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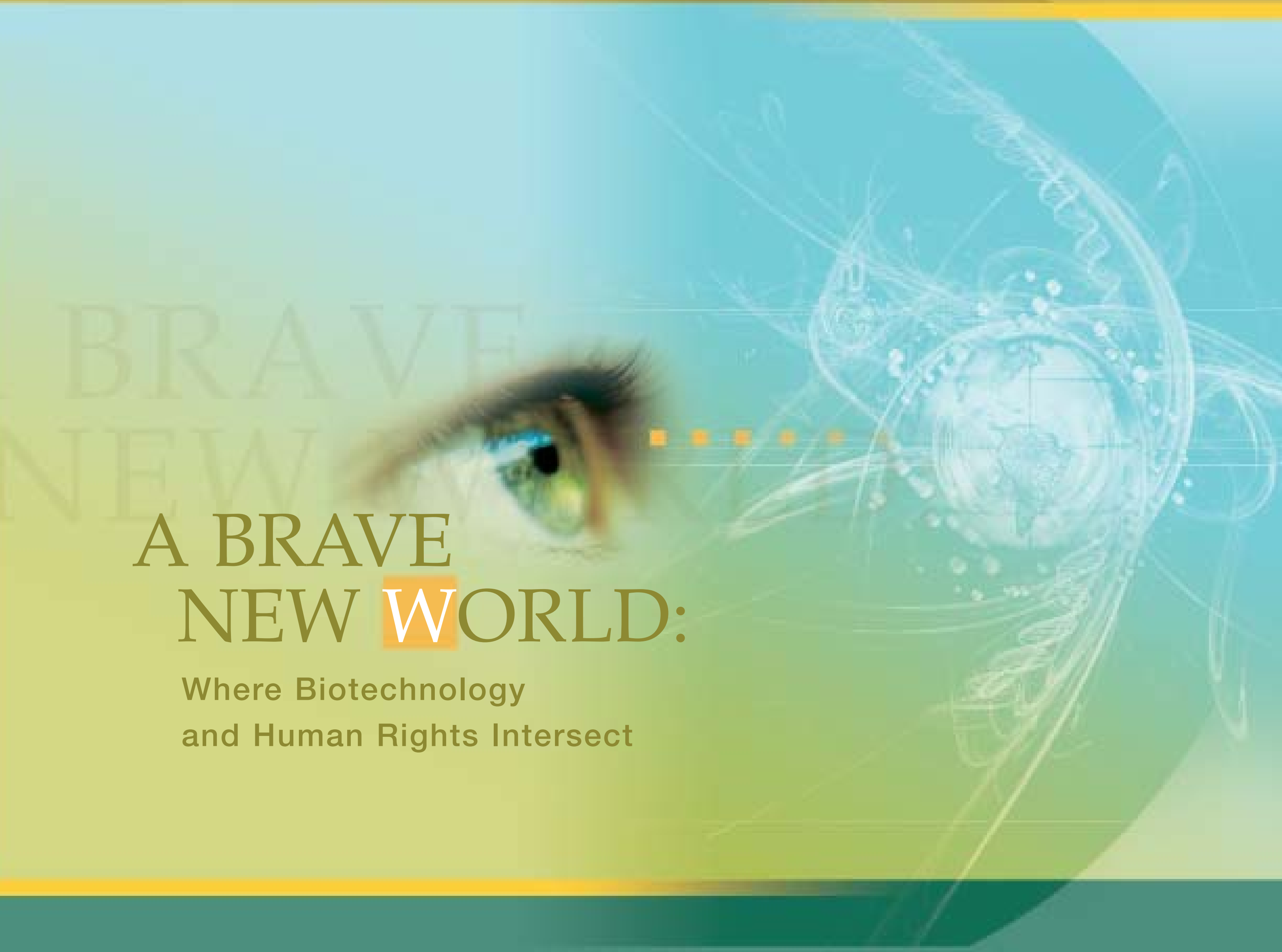

A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Canada

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Human Rights Intersect

July 2005

This document does not reflect the official views or positions of the Government of Canada or the Department of Justice. The document does not constitute legal advice to the government or to individual departments. Rather, it is an overview of the international and domestic law, the law in other jurisdictions and academic commentary with regards to the human rights issues raised by selected applications of biotechnology. The description of law in this document is valid as of March 2005. Please ensure that the information contained herein is accurate and up-to-date before relying on it.

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Preface

This first phase of the two-year Biotechnology and Human Rights Framework Project began in July, 2003, with the document completed in May 2004. The work entailed many hours of research, reflecting, consulting, writing and revising.

The intent of the first phase was to thoroughly examine the current, and in some cases the future, applications of certain applications of biotechnology to determine whether they raised any human rights issues. Where they did, the current human rights framework was examined to determine whether it adequately addressed the issues or whether there was a gap.

The chapter on genetic information and privacy (Chapter 5) summarizes and builds upon the work of the Genetic Information and Privacy Working Group, which had already done extensive research and consultations in this area. The authors examined other areas of biotechnology, including assisted human reproduction, pre-implantation genetic diagnosis, scientific research, patenting of human genes and tissues, and indigenous knowledge and human rights. Time constraints meant that we were unable to examine all the applications of biotechnology. For example, we were unable to examine whether genetically modified organisms raised any human rights issues. This issue is important and should be examined in the not too distant future.

The second phase of the Project will explore in more depth the gaps identified in the first phase and proposes various policy and legislative measures to address the gaps. In addition, consultations will be undertaken with the departments and Legal Service Units ("LSUs") affected by the gaps to discuss the findings and proposed solutions. The ultimate goal is to support the government's objective of enhancing public confidence and awareness by demonstrating that human rights issues will form an essential part of the governance of biotechnology.

Executive Summary

The term "biotechnology" has been defined in the *Canadian Environmental Protection Act* 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.*[1]

It has been predicted that in this century advances in biotechnology will result in more changes in the lives of individuals and in society than those wrought by telecommunications and computers in the last. Even prior to the year 2000, biotechnology affected the food Canadians grew and ate, the fuels they used as energy sources, the drugs they consumed, the medical therapies used to combat disease, and human reproduction. In the 21st century, we are witnessing applications of biotechnology that previously only existed in the realm of science fiction, such as the cloning of human embryos.

As with all technological advances, biotechnology can result in benefits and drawbacks for society. It might be argued, however, that biotechnology raises special concerns and considerations because it involves the manipulation and alteration of natural biological materials and processes. This is especially true in the case of assisted human reproduction ("AHR") and patented inventions using or incorporating human biological materials, such as genetic and cellular therapies.

The ability to fertilize a human egg with sperm outside the body of a woman (*in vitro*) has led to increased knowledge about the embryo and how it develops. It has also led to reproduction and research possibilities that would not have been contemplated even a few years ago.

The technology of AHR makes it possible for a child today to have more than two "parents." A child could have two biological parents who donated sperm and an egg for reproductive purposes. An infertile couple (the social parents) could arrange to use the donated sperm and egg to create an *in vitro* embryo for reproduction. If the social mother was physically unable to bear a child, the couple might arrange for the *in vitro* embryo to be transferred into the body of a surrogate mother to develop and grow. Once the child is born, the surrogate mother would relinquish custody of the child to the social parents. In this example, the child would have two biological parents, two social parents and one surrogate mother, for a total of five parents.

The application of biotechnology raises ethical, moral and novel legal issues, which are discussed in the following chapters. The authors adopted a forward-looking approach to biotechnology and canvassed a wide variety of perspectives and viewpoints in order to fully canvass the human rights issues.

Each chapter examines the application of a particular biotechnology and whether the application raises any human rights issues. International, regional and domestic sources of human rights are examined for each issue.

Chapter 1 provides an overview of the relevant international and regional human rights instruments, and explains how these instruments are used by domestic courts in defining human rights in Canada. Chapter 1 also includes

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[1] *Canadian Environmental Protection Act*, 1999, c.33, s. 3(1).

a brief overview of the sources of human rights in Canada. For example, the *Canadian Charter of Rights and Freedoms* ("*Charter*") is discussed and references made to the most relevant provisions. In addition, the first chapter discusses positive rights, which impose obligations on the state to take a particular action to assist a person to exercise the right, and negative rights, which impose a duty on the state not to interfere with a person's exercise of that right. Important human rights concepts are also discussed in the chapter, such as human dignity and equality.

The next two chapters (Chapters 2 and 3) deal with applications of biotechnology in the area of AHR. Each chapter describes the science, identifies the human rights issues, and sets out the relevant provisions in international and regional instruments, as well as the provisions in the *Charter* and any applicable Canadian legislation. The law in other jurisdictions is examined and academic commentary provided to illustrate the different perspectives and viewpoints on each issue. This is followed by a discussion and a conclusion, which highlights any gaps in the current human rights framework.

Chapter 2 examines the human rights issues that arise when biotechnology is applied to assist with human reproduction. The ability to create *in vitro* human embryos in a dish in the lab has enabled many infertile individuals and couples to reproduce. This chapter examines whether there is a positive obligation on the state to fund AHR services and concludes that at the present time there is no such obligation. The chapter also examines whether persons have a negative right to access AHR services free from state interference. If the state limited access to services on the basis of marital status, sexual orientation, or age, human rights would clearly be implicated. In such a case, the equality rights under s. 15 of the *Charter* would be engaged.

Chapter 2 also examines the rights of children and donors with respect to the disclosure of personal information. Do children have a right to the personal information, including the identity, of the donor whose reproductive material was used in their creation? Rights under international instruments, such as the *Convention on the Rights of the Child*, and the *Charter* are examined. It is clear that the interests of children, born as a result of AHR, to personal information about their genetic parent (donor), and the interests of the donors of reproductive material to privacy are inter-related and have the potential to conflict. This would make it difficult for the courts to determine whose rights take precedence.

What is the status of the *in vitro* embryo, existing as it does outside the body of a woman? Does the *in vitro* embryo have any rights? These questions are also explored in Chapter 2. At the current time, the common law does not consider either the *in vitro* or the *in utero* embryo to be a human being with legal or human rights. The chapter also examines whose rights would control the disposition of stored *in vitro* embryos in the event of a dispute between the progenitors. American jurisprudence has held that the constitutionally protected right to reproductive autonomy, flowing from the right to liberty, contains two equal but opposite rights, the right to procreate and the right **not** to procreate. In the event of a dispute as to embryo disposition, courts in the United States have developed a legal formula in which the right not to procreate is assigned slightly more weight. It is likely that the courts in Canada would find a similar *Charter*-protected right to reproductive autonomy within the liberty interest in section 7, but whether the Canadian courts would adopt a similar approach to settling a private disposition dispute is not clear. The *Charter* would not apply to a dispute between purely private parties. However, the courts may look to the *Charter* and common law as sources of public policy, with respect to reproductive autonomy, especially the right not to reproduce, in order to dispose of any agreement or contract and to inform a decision as to disposition.

Chapter 3 examines pre-implantation genetic diagnosis ("PGD") of the *in vitro* embryo. PGD permits the detection of the *in vitro* embryo's sex, as well as the presence of a chromosomal or genetic anomaly that may be indicative of a genetic disease or disorder, such as Huntington's disease. The worldwide use of PGD is on the rise and is controversial. Some people fear its widespread use signals a return to the eugenics movement of the early 20th century, and others worry that its use to detect the sex of the embryo may lead to a disruption in the natural male/female birth ratio in society.

Do parents have a human right to access information, without state interference, about the genetic status of their *in vitro* embryos, especially when the parents are at risk of passing on a serious genetic disease? Women in Canada have a constitutionally protected right to make decisions free from state interference during the early stages of pregnancy and are free to access a variety of medical procedures, such as amnioscentesis, to discover the genetic status of an *in utero* embryo.

Are a woman's rights any different when the embryo is *in vitro* instead of *in utero*? Assuming that the liberty interest in section 7 ofthe *Charter* protects a right to reproductive autonomy, how broad is that right in Canada? It is likely that the liberty interest would be found to protect a woman's right to make decisions of fundamental personal importance, without state interference, in the area of assisted reproduction. A decision to access PGD to select and transfer to a woman's body only those *in vitro* embryos that are free of a particular genetic disease or disorder would arguably qualify as such a decision. The courts would likely find that any state action prohibiting access to PGD would at least engage a person's section 7 *Charter* rights.

Would the human right to reproductive autonomy be broad enough to allow prospective parents to access PGD to select and transfer *in vitro* embryos based on other characteristics, such as the embryo's sex and the presence or absence of genes indicating disability? For example, if both parents are deaf, they may wish to have a deaf child. Do they have a right to use PGD to select only those *in vitro* embryos that have the gene for deafness? The courts may question whether such information is essential or material to a decision to reproduce, such that access to that information deserves constitutional protection. Women currently are free to access this information once they are pregnant and they are free to undergo an abortion based on that information. In the case of PGD, however, the embryo exists outside the woman's body. Does the embryo's *in vitro* existence affect the woman's right to reproductive autonomy? Another related question may be whether the woman has a right to all the information about the *in vitro* embryo, including its sex and other characteristics, prior to giving a free and informed consent to its transfer into her body.

Chapter 3 also examines whether the *in vitro* embryo has a human right to be born with a sound body and mind. American jurisprudence in some states has held that children have a legal right to be born with a sound body and mind, and have allowed tort claims by the child based on "wrongful life." Furthermore, some states allow children to sue for preconception torts, i.e., for negligent acts before conception that have resulted in an injury. Is it possible that the courts might at some point determine that the *in vitro* embryo, existing as it does outside the body of a woman, has human rights? Arguably, its existence outside the body of a woman means that there is no conflict with the liberty and security of the person rights of the woman. However, at least for the foreseeable future, the *in vitro* embryo must be transferred into a woman's body to realize its potential for human life, and to develop and grow to the point of viability. The courts in Canada have not been asked whether such a right exists under the *Charter* and predicting the outcome of such a question is highly speculative. The current situation may represent a gap in human rights protection.

It is important to note that despite the fact that state actions may be found to engage certain rights under section 7 of the *Charter*, the onus remains on the claimant to establish that the state's deprivation of the right was not in accordance with the principles of fundamental justice. If the state's deprivation was found not to be in accordance with the principles of fundamental justice, it is unlikely that the state would be asked to justify the violation, under section 1 of the *Charter*, since a violation would have already been made out and the courts consider it unlikely that the state would be able to provide an adequate justification. With respect to the other rights in the *Charter*, the state would have an opportunity to argue that the violation represents a justified limitation in a free and democratic society under section 1. If the state is successful, the violation would be found to be constitutionally valid.

Research is the focus of Chapter 4. Do scientific researchers have a right to engage in research or scientific inquiry? Would the *Charter* right to freedom of thought, belief, opinion and expression in section 2(b) protect a researcher's right to experiment? Chapter 4 examines this question in the context of research using stem cells derived from therapeutically cloned *in vitro* embryos. This research is believed to hold much promise for developing medical cures and therapies for many degenerative human diseases, such as Alzheimer's, spinal cord injuries, and juvenile-onset diabetes. Furthermore, one day these stem cells may be used to grow replacement tissues and organs that would not be rejected by the recipient's body.

At the level of international human rights instruments, provisions advocating a right to undertake scientific research are generally balanced by provisions allowing the state to interfere with such a right in the interests of health, safety, *ordre public* and public morality. It is likely that a state restriction against scientific research would be found by the courts to engage a researcher's right to freedom of thought, belief, opinion and expression in section 2(b) of the *Charter*. The state would have the opportunity to justify any limitation or restriction on the researcher's rights under section 1 of the *Charter* and if successful, the limitation would be found to be constitutionally valid.

Advances in biotechnology have resulted in a significant increase in our knowledge of the human embryo and embryonic development. The last issue in chapter 4 examines whether the method or the purpose of creation has any affect on the moral status of the *in vitro* embryo. For most individuals, the use of an *in vitro* embryo in research that results in its destruction raises moral and ethical concerns. When *in vitro* embryos are created for research purposes and have little or no potential for human life, would the moral and ethical concerns be diminished? Five sources of *in vitro* embryos are discussed to determine whether differences in potentiality and purpose affect the moral status of the embryo.

The human rights issues related to genetic information and privacy are discussed in Chapter 5. Genetic information has taken on increased importance since the mapping of the human genome. Scientists are discovering the genes responsible for many genetic diseases and disorders. Genetic information about an individual is personal information and can be obtained through a family history or through genetic testing. The chapter focuses on two issues related to genetic information: discrimination and privacy.

Chapter 5 examines discrimination in the employment and insurance context. It concludes that although no statutory prohibition exists against discrimination on the basis of a genetic predisposition to disease, recent jurisprudence suggests that it would be caught under the rubric of disability. The *LaForest Report* recommended that the definition of disability in federal human rights legislation be amended to include genetic predisposition to illness.

Privacy encompasses the liberty and integrity interests of individuals. Privacy is closely related to confidentiality. Chapter 5 examines privacy in the context of whether a right to know or not know exists with respect to genetic information. The *Charter* is an important source of protection for privacy in Canada, as well as federal and provincial privacy legislation and the common law.

Although the *Charter* does not provide a specific right to privacy, sections 7 and 8 encompass privacy interests. As with any *Charter*-protected right or interest, it is not absolute. In the case of sections 7 and 8, the courts undertake a limited balancing of the competing interests at stake. In addition, the state may limit a right or interest as long as the limitation can be justified under section 1 of the *Charter*. The chapter concludes that there does not appear to be a legal right in Canada to know the genetic information of a close family member or to be informed of whether one is at risk of developing a genetic disease on the basis of a close family member's test results. In Canada, a person's genetic information would be protected under constitutional and privacy law, and unauthorized disclosures may result in legal action.

Chapter 6 explores patents and human rights. It begins with a brief history of patents and an explanation of the science relating to patents in the area of biotechnology. The chapter examines whether individuals have property rights in their body, including their excised bodily materials. The common law is examined, including the pivotal American case of *Moore v. The Regents of the University of California*, along with statutory provisions that grant limited property rights in the human body, as well as the principle of human dignity. Recent Supreme Court of Canada decisions regarding patentability, scope and infringement are reviewed.

This chapter explores, with the assistance of hypothetical scenarios, whether the patenting of human biological materials, such as a single human cell, raises any human rights issues. Based on the hypothetical examples, one is able to conclude that the patenting of human materials may raise human rights norms and values, specifically liberty and security of the person. However, the analysis illustrates that it is not always possible to determine with certainty whether patenting engages human rights under the *Charter*. In those hypotheticals where there is no government action implicated, it is possible to conclude that the *Charter* will not apply. This is the case where the deprivation occurs as a result of the actions of a patentee who is a private entity. However, in other situations where the patentee is a government department or agency, or where the courts issue an injunction, on the basis of the *Patent Act*, the answer is less clear.

Chapter 6 also examines whether the patenting of a human single-celled or pronuclear *in vitro* embryo raises any human rights interests or issues. There are some regional instruments, such as the European Parliament's *Directive*, that prohibit the patenting of *in vitro* embryos that are used for industrial or commercial purposes, and some foreign jurisdictions that consider the embryo as a human being from the moment of conception. In some of these jurisdictions, the human embryo is assigned legal rights. In the state of Louisiana, for example, the *Civil Code* protects the *in vitro* embryo and deems it a juridical person who can sue and be sued.

Both the majority and dissenting opinions of the Supreme Court in *Harvard Mouse* noted in *obiter* that a fertilized mouse egg[2] would be patentable subject matter under the *Patent Act*. If the human pronuclear *in vitro* embryo was found to be patentable subject matter under the Act, it would raise moral and ethical concerns for many individuals. The inability to exclude certain subject matters from patentability under the *Patent Act* may represent a gap in legislative protection.

Chapter 7 examines indigenous traditional knowledge and human rights. This chapter is divided into two parts. The first part articulates wording for a possible indigenous right to use and control traditional knowledge after examining statements of several indigenous groups. The second part of the chapter examines the existence of such a right at the international level and the domestic level.

The chapter's introduction describes traditional knowledge, as well as its connection to "rights." For indigenous peoples, traditional knowledge is intimately connected with the land, culture and language. Traditional knowledge is something owned by the indigenous community, as a community "asset" to be shared and used for the benefit of the members, and not "private property" held and controlled by an individual member. This view of "natural resources" and "knowledge" is contrary to the view reflected by the legal regimes internationally and in Canada, which tend to favour the promotion of innovation in biotechnology research by rewarding creators and inventors through, for example, a system of patents. In the past, indigenous peoples willingly shared their special knowledge of the natural world only to have it used for the commercial gain of others. This knowledge was often used without the consent of indigenous communities, by researchers engaged in bioprospecting or so-called "bio-piracy," to gain access to valuable genetic or biological resources.

The chapter explores whether a right to traditional knowledge exists at the international level. Despite the fact that no international instrument provides indigenous peoples with a right to control traditional knowledge, "rights talk" respecting traditional knowledge has been recently finding its way into the decisions of international bodies, such as the *Conference of the Parties* under the *Convention on Biological Diversity*. Developments internationally provide guidance to States regarding the utilization of traditional knowledge in ways that respect the concerns and interests of indigenous peoples.

The chapter also examines the possible existence of a basis in Canadian law for an assertion that Aboriginal peoples have a right to own and control their traditional knowledge. Traditional knowledge has not yet been the specific

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[2] Patent Office practice in Canada is to patent only single cell organisms. The majority opinion in *Harvard Mouse* was that there was no reason to alter the line drawn by the Patent Office regarding the patentability of life forms. Given that Patent Office practice is to patent only single cell organisms, it may be reasonable to conclude that the Court's comment with respect to the patentability of a fertilized mouse egg was to a single-celled mouse embryo.

subject of "aboriginal rights" litigation. It is, however, relevant to land claims and self-government negotiations and has been addressed in bilateral agreements between Aboriginal communities and resource development companies or researchers. Since it has not itself been the subject of litigation, comments about the relationship between traditional knowledge and aboriginal rights jurisprudence are highly speculative. General conclusions about the existence or non-existence of rights to traditional knowledge under Canadian law therefore cannot be drawn. Although there is no case law in Canada confirming an Aboriginal right respecting traditional knowledge, the approach taken in jurisprudence to date could be used to inform efforts to address indigenous peoples' concerns respecting the use of traditional knowledge.

Chapter 7 concludes with a brief overview of some options that could be used to respect, preserve and maintain traditional knowledge, such as intellectual property laws or *sui generis* laws and policies. Viewing traditional knowledge through the lens of "rights" raises the issue of balancing. The rights of the Aboriginal community must be balanced against the rights of the broader society to knowledge that may carry with it significant social benefits. The chapter ends by proposing that domestic and international experience suggests that a key element in any effort to find ways to address concerns about the misuse of traditional knowledge would include giving indigenous people opportunities to play a central role in law and policy making about issues such as traditional knowledge in biotechnology research.