievable rate of genetic improvement.

Genetic improvement is cumulative in nature. Therefore, the longer a patent holder has a monopoly on a particular genetic improvement, the greater the competitive advantage to the patent holder, as this improvement may be reproduced and strengthened through generations of livestock before it becomes available to any other breeder.

Many individual breeders or groups of breeders lack the financial and physical resources to embark on the research necessary to make biotechnological advances or to purchase available technology. As a result, there is concern that a small group of large companies could control genetic improvements. This would offer these companies a substantial competitive advantage in livestock. There is also the concern that Canadian breeders might not be able to compete internationally in the face of patents held by non-residents.

Government may have a key role, through funding and legislation, in balancing the need for innovation with the preservation of genetic resources and an independent Canadian livestock genetic industry. Another key role may be to keep genetic technology available to and affordable for Canadian breeders.

Some possible approaches to the development of intellectual property rights strategies with respect to the Canadian livestock genetics industry include:

- Methods to encourage innovation through strong public and private research sectors.
- Enhanced intellectual property rights policies and strategies that encourage and foster development while not creating barriers to entry, access to technology or significant consolidation in the industry.
- Policies and agreements to ensure that sufficient genetic resources are available both domestically and internationally for use by the Canadian livestock genetic industry.
- Public consultations with the Canadian livestock genetics industry to increase its awareness of the issues of intellectual property rights and gather input for public policy development.

CANADIAN COUNCIL ON ANIMAL CARE[26]

As animals are considered property and therefore fall under exclusive provincial jurisdiction, no national legislation exists concerning the use of animals in scientific research. However, the Canadian Council on Animal Care (CCAC), a national non-profit body, oversees the care and use of animals in research, testing and teaching in Canada.[27] CCAC's ethical review system is designed to balance the needs of scientists, animals and the community at the local level, and to set standards for the care and use of animals in science at the national level.

CCAC's primary goal is to reduce the pain and distress of the animals used in research, testing and production, while meeting the needs of science, industry, decision makers and the public. CCAC has adopted what it calls the three R principles to meet this goal. The three R principles are as follows:

- Refine methods to minimize pain and distress.
- Reduce the number of animals used to get the same information.
- Replace the use of animals with other alternatives whenever possible.

CCAC ensures public accountability by means of a peer review assessment program that centres on Animal Care Committees in each member institution. Using a certification approach, the organization's goals centre on the three Rs. CCAC is funded primarily through three-year grants from the Medical Research Council (MRC) and Natural Sciences and Engineering Research Council (NSERC), with additional contributions from other federal departments and private institutions. If a member institution fails to meet CCAC standards, it can lose its MRC/NSERC funding, which serves as an enforcement mechanism for CCAC's guidelines.[28]

However, while compliance with CCAC's guidelines is mandatory for universities and other research bodies that rely on government funding, it is voluntary for others; that is, neither private nor public laboratories are required by federal regulation or program to comply with CCAC guidelines. While many companies and federal and provincial laboratories choose to comply with these guidelines, CCAC has no mechanism to ensure that all do.

CCAC has developed a powerful enforcement tool on xenotransplantation in collaboration with Health Canada. It suggests that additional mechanisms be designed in collaboration with the Treasury Board Secretariat and Industry Canada to ensure that all public and private sector animal users participate in its programs.[29] These tools could include, for example, a requirement that data submitted to the Canadian Intellectual Property Office must be originated in a CCAC-certified institution, and that Scientific Research and Experimental Development tax credits involving the use of animals must be linked to a Certificate of Good Animal Practice®. It should be noted that these suggestions are not necessarily compatible with Canada's international obligations under NAFTA and TRIPs, and would have to be evaluated in light of these obligations.

GENETICALLY MODIFIED ANIMALS[30]

Certain genetic modifications may potentially cause pain and distress for both the animal and its offspring. Cloning may, for example, create congenital abnormalities, particularly cardiac problems. Genetic manipulation to develop animal models of disease may generate animals that have that disease. Concern also exists for livestock animals that have already been pushed to their physiological limits by conventional breeding

[26] Unless otherwise indicated, the section "Canadian Council on Animal Care" is based on "CCAC Use" and "CCAC Alternatives."

[27] CCAC notes that its standards are recognized as equivalent or superior to those outside Canada.

[28] Federal funding cutbacks and increasing private sector research sponsorship have decreased the portion of academic research funded by the Government of Canada, which in turn means that animal-based research directly tied to the funding of CCAC programs has also reduced.

[29] It is estimated that about $1.2 million would be needed to expand the implementation of the CCAC program to achieve universality in the government and private sector while maintaining quality of the program.

[30] Unless otherwise indicated, the section "Genetically Modified Animals" is based on "CCAC Use" and "CCAC Alternatives."

practices.[31] Routine procedures such as blood sampling and handling, which are usually not stressful for animals, can be more problematic for genetically modified animals (GMAs) that are already compromised. Housing can also be a problem because some GMAs must be kept in a specific pathogen-free or gnotobiotic environment,[32] which can impede their social and behavioral requirements.[33] For these and similar reasons, CCAC guidelines require that all new studies to create a GMA be very carefully examined until the effect of the new gene on the animal has been evaluated.

A list of ethically unacceptable procedures involving GMAs does not exist per se in Canada. However, CCAC guidelines state that all animal-use protocols must be examined for their ethical merit and must have undergone scientific merit review. Any studies that could cause pain or distress warrant special attention, and Animal Care Committees must not approve studies where harm to the animals exceeds the scientific promise of the study.

While the overall number of animals used in research, testing and teaching in Canada has declined over the past 10 years, the use of GMAs has increased. GMAs are increasingly used in research to better understand the role of particular genes and as disease models. In testing, they are used as more sensitive test animals and for efficacy testing of vaccines. In production, they are used as a source of organs for xenotransplantation, for production of therapeutic proteins and for agricultural manipulation of livestock production. The increased use of GMAs will likely continue in the short term but could drop off in the long run by better-defined methodology, purchasing existing strains of animals from certified sources and cryopreservation of embryos. GMAs may, however, be used increasingly for animal-to-human organ transplants.

Traditionally, animals have been used in the development of products during developmental phases (research) and quality or safety assessment stages (testing). The assumption has been that the product itself will have been manufactured through some chemically or mechanically engineered process. This assumption, however, is no longer valid. Genetic engineering means that the animals can now be used as production vessels; that is, they can now be the factory of chemicals, cells, tissues and organs. Animals are used, for example, in the production of therapeutic proteins, medical devices and recombinant proteins for industrial application.

There has been a move away from the use of animals (usually mice) for producing monoclonal antibodies (mAbs) in recent years both in Canada and internationally. As *in vivo* mAb production is a painful and distressing procedure for the animals, CCAC guidelines on antibody production (currently being prepared) encourage the use of *in vitro* methods whenever possible. Germany, the Netherlands, Switzerland and the U.K. now prohibit the routine use of mice for ascites production, and the U.S. Office of Protection of Research Risks has recommended that the *in vitro* production of mAbs be the default method with justification required for *in vivo* production.

In 1998, CCAC suggested a framework for animal welfare oversight, bridging the gap between the research and production environments to ensure seamless animal welfare oversight and regulation between CCAC and pertinent federal departments. This bridging framework has been implemented regarding the use of animals for xenotransplantation and is at mid-stage regarding livestock derived from biotechnology. Work has not yet begun concerning animals used as bioreactors for the production of biological materials.

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[31] This concern is exemplified by Health Canada's decision not to approve Recombinant Bovine Somatotropin (rbST) for sale in Canada on the basis of animal welfare grounds (January 14, 1999). The report of the Canadian Veterinary Medical Association Expert Panel on rbST, upon which Health Canada's decision was based, cited an increased risk of mastitis of up to 25 percent, of infertility by 18 percent and of lameness by up to 50 percent.

[32] A gnotobiotic environment is a controlled environment containing one or a few kinds of organisms.

[33] For example, pigs reared as potential donors for xenotransplantation must have such an environment to minimize the possibility of transferring disease to humans. This would likely include delivery of piglets by caesarean section into incubators isolated from the sow and other piglets. On the other hand, in some cases – for example, livestock used to produce biopharmaceuticals – the animals are likely to live in a better environment than they would in regular farm settings.

The regulatory framework to oversee GMAs in the production environment is not yet in place. Ensuring that CCAC is responsible for the oversight of the welfare of these animals until all of the research questions have been answered provides assurance that non-animal methods have been considered, that the fewest possible animals have been used and that efforts have been made to minimize pain and distress. CCAC believes this should be seen as a necessary component of the regulatory framework for GMAs.

The question of whether or not the use of GMAs contributes to the three Rs is much debated. While GMAs potentially experience more distress and pain than do other animals, they do answer some three R principles. For example, the ability to develop models of human disease using genetic modification means that animals of a lower sentiency can be used more often in research. As well, the use of transgenic rodents such as the p53 rat for carcinogenicity testing could lead to the use of fewer animals and shorter-term tests that would reduce suffering. As genetic variation tends to confound the often subtle responses to test drugs, etc., the use of cloned animals could potentially reduce the numbers of animals used.

The shortage of human organs for transplantation has led scientists to search for new ways to help patients needing transplants. Work is under way to develop animal organs that can be transplanted into humans. Chimpanzees and baboons would be the best organ donors for humans but this is not feasible on a widespread basis due to ethical concerns, the small size of the animals and the risk of disease transmission. Instead, much interest has focussed on pigs and, to overcome rejection problems, pigs have been genetically modified to incorporate the human genes that will decrease immunological rejection. Canada is a leader in developing national standards concerning the safety of tissues and organs used in transplantation.[34]

The potential to treat disease using stem-cell therapies could decrease future reliance on animals for the development and production of cells, tissues and organs. Human stem-cell research holds enormous potential for better understanding fundamental human biology. Evidence from animal studies already exists that stem cells can be made to differentiate into cells of choice and that these cells will act properly in their transplanted environment. It is likely that increased animal use will initially be required in this area to further explore the potential for stem cells.

Transgenics[35] is the term to describe procedures used to create organisms with characteristics that are advantageous to farmers, producers or industrialists. Various animals have been modified to express particular genes. For instance, a sheep germ line has been modified to produce the human protein insulin that is used to treat diabetes. New products such as this will undergo years of rigorous scientific and regulatory testing. While genetically modified animals promise environmental, health and economic benefits, they could also have unforeseen long-term negative consequences. As transgenic animals become increasingly commercialized, they will have a major impact on investment and competitiveness. CCAC released guidelines on transgenic animals in 1997.[36]

REGULATORY SYSTEM AND ANIMALS[37]

While genetically modifying organisms promises environmental, health and economic benefits, there could also be unforeseen long-term negative consequences. Regulators assess all products, including biotechnology products (and GMAs), for their potential impact on animal and human health. As well, the *Canadian Environmental Protection Act* requires an evaluation of the potential impact of organisms bearing novel traits on the ecosystem.

To help manage risks, regulatory bodies can require that procedures be carried out using certain species and in a certain manner. The *Proposed Canadian Standard for Xenotransplantation*, for example, outlines a stringent framework including requirements for the care of the animals, the use of certain monitoring techniques

[34] For more information on Canada's national xenotransplantation standards, see the CBAC Web site (*http://cbac-cccb.ca*).

[35] The transfer or deletion of a gene in an animal, plant, bacteria or other organism.

[36] See "CCAC Use" under subheading "Guidelines Development" and "Genetically Modified Animals, Pertinent Guidelines."

[37] Unless otherwise indicated, the section on Regulatory System and Animals is based on "CCAC Use" and "CCAC Alternatives."

and the use of pigs instead of primates in research.[38] In particular, it requires facilities producing source animals for xenografts[39] to adhere to CCAC guidelines and policies and to participate in the CCAC program.

In general, regulatory agencies tend to be cautious and require data that have been derived using familiar (hence, often animal-based) tests. The possibilities for reducing the reliance on animal-derived data in testing depend largely on the willingness, particularly of regulatory agencies, to consider new methodologies on the basis of sound science. With regard to toxicity testing, some laws and regulations demand the use of animals in testing (reflecting public concern about the safety of chemicals, etc.) while others seek to reduce the use of animals (reflecting public concern about the use of animals in painful procedures). Particular emphasis has been placed over the past 20 years on developing non-animal methods and strategies for toxicity testing. CCAC believes the potential conflict between competing regulations for safety evaluation and animal welfare is best addressed in a flexible system where animal-testing requirements are not encapsulated in legislation. Canada has such as a system.

Box 2

One obstacle to reducing the number of animals used is that non-animal research costs more. For example, it can cost up to three times more to produce monoclonal antibodies using in vitro *systems versus* in vivo *systems. As well,* in vitro *methods can be an oversimplification of the complex physiological, biochemical and molecular processes of the living organisms. However, simpler systems can be a means of identifying toxicological mechanisms and can serve as useful screening tools.*

Several international initiatives are helping to define the steps necessary to ensure that alternative methods undergo sound scientific validation. As well, some countries incorporate the three R principles in animal welfare legislation to help ensure that animals are used only when necessary. In Canada, the only way to ensure that alternative approaches have been considered is if the institution is CCAC-certified.

[38] *Proposed Canadian Standard on Xenotransplantation*, Therapeutic Products Programme, Health Canada, Ottawa, Ontario, 1999.

[39] The cells or organs to be transplanted from the animal to humans.

HUMAN RIGHTS AND THE PATENTING OF HUMAN MATERIALS[40]

The possibility of obtaining a patent on a living organism raises novel legal and ethical issues. These issues take on additional significance and dimension when the subject matter is human. The special status that humans afford themselves is manifested in the recognition and enforcement of human rights. Some people believe that discussions of genetics, biotechnology, patenting and ethics should include an analysis of human rights and the implications of these advances for human dignity.

The resolution of human rights issues inherent in the patenting of human materials would benefit several groups including: government, in order to identify and comply with relevant human rights obligations; individuals, to know which rights are protected and how; and industry, investors and researchers, to have some certainty about what activities are permissible and what patents may be obtained and exploited.

INDIVIDUAL AUTONOMY

The patentability of parts of the human body and human materials[41] raises concerns about the possibility of ownership of humans or, in human rights terms, individual autonomy.

Materials Originating in the Human Body: Canada grants patents on human genes if they have been isolated and purified, and are part of an invention that meets the statutory criteria of novelty, utility and non-obviousness. Canada does not grant patents on the human body or its parts. While some jurisdictions such as the European Union specifically state this in their legislation,[42] Canada and the U.S. do not, nor have Canada's courts pronounced on the issue. Nevertheless, it has generally been assumed that in neither Canada nor the United States is the human body itself patentable.

The prohibition on slavery is well established in international law, and includes similar practices such as debt bondage, forced marriage, the traffic of women and children, use of children in armed conflict and the sale of organs. Canada is a party to relevant international conventions and, although our domestic law contains no specific prohibition on slavery, it would surely be contrary to the *Canadian Charter of Rights and Freedoms* as violating rights to liberty and security of the person and equality rights. These Charter guarantees (and equivalent rights in international law) also cover a broader scope, proscribing infringements that might not be caught by the definition slavery. Obviously, a statutory provision allowing the patenting of "humans" would seem to fall afoul of this prohibition.

Box 3

The possibility of patenting a human being might seem to be of purely academic interest, but events have illustrated that this is not so. For example, the claims of a patent granted on December 8, 1999, by the European Patent Office mistakenly included a method of preparing a transgenic human in its scope. The error arose from the failure to qualify the term "transgenic animal" with "non-human." The European Patent Office admitted the error but pointed out that the patent granted in fact does not extend to human cloning because such a claim is not supported by the patent description. The European Patent Office cannot amend the patent on its own initiative but must rely on an opposition *challenging the patent. (European Patent Office, Press Release 1/2000, "Declaration of the European Patent Office with regard to Patent No. EP 0695351 granted on 8 December 1999," February 22, 2000, as cited in H.R.)*

[40] This section is based on *Human Rights Issues Related to the Patenting of Human Biological Materials* ("Human Rights, von Tigerstrom") and *Human Rights Issues in Patenting of Higher Life Forms – The Role of the Canadian Charter of Rights and Freedoms* ("Charter, von Tigerstrom"), both by Barbara von Tigerstrom, B.A., M.A., LL.B.

[41] "Human materials" is used by von Tigerstrom to refer to human beings, human embryos, human organs and human tissues, cell lines, genetic material and proteins. "Charter, von Tigerstrom" and "Human Rights, von Tigerstrom" are also concerned with processes by which any of these are created or modified, because processes themselves may also be patentable.

[42] See, for example, EC, *Directive 98/44 of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions,* O.J. Legislation (1998) No L213 at 13.

Defining "Human Beings": Assuming that there are some constitutional barriers to the patenting of human beings, how would we define "human beings" as the subjects of this protection? This question has been raised in the context of embryos and anencephalic infants.[43] A human embryo or fetus is not a person in Canadian law, but if it were determined that there was or should be a prohibition on patenting human beings or relevant processes, such a prohibition may have to extend to embryos to have any real effect.

Given the technology to create transgenic animals, hybrids and chimaeras,[44] if an animal is part human and part non-human, at what point is it to be considered a human being and entitled to legal protection as such? The question may not be a serious one when dealing with transgenic animals such as the Harvard Onco-mouse, which has a very limited amount of genetic material taken from a human being, but it would be another matter in the case of, for example, a human/chimpanzee chimaera.[45]

A patent application in the United States sought to test these limits, at least under U.S. law. Jeremy Rifkin and Dr. Stuart Newman filed a patent application at the United States Patent and Trademark Office (USPTO) covering the production of human/animal chimeras that could be up to 50 percent human.[46] The aim of the application was to test the rules on patenting life forms and to use patent rights to prevent anyone from attempting to produce these animals. The application was rejected in part on the basis that it included a human being within its scope and human beings are not patentable.

Human Body Elements: The patenting of human elements such as organs and tissues, where permissible, does not refer to these elements in their natural state. An element in its natural state or an unmodified organ would not be patentable because it would be a "product of nature" that cannot be patented under patent law. However, if an element were modified in some way — for instance, if a lung were genetically engineered to be immune to carbon monoxide — it could potentially be patentable.

In Canada, transgenic human organs are considered to be unpatentable subject matter within the *Patent Act's* section 2 definition. Human organs are not patentable under the European Patent Convention. In Australia and the U.S., human organs are eligible to be patented although no such patents have been granted. In Japan, although the legal position seems unclear, it is postulated that the patenting of human organs would contravene that country's "ordre public" or morality clause.[47]

What patents on human materials, as opposed to human beings per se, might give rise to human rights violations? In a European case involving a patent on a gene encoding a protein called relaxin, which had been isolated from tissue taken from a pregnant woman, opponents to the patent argued that the patent and its exploitation constituted slavery and would involve the "dismemberment and piecemeal sale of women." This argument was dismissed by the European Patent Office's Opposition Division.[48]

Although some perceive serious ethical problems with patents on human materials in general, from a human rights law point of view one must consider in each case if the invention would infringe on the legally recognized rights of individuals.

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[43] R.W. Walker, "Patent Law – Should Genetically Engineered Human Beings be Patentable?" (1991) 22 Memphis State U.L. Rev. 101 at 106ff; D.L. Burk, "Patenting Transgenic Human Embryos: A Nonuse Cost Perspective" (1993) 30 Houston L.Rev. 1597 at 1649-50.

[44] A transgenic animal contains one or more genes from another species; a hybrid is a genetic cross between a male of one species and a female of another; a chimaera (or chimera) is a "mosaic" of cells from more than one species. Unlike a hybrid, which contains material from both species in every cell, the cells in a chimaera remain distinct. There are various methods for producing such animals. No one has ever created a human/non-human chimaera, but there is apparently no technical barrier to doing so.

[45] Increasing knowledge about the genetic and behavioral similarities of humans and non-human primates is challenging the exceptional status of human beings in law. In 1999, in New Zealand, a law was introduced that would have conferred "the equivalent of human rights on great apes": "NZ bill aims to give apes same rights as humans" (1999) 397 Nature 555. This legislation has never come into force.

[46] D. Dickson ". . . as US bid to patent human-animal hybrid fails" (1999) 399 Nature 626; E. Marshall, "Legal Fights Over Patents on Life" (1999) 284 Science 2067 at 2067.

[47] Some patent offices have an "ordre public" or morality provision, allowing them to withhold a patent if the invention's commercial use could cause significant public unrest or disorder or if it violates fundamental norms.

[48] See Howard Florey/Relaxin [1995] E.P.O.R. 541, at para. 6.3.3.

OTHER HUMAN RIGHTS

While the patenting of the human body and its elements brings into question primarily the issue of individual autonomy, several other human rights concepts are also relevant.

Human dignity: The concept of human dignity surfaces frequently in the context of biotechnology discussions, especially with regard to human genetics research. While it constitutes a powerful and centrally important concept, its application is often difficult given the lack of clear agreement on its meaning and how to recognize and prevent its violation. From a human rights perspective, there is no "right to dignity" as such. Rather, it can be seen as the foundation of human rights. Human dignity is explicitly invoked in the European *Directive on the legal protection of biotechnological inventions* and UNESCO's *Universal Declaration on the Human Genome and Human Rights* (UNESCO Declaration). It is also addressed in the Vienna *Declaration and Programme of Action*. The *Canadian Charter of Rights and Freedoms* does not include a generalized right to dignity, although human dignity is an important underlying value recognized by Canadian courts.

Rights to protection of intellectual property: International law, namely the International Covenant on Economic, Social and Cultural Rights (ICESCR)[49] article 15(1)(c) and the *Universal Declaration of Human Rights* (UDHR)[50] article 27, recognizes the right to protect intellectual property as part of the human rights framework. This has not gone without criticism, however, and, like any right, it may be limited as necessary to protect other rights.

Rights of people to health and to benefit from scientific progress[51]*:* Three concerns emerge in this context. One is that patents could pose financial and logistical constraints to advancing research to the next stage, thus denying people access to the potential benefits. This is particularly so in the context of gene patents that, it is feared, could have a chilling effect on further research. The counter-argument is that without the incentive that patents create, research would be even more seriously hampered by a lack of financial support.

The second concern is one of "equitable access"; that is, patents could make the therapeutic applications of research so expensive that not all people could afford them. However, it could also be argued that if researchers cannot patent their innovations, their products might not be marketed and no one would benefit from the research.

The third concern is that reliance on patents as research incentives could direct research priorities toward products that are likely to be patentable and commercially lucrative, and leave gaps in areas that could be important to the general population or disadvantaged groups. This has led to calls for government funding in areas likely to be neglected by commercial interests.

Research subjects, informed consent and self-determination: The idea that research subjects and people who donate biological material are entitled to some additional or specific benefit is increasingly accepted, at least in theory, as an ethical obligation of researchers. However, human rights law contains no clear support for claims to benefit based on the recognition of property rights in one's own body and biological material. Rights to bodily integrity and self-determination, however, may be relevant. These rights are protected in the context of medical treatment and research by the requirement of informed consent, which is based on the principle that every competent person has the right to determine what is done with his or her own body and to be informed of the attendant risks. In Canada, this right is constitutionally protected under section 7 of the Charter (liberty and security of the person). This protection only applies, however, to those activities undertaken or regulated by government.

[49] 16 December 1996, Can. T.S. 1976 No. 46 993 U.N.T.S.3.

[50] 10 December 1948 UN G.A. Res. 3/217A.

[51] ICESCR article 1(3), UDHR article 25(1).

Box 4

Many well-known and controversial cases have highlighted concerns in this area. In Moore v. Regents of the University of California,* *John Moore sued his doctor after discovering that the doctor had, without Moore's knowledge or consent, used some of his tissue removed for treatment purposes to develop, patent and commercialize a cell line. Moore unsuccessfully argued that he had property interest in his own biological material, which entitled him to a share of the potential profits. The court held instead that, provided Moore could prove his claims, he would be entitled to compensation for the doctor's breach of his fiduciary duties to obtain informed consent to research.*

Other cases involve the alleged exploitation of vulnerable peoples. For example, a U.S. researcher with funding from the U.S. National Institutes of Health (NIH) patented a cell line using blood taken from a member of the Hagahai tribe in Papua New Guinea at the request of the tribe. The researcher later abandoned the patent.† Such cases have sparked opposition to the Human Genome Diversity Project[52] *and raised concerns about the exploitation of individuals and populations.*

** 793 P.2d 479 (Cal. 1990)*

† For a discussion of this case, see A. Pottage "The Inscription of Life in Law: Genes, Patents and Bio-politics" (1998) 61 Modern Rev. 740 at 740-742; K.H. Ching, "Indigenous Self-Determination in an Age of Genetic Patenting: Recognizing an Emerging Human Rights Norm" (1997) Fordham L. Rev. 687 at 701-702.

Informed consent may require the disclosure of any financial interest or commercial potential of the research.[53] However, recognition of individual rights in the consent process would ensure only that subjects are aware of commercial interests, not that they have a right to receive benefit or compensation. More extensive claims may be possible using the right to self-determination. In its current formulation, however, this right is recognized to belong only to "peoples" under international law.

Other human rights issues may arise by the targeting of certain ethnic or indigenous populations. For example, if the group is already disadvantaged in some way or vulnerable to discrimination, discrimination claims are a possibility. As well, if the group holds strong religious or spiritual beliefs that oppose the patenting of human or other biological material, there might be allegations that patents on material derived from the group infringe their freedom of religion or aboriginal rights.

Box 5

In April 2000, the Human Genome Organization (HUGO) Ethics Committee released a Statement on Benefit Sharing concerning whether and how to distribute profits that may accrue to commercial enterprises, governments and academic institutions on the basis of the participation of particular communities or populations. Among its recommendations are that all humans have access to the benefits of genetic research; that prior discussion be held with the communities and populations concerning benefit sharing; that even in the absence of profits, community health needs could be provided; and that profit-making entities should dedicate 1–3 percent of annual net profits to health or humanitarian efforts.

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[52] The Human Genome Diversity Project (HGDP) is an international effort to document human genetic variation by collecting and analysing genetic data from around the world. It has been widely criticized by indigenous peoples. See for example, *Declaration of Indigenous Peoples of the Western Hemisphere Regarding the Human Genome Diversity Project*, 19 February 1995, online: **http://www.ipcb.org/resolutions/phxdecla.html**. These concerns have led to the formulation of ethical guidelines for the project including provisions on patenting and commercial use: Human Genome Diversity Project North American Regional Committee, *Model Ethical Protocol for Collecting DNA Samples*, online: **http://www.stanford.edu/group/morrinst/hgdp/protocol.html.**

[53] As was the case in *Moore v. Regents of the University of California*, 793 P.2d 479 (Cal. 1990)

Privacy and protection from discrimination:[54] Genetic research gives rise to serious concerns about both personal and group privacy. For example, genetic information could reveal a person's propensity to contracting a certain disease (which could be the basis for discrimination) and, if certain genetic traits are associated with identifiable groups, it could raise concerns regarding "group privacy" and discrimination. While privacy and protection from discrimination are important issues in the area of genetics research, it is not clear to what extent the concerns regarding genetic privacy and the potential for discrimination are related to patenting itself.

PATENT LAW AND THE *CANADIAN CHARTER OF RIGHTS AND FREEDOMS*

Canada's major sources of human rights law are the *Canadian Charter of Rights and Freedoms* and pertinent legislation. The Charter, which is part of the Constitution and which sets out the fundamental rights and freedoms of individuals, is the most relevant to discussion of the patenting of human elements. It applies only to government actions and not to those of private individuals or organizations.

Section 7 of the Charter is particularly applicable because it protects individuals' right to liberty and security of the person. In general, the liberty aspect includes freedom from physical restraint (for example, imprisonment) and to make personal decisions such as where to live, medical treatment and reproduction. The security element could be infringed by harm to health or physical integrity, loss of control over one's body (for example, a forced pregnancy termination) or an offence to one's "psychological integrity" such as an invasion of privacy or stigmatization. Section 15(1), which protects the right to equality before and under the law and the equal protection and benefit of the law, may also be applicable. Other rights and freedoms that may be relevant include freedom of conscience and religion (section 2 (a)), and the right to be secure against unreasonable search and seizure (section 8).

The central question is whether or not patent rights might in some cases interfere with the Charter rights of individual liberty, security of the person or equality. While there are some legitimate — albeit remote — cases where this could happen, in fact most patents on human materials would not pose a direct threat to individual rights, although they could indirectly raise other human rights concerns.

MODIFYING PATENT LAW TO PROTECT INDIVIDUALS' CHARTER RIGHTS

One option for dealing with human rights concerns relating to patenting of human materials is to modify patent law to exclude certain subject matter from patentability or, in some cases, to modify the operation of rights granted to patent holders. This may be done either judicially or legislatively. (Note: The main consultation document addresses the issue of legislative versus policy versus jurisprudential approaches in the section "What are the Mechanisms of Governance Available for Change?")

OPTIONS FOR ADDRESSING HUMAN RIGHTS ISSUES OUTSIDE THE CHARTER

Several options exist to address humans rights issues that do not pertain to the Charter. Some involve changes to the patent system ,while others may serve as supplements or alternatives to the system. These include, for example, a broader use of exceptions or excluding certain materials and processes from patentability; integrating human rights protections into the patent system; an alternative statutory scheme for some human biological materials, which would allow consideration of non-economic values and could include a variety of human rights issues; statutory or regulatory measures independent of the patent system such as legal and ethical rules to protect privacy in the context of patenting human materials; and fully implementing international human rights law commitments in Canadian law.

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[54] Both Canadian and international law recognize the right to privacy. Although the Charter contains no specific right to privacy, courts have recognized this right based on sections 7 (liberty and security of the person) and 8 (freedom from unreasonable search and seizure). This right receives special protection when the personal information involves an individual's health. In international law, the *International Covenant on Civil and Political Rights* recognizes the right of everyone to protection from arbitrary or unlawful interference with one's privacy. Equality rights are also protected in Canadian law by the Charter and human rights legislation, as well as in various international law documents. 793 P.2d 479 (Cal. 1990)

INTERNATIONAL PERSPECTIVES

CANADIAN PARTICIPATION IN INTERNATIONAL AGREEMENTS[55]

The World Trade Organization Agreement on the Trade Related Aspects of Intellectual Property (TRIPs): Canada is a party to the TRIPs agreement. The purpose of this agreement is to establish consistency among WTO members on the protection of intellectual property rights, including patents. Of all the international treaties, TRIPs has the greatest impact on Canada's choice of whether or not to patent higher life forms. This is because Canada could potentially face trade sanctions if it failed to abide by its TRIPs commitments.

TRIPs sets out general rules that WTO members must follow regarding the subject matter of patent rights (that is, which things and processes must be patentable and those over which a country has the option).[56] TRIPs Article 27.3 provides countries with the option of granting patents on plants and animals, on essentially biological processes and on diagnostic, therapeutic and surgical methods, while Article 27.2 permits countries to exclude from patentability those inventions whose commercialization would violate "ordre public" or morality. The agreement requires all WTO members to use the substantive criteria of novelty, non-obviousness and utility, and only those criteria in assessing patentability.

WTO members can challenge domestic laws for non-compliance with WTO obligations, and rulings are subject to trade sanctions if they are not implemented. Canada has recently been the subject of two separate WTO complaints launched by the European Community in relation to early working and stockpiling of pharmaceuticals, and by the U.S. challenging the length of the term of a Canadian patent. In April 2000, the WTO Dispute Settlement Body endorsed Canada's early working regime but found the stockpiling inconsistent with Canada's TRIPs obligations. Canada has agreed to comply with the ruling.[57] In May 2000, a WTO panel found that Canada failed to make a minimum of 20 years of protection available for patents filed before October 1, 1989.[58] The Canadian government appealed but the WTO Appellate Body upheld the decision.[59] A bill to address this challenge has been tabled.[60]

North American Free Trade Agreement (NAFTA): Like TRIPs, NAFTA permits exclusions to patentability where necessary to protect "ordre public" or morality; human, animal and plant life; or the environment. Countries may also specifically exclude diagnostic, therapeutic and surgical methods for the treatment of humans and animals, as well as plants and animals (other than micro-organisms) and essentially biological processes for the production of plants and animals. Also like TRIPs, NAFTA contains provisions on patent protection that limit, for example, the circumstances in which compulsory licensing is permitted.

World Intellectual Property Organization (WIPO): Canada is a member of WIPO and four patent-related WIPO treaties. WIPO was created in 1970 to promote the protection of intellectual property and to ensure administrative cooperation among member states.

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[55] The section on Canadian participation in international agreements is derived from *A Brief History of the Canadian Patent System* by Vic Duy; *Patenting of Higher Life Forms and Human Biological Materials, An Introduction to the Issues* by Ted Schrecker and Alex Wellington; *Patenting of Biotechnological Innovations Concerning Animals and Human Beings*, by Ted Schrecker and Alex Wellington; and *Patenting Higher Life Forms: An International Comparison* by Richard Gold.

[56] TRIPs makes it mandatory for WTO members to grant patents over certain biological material, such as micro-organisms and micro-biological processes (processes such as fermentation that rely on the action of micro-organisms). It also requires that countries either grant patents over plants or provide an alternative system to protect those who create new plant varieties (for instance, a particular variety of a flower rather than flowers within the same species). It gives members the option of excluding animals and certain processes related to medical diagnostics and treatment of humans or animals such as CAT scans, surgery and dialysis.

[57] *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R, released 17 March 2000.

[58] *Canada – Term of Patent Protection*, WT/DS170/R 5 May 2000, Report of the Panel.

[59] Canada – Term of Patent Protection WT/DS170/AB/R AB-2000-7, 18 September 2000, Report of the Appellate Body.

[60] Bill S-17.

It became a specialized United Nations agency in 1974, thus taking on the additional responsibility of promoting creativity in and facilitating the transfer of technology to developing countries. In June 2000, WIPO concluded a Patent Law Treaty (PLT) to harmonize formality requirements for the filing of patent applications and maintenance of patents. It is expected that the treaty will come into force within the next several years. Initial work toward the harmonization of substantial patent issues was planned for 2000.

Canada is also a member of the world intellectual property system established by various conventions such as the International Convention for the Protection of New Varieties of Plants and the Paris Convention.

EUROPEAN UNION DIRECTIVE [61]

The directive on the Legal Protection of Biotechnological Inventions was adopted by the Council of the European Union and the European Parliament on July 6, 1998.[62] Its purpose is to establish a unified European approach to biotechnology patents, harmonize European patent law with major trading partners, maintain a vibrant research and development community, and provide independence from the EU's trading partners. The EU Directive sets out detailed rules concerning the patentability of biological materials within member states. It builds on the general principle of patent law that only inventions that are new, non-obvious and useful can be patented, and applies these rules to biological materials.

Patentability of biological material: Under the directive, patentable biological material must be new, non-obvious, have industrial application and be an invention, not merely a discovery. Biological materials that exist in a form that results from human intervention are patentable. The contemplated industrial application must be disclosed in the application. For genetic sequences, the function must be described, including the protein produced by the expression of the gene sequence. The human body at all stages of development is unpatentable. Naturally occurring plants and animals are not patentable, nor is their production using natural means. Invented plants and animals are, however, patentable provided the invention is not necessarily restricted to a particular variety.

Box 6

Lessons for Canada

The directive may suggest some important lessons for Canada. Public debate regarding biotechnology is important, and an approach that relies on judge-made law to solve current concerns should be avoided. Solutions to both ethical and economic concerns must be flexible and transparent. Industry's role in advancing biotechnology must be clearly defined.

To address these factors, Canada may wish to initially separate two sets of decisions. The first set involves the initial allocation of rights and responsibilities regarding biotechnology, and must be addressed before Canada tackles the regulation of biotechnology. These issues include whether or not biotechnological innovation is in accord with moral principles, whether or not society will accept the potential risks of biotechnology, public sector roles and the allocation of liability among stakeholders.

Once these threshold issues are determined, Canada requires mechanisms to encourage industry to perform its role within the general framework that the country has chosen and mechanisms to monitor developments in science and industry that are flexible enough to allow for changes in the way biotechnology is innovated.

The directive also suggests more specific measures that Canada may wish to consider: the possible use of an "ordre public" or morality clause, an exemption to permit farmers to reuse patented seeds, compulsory licensing to avoid conflicts between plant variety legislation and patent law, and clarification of Canada's experimental use defence.

[61] Information on the EU Directive derives from the report *The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation, and Lessons for Canada* by Dr. Richard Gold and Alain Gallochat.

[62] While the directive was due to be implemented by July 30, 2000, most member states have not yet transposed it into their national laws. However, whether they do or not, they are subject to its rules. Some countries have delayed doing so based on ethical concerns — primarily the concern that patenting human genetic sequences will stifle health-related research. In October 1998, The Netherlands, later joined by Italy and Norway, commenced a challenge against the directive before the European Court of Justice, which has been heard but not decided.

Farmers' privilege: The directive contains a "farmers' privilege" clause allowing farmers to retain seeds from patented plants and to use them on their land. Farmers' privilege extends to animals and animal reproductive material.

Compulsory licensing: Under the directive, compulsory licences are available to holders of plant patents wanting to exploit plant variety rights and vice versa. These patent holders (or plant variety holder, as the case may be) must first seek a licence from the plant variety right owner and show inability to obtain one. Proposed exploitation must be a significant commercial advance over the blocking technology.

Standard of utility: The directive contains a standard of "industrial application." The U.S. has clarified an analogous utility standard applicable to biotechnology through USPTO guidelines. Canada has not clarified a standard of utility through legislation or guidelines.

"Ordre public" or morality clause: The directive contains an "ordre public" or morality clause, and deems certain inventions such as human cloning, modifying human germ-line identity, using human embryos for commercial purposes and causing suffering to animals without substantial medical benefit to humans or animals, as violations to the clause. Determination is initially made by the applicable patent office.

Ethical review: The directive has two review mechanisms to ensure conformity with ethical considerations: regular reports by the European Commission to the European Council and the European Parliament on ethics and research implications of the directive; and ongoing review of the ethical aspects of biotechnology and patent law by expert bioethicists.

Experimental use: While the directive does not explicitly set out an experimental use defence or exemption, all Member States of the European Union have in fact implemented such a defence in conformity with the Community Patent Convention (not yet ratified).[63] Research may be conducted on the subject matter of a patented invention without infringement of the patent.

Informed consent: The directive recognizes the moral imperative to ensure that human donors provide fully informed consent for removal of biological materials. This is not legally mandatory.

[63] *Convention for the European Patent for the Common Market (Community Patent Convention)*, signed at Luxembourg on 15 December 1975, revised 15 December 1989, Article 27(b).

BIOTECHNOLOGY PATENTS AND COMPETITION LAW[64]

Canada needs to contend with legitimate competition concerns arising from patent abuse: Some believe that Canada does not vigorously enforce pro-competition policies. The United States has a more active legal response to anti-competitive conduct than does Canada. The European Union recently became more active by adopting a competition-based regime that directly deals with patent rights (the regime is stricter than Canada's and very different from that in the United States).

Limitations on enforcement of competition through the Patent Act *imposed by NAFTA, Chapter 17:* NAFTA Art. 1709 deals with patents, forcing Canada to abandon abuse provisions and remedies found in sections 65 to 67 of the *Patent Act* and compulsory licences for generic pharmaceuticals. Art. 1704 provides that a party to NAFTA can specify in its domestic law licensing practices or conditions that constitute an abuse of intellectual property rights having an adverse effect on competition, and can adopt appropriate measures to prevent or control such practices or conditions. Canada has not made use of Art. 1704. Art. 1709.6 allows Canada to provide limited exceptions to exclusive rights conferred by a patent if they do not reasonably conflict with normal exploitation of the patent and unreasonably prejudice the legitimate rights of the owner taking into account the interests of others.

Canadian interface between competition law and patents: There is a distinction between the legitimate use of patent rights and use made to restrict competition in a manner or to an extent not authorized by the *Patent Act*. Under the old "working provisions" of the *Patent Act* (s. 65 to 71), the Commissioner could require a patentee abusing patent rights to grant a licence to work the invention to an applicant. (The U.K. has similar provisions.) Canada, like U.S., has measures of anti-trust law (*Combines Investigation Act*). The U.S. has historically stepped into Canadian sovereignty and taken action in Canada's stead to prevent anti-competitive activity using patents. Under the "reviewable matters" provision contained in the Canadian *Competition Act* whereby the Commissioner can bring reviewable matters before the Competition Tribunal, there have been only three contested intellectual property proceedings. Despite several statements made by the Competition Bureau about the interface of intellectual property and competition law, little has been done to articulate a clear Canadian approach. In any event, the Bureau's approach has been softening over time to a position whereby general competition law frameworks applicable to business arrangements involving property apply equally to those involving intellectual property, the ability to prevent others from using intellectual property does not necessarily confer market power, and the licensing of intellectual property is seen to be generally pro-competitive.

U.S. interface between patent and anti-trust law: The United States has a doctrine of patent misuse that arises out of court decisions. Under this doctrine, a patent is held to be unenforceable against anyone in the world where a patentee has licensed the patent on conditions destructive of competition, until the patentee purges the misuse. Patent misuse is a defence to an infringement action grounded in the theory of anti-trust. Today, this doctrine is limited by the *Patent Misuse Reform Act* to situations where the patentees have market power.

The United States awards treble damages against patent holders in certain circumstances. These include where the patentee is aware the patent is unenforceable because of anti-competitive licensing provisions but still brings an infringement action. This action brings into play the monopolization provisions of s. 2 of the *Sherman Act* whereby treble damages would be awarded.

Intellectual Property Enforcement Guidelines (IPEG), published in Canada, September, 2000: These guidelines use the approach that competition policy will not be used if conduct can be remedied under the relevant

[64] The points raised in the section on biotechnology patents and competition law are taken from the paper *The Interface of Biotechnology Patents and Competition Law* by Warren Grover, Q.C., Barrister and Solicitor.

intellectual property statute. The Competition Bureau could intervene in proceedings in which the extent of intellectual property rights are being considered but has not chosen to do so. IPEG specifically states that the Bureau will act only in very rare circumstances and when the conduct cannot be remedied by the relevant intellectual property statute. Remedies include declaring a licence void, restraining the enforcement of the licence or part thereof, and compulsory licence. The remedy must be consistent with Canada's treaty obligations. Unilateral exercise of intellectual property rights does not violate the *general* provisions of the *Competition Act* in any circumstances. Unilateral exercise of intellectual property rights might possibly fall under s. 32 of the *Competition Act* (special remedies). Overall, the role of the Competition Bureau is restricted.

European approach to patent licensing to take into account competition: The European Union prohibits the use of certain types of restrictions in licence agreements (for example, payment of royalties that go beyond the life of the patent). Some restrictions in licences are clearly permissible. Other restrictions contained in licence agreements must be examined on a case-by-case basis. The European Union will not tolerate restrictive licensing conditions that it views as anti-competitive. Under appropriate circumstance, the European Union calls for the grant of compulsory licences.

ECONOMIC MATTERS PERTAINING TO PATENTING AND BIOTECHNOLOGY[65]

Hurdles to commercialization: Several hurdles stand in the way of biotechnology commercialization: limited access to capital, regulatory approval costs, lack of skilled human resources, difficulties with consumer acceptance of biotechnology products and techniques, lack of market data and access to technology, and impediments caused by international harmonization, intellectual property protection and labelling requirements.

Shortage of qualified people to fill high-skill, high-wage biotechnology positions: Attracting qualified employees is as important to success as the availability of financing. Too few senior skilled managers with an understanding of science, marketing, financing and regulatory systems (which requires multidisciplinary training) are available. Business failure is more likely to result from poor management than poor technology. A large exodus of highly skilled Canadian workers to the United States would have serious consequences for Canada's biotechnology industry.

Biotechnology firms lack access to capital: The long time frame and high costs to move from basic research to commercialization in the biotechnological industry make it difficult to attract investors. Most biotechnology firms are not yet generating sales. Biotechnology's complex products and processes require assurance of safety and efficacy. Products must undergo trials/field testing and regulatory approval before being sold. Equity markets are unwilling to invest heavily because of the long lead times before commercialization and the expenses involved in obtaining regulatory approval. The reliance of small biotechnology companies on capital markets encourages them to sell intellectual property early and to let large, established companies do the development of the technology. Potential investors prefer to support high-technology companies with shorter-term cash flow and profitability expectations than biotechnology companies. Possible sources of capital include private placement, angels/friends, strategic alliance partners, secondary public offering, initial public offering (infrequently used) and venture capital (most successful).

Facilitating research and development in Canada:[66] Canada faces a number of problems in the facilitation of its research and development that need to be examined to allow continued progress on these fronts. Among others, Canada faces the following biotechnology-related problems: inadequate advancement of biotechnological innovation in Canada; inadequate cooperation between public and private sectors; lack of clear rules on the type of research permissible using patented invention without liability for infringing patent holder's rights (see the discussion in the main consultation document on the experimental use defence); lack of clarity about which higher life forms are patentable (which gives rise to social and ethical concerns) (see the discussion in the main consultation document on the patentability of higher life forms); lack of international harmony on the utility and disclosure requirements for biotechnological innovations; lack of international harmony on the filing of genetic sequences; and insufficient development of orphan drugs (medications for which there exists only a small market).

CBAC's proposed consultations seek to canvass Canadian opinions on salient issues specific to the patent system in the context of higher life forms. Consultation issues touch on the manner in which to address and the significance of many of these hurdles to research and development in Canada. CBAC invites the reader's suggestions on how to address any of them.

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[65] Unless otherwise indicated, the section on economic matters pertaining to patenting and biotechnology is derived from *Economic Profile of the Canadian Biotechnology Sector*, by Kenneth White.

[66] *CBAC President/CEO Industry Hearing on the Intellectual Property/Patenting of Higher Life Forms Project Steering Committee*, rapporteur Richard Gold.

ANNEX — RESEARCH STUDIES

Impact of Canada's Patent System on the Ability of Publicly Funded Organizations to Transfer, and Private Sector Firms to Commercialize, Biotechnological Inventions, by Tom Clarke, Stargate Consultants Ltd., Nanaimo, British Columbia.

A Brief History of the Canadian Patent System, by Vic Duy, Consultant, Ottawa, Ontario.

Intellectual Property Protection for Biotechnological Innovations, by Mona Frendo, Legal Analyst, Corporate Governance Branch, Industry Canada, Ottawa, Ontario.

The Use of Animals in Scientific Research and as Sources of Bioengineered Products, by Dr. Clément Gauthier and Dr. Gilly Griffin, Canadian Council on Animal Care, Ottawa, Ontario.

EU Directive and the Legal Protection of Biotechnological Inventions, by Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health and the Courts; Research Associate, Health Law Institute, University of Alberta; and Alain Gallochat, Advisor, Ministry of Research, Paris, France.

Patents in Genes, by Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health and the Courts; Research Associate, Health Law Institute, University of Alberta, Edmonton, Alberta.

Patenting Life Forms: An International Comparison, by Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health and the Courts; Research Associate, Health Law Institute, University of Alberta, Edmonton, Alberta.

Alternatives to the Use of Animals for Research, Testing and as Sources of Bioengineered Products, by Dr. Gilly Griffin and Dr. Clément Gauthier, Canadian Council on Animal Care, Ottawa, Ontario.

The Interface of Biotechnology Patents and Competition Law, by Warren Grover, Q.C., Barrister and Solicitor, Blake, Cassels and Graydon, Toronto, Ontario.

Intellectual Property Rights in Biotechnology: The Economic Argument, by Dr. Ron Hirshhorn, Hirshhorn Consulting Inc., Nepean, Ontario; and Jock Langford, Economist, Corporate Governance Branch, Industry Canada, Ottawa, Ontario (pending).

Innovation in the Livestock Industry, by Dr. Robert Kemp, RAK Consulting Ltd., Lethbridge, Alberta.

Biotechnology, Ethics and Government: A Synthesis, by Dr. Michael McDonald, Director, Centre for Applied Ethics, University of British Columbia, Vancouver, British Columbia.

New Enclosures: The Impetus for and Potential of Alternative Mechanisms for the Protection of Biotechnological Innovations, by Patrick Mooney, Rural Advancement Foundation International (RAFI), Winnipeg, Manitoba.

Patenting of Biotechnological Innovations Concerning Animals and Human Beings, by Ted Schrecker, Consultant, Ted Schrecker-Research and Consulting, Montréal, Québec; and Alex Wellington, Department of Philosophy, Ryerson Polytechnic University, Toronto, Ontario.

Patenting of Higher Life Forms and Human Biological Materials, by Ted Schrecker, Consultant, Ted Schrecker-Research and Consulting, Montréal, Québec; and Alex Wellington, Department of Philosophy, Ryerson Polytechnic University, Toronto, Ontario.

International Obligations for Intellectual Property and Biotechnology, by Sanjay Venugopal, Legal Analyst, Corporate Governance Branch, Industry Canada, Ottawa, Ontario (pending).

Human Rights Issues in Patenting of Higher Life Forms: The Role of the Canadian Charter of Rights and Freedoms, by Barbara von Tigerstrom, Professor of Law, Health Law Institute, University of Alberta, Edmonton, Alberta.

Human Rights Issues Related to the Patenting of Human Biological Materials, by Barbara von Tigerstrom, Professor of Law, Health Law Institute, University of Alberta, Edmonton, Alberta.

Economic Profile of the Biotechnology Sector, by Kenneth White, Acton, White and Associates, Manotick, Ontario.

Towards an Adequate Ethical Framework for Setting Biotechnology Policy, by Dr. Susan Sherwin, Munro Chair in Philosophy, Department of Philosophy, Dalhousie University, Halifax, Nova Scotia.

CBAC Hearings 2000–2001:

Summary Report of the President/CEO Industry Hearing to CBAC, September 29, 2000, rapporteur Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health and the Courts; Research Associate, Health Law Institute, University of Alberta, Edmonton, Alberta.

Summary Report of the Non-governmental Organization (NGO) Hearing to CBAC, November 22, 2000, rapporteur: Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health and the Courts; Research Associate, Health Law Institute, University of Alberta, Edmonton, Alberta.

Summary Report of the Scientific Researcher On-line E-forum, February 5-9, 2001, rapporteur Dr. Richard Gold, Assistant Professor, Faculty of Law, University of Western Ontario, London, Ontario; Assistant Professor, Senior Fellow, Einstein Institute for Science, Health and the Courts; Research Associate, Health Law Institute, University of Alberta, Edmonton, Alberta.