Human Rights Issues Related to the Patenting of Human Biological Material

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By

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Human Rights Issues Related to the Patenting of Human Biological Material

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EXECUTIVE SUMMARY

The patenting of higher life forms and their biological material has become the focus of concerns about biotechnology and about the patent system. There has been much discussion of ethical, legal and social issues relating to genetics, biotechnology and patenting. However, human rights law analysis as such is strikingly under-represented in the literature an unfortunate gap given the important issues at stake. Consideration of human rights is fundamental to any full discussion of the patenting of human material because they reflect the special status that human beings have in our legal system, which makes patenting of human material different from other higher life forms.

Discussions about patenting tend to attract a variety of concerns about biotechnology generally, some of which are directly related to patenting, while others are not. Similarly, an attempt must be made to identify issues which are specifically human rights issues as opposed to more general concerns about ethics or patent law.

The rationale for the patent system is that by giving inventors a limited monopoly we provide an incentive for innovation and encourage the disclosure of information so that society can benefit from innovation. In Canada, micro-organisms, cell lines, and purified or isolated genes and proteins are patentable; non-human higher life forms were recently found to be patentable by the Federal Court of Appeal. The US and Europe have allowed the patenting of non-human animals but not humans. European patent law also has a general exclusion based on public order or morality. International trade law imposes some requirements on states as to what patents should be allowed and what protection should be provided.

In Canada human rights are protected by legislation, which generally deals with discrimination, and the Canadian Charter of Rights and Freedoms. Some of the rights and freedoms that may be relevant include: freedom of conscience and religion (section 2(a)); the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice (section 7); the right to be secure against unreasonable search and seizure (section 8); and equality rights (section 15(1)). Infringements of Charter rights are permitted only if they meet the test for justification under section 1. Charter rights are to be interpreted in a purposive manner, and are to be given a large and liberal interpretation. The Charter applies to government actions, including legislation or the issuance of a patent. A law is void to the extent of that it infringes the Charter. Remedies for Charter violations may include striking down legislative provisions, reading in or reading down provisions in legislation to make them consistent with the Charter, or making a declaration or an order.

International human rights law may be contained in treaties, customary international law or general principles of law, as well as non-binding soft law documents. Canada is a party to the International Covenant on Civil and Political Rights and the International Covenant on Economic, Social and Cultural Rights as well as a number of other major human rights conventions.

Human materials may refer to human beings, human embryos, and elements or products of the human body including human organs and tissues, cell lines, genetic material and proteins. All of these are considered for the purposes of discussion although human beings are almost certainly not patentable. In patenting we are not dealing with materials in their natural form, but with isolated or purified materials or other products of human intervention.

The concept of human dignity is frequently raised in the context of biotechnology and especially human genetics research. It is a powerful and important concept, but difficult to define. There is no right to dignity as such, but the concept of human dignity can be used to interpret specific rights and their meaning in a given context.

It would be a mistake to assume that the relationship between patenting and human rights is necessarily antithetical. The patent regime plays a role in generating important benefits for individuals. In addition, international law has recognized rights to the protection of intellectual property as part of the human rights framework. The right to protection of intellectual property, like other rights, is not absolute, and rights may have to be limited to accommodate each other where there is a conflict.

International law affirms the right to the highest attainable standard of physical and mental health. The right of everyone to enjoy the benefits of scientific progress and its applications is also recognized. Some people have raised concerns about equitable access to benefits from medical research which may be related to patenting. First, the granting of patent rights is designed to create incentives for research, but it may also hamper research that could lead to beneficial discoveries. Second, there are concerns that the exclusive rights held by patent owners will result in prohibitive costs for therapeutic applications of research, and thus lead to serious inequities of access to the benefits of research. Finally, there is a concern that reliance on patents as incentives for research will direct research priorities toward certain types of products (those which are likely to be patentable and to be commercially lucrative) and leave gaps in areas which may be of great importance to the general population or to disadvantaged groups within a nation or in the international community.

A number of distinct issues are raised with respect to patenting human material due to the fact that the patented inventions are derived from material obtained from human beings. The question therefore arises whether the individuals from whom material is taken are entitled to some specific benefit or compensation if the material is used to produce a patented invention. A number of well-known and controversial cases have highlighted concerns in this area, some of them involving the alleged exploitation of vulnerable peoples.

To the extent that research subjects claims to benefit are based on the recognition of property rights in one s own body and biological material, there is no clear support in human rights law. However, these claims may also be based in equity. Furthermore, individual autonomy and bodily integrity are protected in the context of medical treatment and research by the requirement of informed consent. Informed consent requires the disclosure of any financial interest or commercial potential of the research. Groups such as indigenous peoples may make more extensive claims using the right to self-determination. This right might entail a greater

degree of control over any research involving a particular population, possibly including some rights to financial, health or other benefits.

Other human rights issues may be raised by the targeting of certain ethnic or indigenous populations, where the group is one that is vulnerable to discrimination, or that holds strong religious or spiritual beliefs which are inconsistent with the patenting of human or other biological material.

Modern genetic research has given rise to serious concerns about personal privacy and the possibility of discrimination based on genetic heritage. The right to privacy and to protection from discrimination is recognized both in Canadian and international law. Possible implications for the patent system need to be further investigated.

The U.S. Patent and Trade Office has taken the position that patenting of human beings is contrary to the Constitution which prohibits slavery. A patent holder does not own the invention, but it must be determined whether the property interests of a patent holder might entail sufficient control that the patent offends the prohibition on slavery or broader rights to liberty and security of the person. In the Canadian context we must consider whether patent rights might in some cases offend the Charter s guarantees of liberty, security of the person and equality. This must be undertaken with reference to the rights that the patent holder would have, i.e. exclusive rights to make, use or sell the invention. Some have suggested that excluding others from using or making the invention could interfere with individual autonomy (e.g. a individua l s right to reproduce).

Further questions arise as to the scope of any constitutional prohibition on patenting humans. First, what patents on human materials, as opposed to humans per se might give rise to potential of infringements? Second, assuming that there are some constitutional barriers to patenting human beings, how would we define human beings as the subjects of this protection? This question arises with respect to human embryos and transgenic animals, hybrids and chimaeras which are part human.

Resolution of the issues raised in this paper is important for government, individuals, industry, investors and researchers. Various options have been suggested to modify or supplement the patent regime. A rigourous analysis of human rights issues can help take the debate toward a more comprehensive assessment of potential harms and benefits. This will allow in turn a more precise consideration of possible responses. Further discussion of human rights issues within Canada and interntaionally should therefore provide a useful contribution to policy debate in this area.

I. Introduction

The patenting of higher life forms and their biological material has become a point of convergence for concerns about biotechnology and about the patent system. The particular issues surrounding patenting of genetic material, for example, have been the subject of much debate[2] and there are patent law issues associated with other controversial topics, such as cloning and embryonic stem cells. As a result, patent law has become an important locus of public policy discussion.

The ongoing public debate on these topics has generated a large body of literature, including discussion of ethical, legal and social issues (ELSI) relating to genetics, biotechnology and patenting. Much of this literature discusses ethical concerns and in that context raises issues of human rights and human dignity. However, human rights law analysis as such is strikingly under-represented in the literature an unfortunate gap given the important issues at stake.

The possibility of obtaining a patent on a living organism raises novel legal and ethical issues.[3] When the potential subject matter of the patent is human biological material, these issues are supplemented by others which result from the special status that human beings (as compared to other animals) have in our society and our legal system. This status is manifested in the recognition and enforcement of human rights. Consideration of human rights is thus fundamental to any full discussion of the patenting of human material.

A useful analysis of this subject depends on a precise definition of the issues. Discussions about patenting tend to attract a variety of concerns about biotechnology generally, some of which are directly related to patenting, while others are not. Similarly, an attempt must be made to identify issues which are specifically human rights issues as opposed to more general concerns about ethics or patent law. To a certain extent these distinctions are artificial: for example, if we accept the role of patents in encouraging innovation in particular areas, the availability of patent protection cannot be completely separated from concerns about the underlying technologies. However, the scope of this paper will be limited to specifically considering human rights issues relating to patenting of human materials.

The first section will briefly review key points of patent law and the patenting of higher life forms. Next, some background information on human rights in Canadian and international law will be provided, and then the third section will identify and discuss some human rights issues which may be implicated in patenting human materials. Finally, the concluding section will

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[2] See e.g. B. Evenson, Gene Map Belongs to All: Clinton National Post (15 March 2000) A1. The USPTO responded with a statement that its policy was unaffected by the announcement: United States Patent and Trademark Office, Press Release #00-17, US Patent Policy Unaffected by US/UK Statement on Human Gene Sequence Data (16 March 2000).

[3] The U.S. Office of Technology Assessment has suggested that patenting of living organisms is novel for three reasons: the invention itself is alive, the invention can in some instances reproduce itself, and a deposit of the invention may be required because it cannot be adequately explained in words; see Kevin O Connor, Patenting Animals and Other Living Things (1991) 65 S. California L. Rev. 597 at 598.

offer some suggestions for further research and policy development.

II. The patent system and patenting of higher life forms

Any discussion of patenting must consider the rationale for the patent law system. This rationale has been described thus:

> *One who has created a novel invention which is of perceived benefit to the wider community is rewarded by the grant of a monopoly to exploit his or her creation for a fixed period of time. In return, the inventor must disclose details of the invention so that the community can make use of it on the expiry of the monopoly. In this way it is thought that several interests are served well. The inventor is rewarded for his or her industry, while the community is assured of some kind of benefit albeit in the long term. Furthermore, it is believed that such a system is a source of encouragement to others to invent and innovate.*[4]

Society benefits from the disclosure of information that occurs through the patent system. Without patent protection, it is argued, researchers would be less willing to disseminate information. In short, the theory behind the patent system is that economic growth is advanced by scientific research and that research flourishes best in an environment where information can be shared openly. [5]

In Canada, an invention which is eligible for patent protection is defined as any new and useful art, process, machine, manufacture or composition of matter, or any new or useful improvement in any art, process, machine, manufacture or composition of matter. [6] *The subject matter of the patent must not have been previously disclosed to the public*[7] *and must not have been obvious to a person skilled in the art or science to which it pertains.* [8] *These three basic requirements of novelty, non-obviousness and utility are fairly uniform from country to country.*

In order to obtain a patent, an application must be filed including a specification of the invention. The specification must set out a full description of the invention and the claims

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[4] G. T. Laurie, Biotechnology and Intellectual Property: A Marriage of Inconvenience? in S. A. M. McLean, *Contemporary Issues in Law, Medicine and Ethics* (Aldershot, U.K.: Dartmouth, 1996) 237 at 241 [footnotes omitted].

[5] S. R. Avisar, The Ethics of Biotechnology The Argument in Favour of Patents (1993) 10 C.I.P.R. 209 at 209.

[6] *Patent Act*, R.S.C. 1985, c. P-4, s. 2.

[7] *Ibid*., s. 28.2 (1).

[8] *Ibid*., s. 28.3.

defining precisely the subject matter for which the patent is claimed.[9] *This may include a product, a process for making the product, a novel use for a known product, and/or an improvement of any of these. If a patent is granted, the patent holder will have the exclusive right to make, use and sell the invention for the term of the patent*[10] *(twenty years from the date of filing).*[11]

Some biotechnological products and processes were patented even before the twentieth century, however advances in genetics and in particular the development of recombinant DNA technology made the question of patenting living organisms a pressing one.[12] *In 1980, the United States Supreme Court decision in Diamond v. Chakrabarty*[13] *allowed the patenting of genetically engineered bacteria and established a broad definition of patentable subject matter: anything under the sun made by man,* [14] *including living matter produced by human intervention. Canadian law has permitted the patenting of micro-organisms and cell lines since 1982.*[15] *Elements of the human body such as proteins and genes which are in isolated and purified form are also patentable in Canada, as elsewhere, provided the standard requirements are met.*[16] *Canadian law, however, prohibits patenting of methods of medical or surgical treatment.*[17]

U.S. law has permitted patents on multicellular life forms since 1987[18] *and the first such patent was issued in 1988 the now-famous Harvard mouse patent.*[19] *In Canada, however, higher life forms (multicellular living organisms) were not, until recently, considered to be patentable. In the summer of 2000, the Federal Court of Appeal held that transgenic non-human mammals*

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[9] *Ibid*., s. 27. The description provided is the *quid pro quo* for which the inventor is given the monopoly and thus this requirement is central to the patent system: *Consolboard v. MacMillan Bloedel (Sask.) Ltd*., [1981] 1 S.C.R. 504 at 517.

[10] *Ibid*., s. 42.

[11] *Ibid*., s. 44.

[12] O Connor, *supra* note 3 at 602. The U.S. Patent Office had granted a patent for yeast in 1873, but later, until the decision in *Diamond* v. *Chakrabarty* (*infra* note 13), took the position that living matter could not be patented. See P. A. Rae, Patentability of Living Subject Matter (1993) 10 C.I.P.R. 41 at 41-42.

[13] 447 U.S. 303.

[14] *Ibid*. at 309.

[15] *Re Application of Abitibi Co*., (1982) 62 C.P.R. (2d) 81 (Patent Appeal Bd.). See J. D. Morrow, Patentable Subject-Matter: Emerging Technologies in G. F. Henderson et al., eds., *Patent Law of Canada* (Toronto: Carswell, 1994) 23 at 26.

[16] Morrow, *ibid*. at 25. See also *Kirin-Amgen Inc. v. Hoffmann-La Roche Ltd*., [1999] F.C.J. No. 203.

[17] *Tennessee Eastman Co. et al. v. Commissioner of Patents* (1972), 8 C.P.R. (2d) 202 (S.C.C.).

[18] *Ex parte Allen*, 2 U.S.P.Q. (2d) 1425 (U.S.P.T.O. Bd. Pat. App. & Int.).

[19] U.S. Patent 4,736,866.

are patentable.[20] *The Court suggested that this holding is limited to non-human animals.*[21] *However, there is no specific statutory or judicial prohibition in Canada against patenting humans or human body elements, human cloning or modification of human germ line identity.*[22]

In Europe, biotechnology patenting is governed by several levels of law, including the European Patent Convention (EPC), European Union (EU) law and national laws. The EPC differs from Canadian and U.S. law in that it allows an exception to patentability where exploitation of the invention would be contrary to ordre public or morality.[23] *The morality exclusion has been quite narrowly interpreted*[24] *but has been used to weigh the benefits and risks of the invention.*[25] *Plant and animal varieties are also excluded by the EPC, but transgenic plants and animals are considered patentable provided the claims are not restricted to a single variety.*[26]

In 1998, the EU approved a Directive on the legal protection of biotechnological inventions (the EU Directive).[27] *The EU Directive states that the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions. However, an element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even*

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[20] *President and Fellows of Harvard College* v. *Canada (Commissioner of Patents)*, [2000] F.C.J. No. 1213 (F.C.A.) (QL) [hereinafter *Harvard College*], rev g *Harvard College* v. *Canada (Commissioner of Patents)*, [1998] F.C.J. No. 500 (T.D.). On October 2, 2000, the Commissioner of Patents applied for leave to appeal this decision to the Supreme Court of Canada: Supreme Court of Canada, *Bulletin of Proceedings*, 13 October 2000 at 1747.

[21] *Ibid*. at para. 127: the Patent Act cannot be extended to cover human beings.

[22] Similarly, in the U.S., there is no prohibition against patenting humans, although it is generally accepted that patents on human beings would not be granted.: see *infra* note 96 and accompanying text. Specific statutory prohibitions do exist, however, for example in Australia: *Patents Act 1990*, s. 18(2).

[23] *European Patent Convention*, 5 October 1973, U.K.T.S. 1978 No. 20 [hereinafter EPC], article 53(a).

[24] The exception applies only in rare and extreme cases where the invention would universally be regarded as outrageous : *Howard Florey / Relaxin*, [1995] EPOR 541, para. 6.2.1.

[25] *Harvard / Onco-mouse*, [1990] EPOR 4, para. 5. It is not clear to what extent this approach has survived the later interpretation articulated in *Howard Florey / Relaxin*, *ibid*.

[26] *Ibid*., para. 4.1-4.8.

[27] Directive 98/44/EC, O.J. L 213, 30/07/1998 p. 0013-0021 [hereinafter *EU Directive*]. National laws were required to be in compliance with the Directive by July 30, 2000. The government of the Netherlands initiated a challenge in the European Court of Justice seeking to have the Directive annulled on various grounds, mainly procedural but also including allegations that the Directive breaches fundamental rights. Case C-377/98, *Netherlands* v. *Parliament* [1998] O.J. C378/13. As of the date of writing the outcome of this case had not been determined. For a discussion see A. Scott, The Dutch Challenge to the Bio-Patenting Directive [1999] 4 E.I.P.R. 212.

if the structure of that element is identical to the natural element. [28] *The exception with respect to ordre public and morality is also confirmed, and the following are considered to be unpatentable on that basis:*[29]

> *(a) processes for cloning a human being;*
> *(b) processes for modifying the germ line genetic identity of human beings;*
> *(c) uses of human embryos for industrial or commercial purposes;*
> *(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.*

Finally, a complete picture of the state of patent law internationally requires consideration of international trade agreements containing provisions on intellectual property protection, notably the North American Free Trade Agreement (NAFTA) and the Agreement on Trade-Related Aspects of Intellectual Property (TRIPS). Both of these agreements permit exclusions to patentability where necessary to protect ordre public or morality, to protect human, animal or plant life or to prevent serious prejudice to the environment.[30] *States may also specifically exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals, as well as plants and animals (other than micro-organisms) and essentially biological processes for the production of plants and animals.*[31] *Both the NAFTA and TRIPS also contain provisions on patent protection, which limit, for example, the circumstances in which compulsory licensing is permitted.*[32]

III. Overview of relevant human rights law

A. Human rights law in Canada

There are two major sources of human rights law in the Canadian domestic legal system: the

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[28] *Ibid*., article 5.

[29] *Ibid*., article 6. For a critical examination of this article, see R. B. Skarstad, The European Union s Self-Defeating Policy: Patent Harmonization and the Ban on Human Cloning (1999) 20 U. Pa. J. Int l Econ. L. 353.

[30] *North American Free Trade Agreement Between the Government of Canada, the Government of Mexico and the Government of the United States*, 17 December 1992, Can. T.S. 1994 No.2, 32 I.L.M. 289 [hereinafter NAFTA], Article 1709(2); *Final Act Embodying the Results of the Uruguay Round of the Multilateral Negotiations, Marrakesh Agreement Establishing the World Trade Organization, signed at Marrakesh (Morocco), April 15, 1994, Annex 1C, Agreement on Trade-Related Aspects of Intellectual Property Rights*, GATT, Doc.MTN/FA/Add.1 (15 December 1993); reprinted in 33 I.L.M. 1197, 1200 [hereinafter TRIPS], Article 27(2).

[31] NAFTA, *ibid*., Article 1709(3); TRIPS, *ibid*., Article 27(3). States are required to provide some form of protection for plant varieties. The provision in the TRIPS Agreement allowing exclusions for plants and animals was to be reviewed four years after its entry into force (TRIPS came into force 1 January 1995).

[32] NAFTA, *ibid*., Article 1709(10); TRIPS, *ibid*., Article 31.

Canadian Charter of Rights and Freedoms[33] *and human rights legislation. In Canada, human rights legislation primarily deals with discrimination in employment, housing, services, etc. This paper will not consider human rights legislation in any detail, although its potential role must be kept in mind when discussing any discrimination issues raised in the context of patenting.*

For our purposes the most important source of domestic human rights law is the Charter which is part of the Canadian Constitution and sets out the fundamental rights and freedoms of individuals in Canada. Some of the rights and freedoms that may be relevant include: freedom of conscience and religion (section 2(a)); the right to life, liberty and security of the person and the right not to be deprived thereof except in accordance with the principles of fundamental justice (section 7); the right to be secure against unreasonable search and seizure (section 8); and equality rights (section 15(1)).

The rights and freedoms in the Charter are guaranteed subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society. This means that the rights are not absolute; infringements of Charter rights are permitted as long as they meet the test in this provision (section 1). The courts have developed a framework for analysing this test, which requires the government to show the objective of the legislation or other action is pressing and substantial, that the infringement is rationally connected to this objective, that it impairs rights as little as possible and that the effect of the infringement is proportional to the objective.[34]

Charter rights are to be interpreted in a purposive manner, that is: [t]he meaning of a right or freedom guaranteed by the Charter [is] to be ascertained by an analysis of the purpose of such a guarantee; it [is] to be understood, in other words, in the light of the interests it was meant to protect. [35] *The other basic principle of Charter interpretation is that constitutional provisions and human rights guarantees are to be given a large and liberal interpretation* [36] *in order that they may have their full effect.*

The Charter applies only to government actions, not the actions of private individuals or organizations. Section 32(1) states that the Charter applies to Parliament, provincial legislatures and the provincial and federal governments in respect of all matters within [their] authority. Legislation is clearly a government action and so, for example, the Patent Act is

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[33] Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11. The province of Quebec also has the *Charter of Human Rights and Freedoms*, R.S.Q. c. C-12.

[34] This test was first set out in the case of *R. v. Oakes*, [1986] 1 S.C.R. 103. It was subsequently summarized in e.g. *Egan v. Canada*, [1995] 2 S.C.R. 513 at para. 182. Depending on the nature of the alleged infringment, at the first stage of the test it may be appropriate to examine the objective of the legislation generally, or of the specific impugned provision, omission, or other action, or both: *Vriend v. Alberta*, [1998] 1 S.C.R. 493 at para. 109-11.

[35] *R. v. Big M Drug Mart Ltd.*, [1985] 1 S.C.R. 295 at 344.

[36] *Edwards v. Attorney General of Canada*, [1930] 1 D.L.R. 98 at 107; *Canadian National Railway Co. v. Canada (Canadian Human Rights Commission)*, [1987] 1 S.C.R. 1114 at 1134.

subject to the Charter. The issuance of a patent is also a government action.

According to section 52 of the Constitution, the Constitution (including the Charter) is the supreme law of Canada, and any law that is inconsistent with the provisions of the Constitution is, to the extent of the inconsistency, of no force or effect. Therefore, a law is void to the extent of that it infringes the Charter (i.e. that there is a violation of a Charter right that is not justified in accordance with section 1).[37] *Remedies may include striking down legislative provisions, reading in or reading down provisions in legislation to make them consistent with the Charter, or making a declaration or order. Where Charter rights have allegedly been violated by any government act, the person whose rights or freedoms have been infringed or denied may apply, under section 24(1), to a court for a remedy.*

B. International human rights law

International human rights law has a much broader scope than Canadian domestic law, in terms of both the number and diversity of sources and the rights explicitly protected. There are three main sources of international law: international conventions or treaties, customary international law and general principles of law.[38] *A state which is a party to a convention is bound by its provisions,*[39] *and customary international law is generally binding on all states. There is also a large body of what is sometimes called soft law : resolutions, declarations and other documents of international legal bodies (e.g. the UN General Assembly) which are not binding as such but may be persuasive, may be used to interpret binding legal obligations and may, over time, be codified in conventions or solidify into customary law.*

The analysis in this paper will focus on what is sometimes referred to as the International Bill of Rights : the Universal Declaration of Human Rights (UDHR),[40] *the International Covenant on Civil and Political Rights (ICCPR)*[41] *and the International Covenant on Economic, Social and Cultural Rights (ICESCR).*[42] *The UDHR was originally a resolution of the UN General Assembly and therefore not binding, but it is generally accepted that at least some of its content*

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[37] The exception to this is where a government invokes the notwithstanding clause in section 33, which allows the enactment of a law which is expressly declared to operate notwithstanding any violation of the *Charter*.

[38] *Statute of the International Court of Justice*, 26 June 1945, 3 Bevans 1179, Article 38. Judicial decisions and academic writing may be considered as subsidiary sources.

[39] According to the principle of *pacta sunt servanda*, parties to a treaty must perform their treaty obligations in good faith: *Vienna Convention on the Law of Treaties*, 23 May 1969, 1155 U.N.T.S. 331, article 26.

[40] 10 December 1948, UN G.A. Res. 3/217A.

[41] 16 December 1966, Can. T.S. 1976 No. 47, 999 U.N.T.S. 171.

[42] 16 December 1966, Can. T.S. 1976 No. 46, 993 U.N.T.S. 3.

has gained the status of customary international law.[43] *In any event, most of the rights recognized in the UDHR were later codified in the ICCPR and ICESCR, to which Canada is a party. Canada is also a party to a number of other major human rights conventions, which may be relevant to specific issues in this paper.*

International law obligations are primarily binding on states. The extent to which international law may apply directly to individuals and other private entities such as corporations is a subject of debate, although at least some norms, in the area of international criminal and humanitarian law, apply directly to individuals' actions.

In Canada, international treaty obligations are not automatically part of domestic law. The provisions of a treaty to which Canada is a party must be given effect by the enactment of legislation (federal or provincial, depending on which has jurisdiction over the particular subject matter). However, international law may be, and is, also used to interpret Canadian law and in particular international human rights law is used by Canadian courts in interpreting the Charter.[44] *This paper will consider generally international human rights law applicable to Canada, not only those obligations which have been incorporated into Canadian law, since any acceptable government policy must respect international obligations.*

IV. Human rights and the patenting of human materials

In this section we will consider human rights issues which may be raised by, or in the context of, the patenting of human materials. 'Human materials' will be used generally to refer to human beings, human embryos, and elements or products of the human body including human organs and tissues, cell lines, genetic material and proteins. Some of these are unquestionably patentable under current Canadian law (e.g. cell lines, genes, proteins) while others are almost certainly not (e.g. human beings). For the purposes of this section we will assume that any of these or related processes may potentially be patentable inventions provided they meet the standard criteria for patentability. We are therefore not dealing with materials in their natural form, but with isolated or purified materials or other products of human intervention.

A. Human rights and human dignity

The concept of human dignity is frequently raised in the context of biotechnology and especially

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[43] See e.g. H. Hannum, 'The Status of the Universal Declaration of Human Rights in National and International Law' (1995) 25 Georgia J. Int'l & Comp. L. 289 at 317ff; *Filartiga v. Pena-Irala*, 630 F. 2d 876 (2d Cir. 1980).

[44] See e.g. W. A. Schabas, *International Human Rights Law and the Canadian Charter*, 2d ed. (Toronto: Carswell, 1996).

human genetics research.[45] *Human dignity is explicitly invoked in the EU Directive*[46] *and the UNESCO Universal Declaration on the Human Genome and Human Rights (UNESCO Declaration).*[47] *The Vienna Declaration and Programme of Action notes that certain advances, notably in the biomedical and life sciences ... may have potentially adverse consequences for the integrity, dignity and human rights of the individual, and calls for international cooperation to ensure that human rights and dignity are fully respected in this area of universal concern.* [48]

Dignity is a powerful and centrally important concept,[49] *although its application is often difficult given the lack of any clear agreement on its meaning and how to recognize and prevent its violation.*[50] *One suggestion is that it means respect for the intrinsic worth of every person, which prohibits treating individuals merely as instruments or objects of the will of others.* [51]

From a human rights perspective, there is no right to dignity as such; rather, the concept of human dignity can be seen as the foundation of human rights, and specific rights as manifestations of or means of protecting dignity.[52] *The preambles to the ICCPR and ICESCR state that human rights derive from the inherent dignity of the human person. Therefore, the concept of human dignity can be used to interpret specific rights and their meaning in a given context, and to extend and strengthen human rights by formulating new rights or construing existing rights to apply to new situations.* [53]

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[45] See e.g. B. M. Knoppers, *Human Dignity and Genetic Heritage* (Ottawa: Law Reform Commission of Canada, 1991); D. Beyleveld & R. Brownsword, Human Dignity, Human Rights, and Human Genetics (1998) 61 Modern L. Rev. 661.

[46] *Supra* note 27, para. 16.

[47] *Universal Declaration on the Human Genome and Human Rights*, UNESCO Gen. Conf., 29th Sess., 29 C/Resolution 19 (1997). The UNESCO Declaration has been endorsed by the UN General Assembly: *The human genome and human rights*, 9 December 1998, UN GA Res. 53/152. Dignity is mentioned in articles 1, 2, 6, 10, 11, 12, 15, 21, 24.

[48] *Vienna Declaration and Programme of Action*, 25 June 1993, UN Doc. A/CONF.157/24, para. 11.

[49] No other ideal seems so clearly accepted as a universal social good. O. Schachter, Human Dignity as a Normative Concept (1983) 77 Am. J. Int'l L. 848 at 849.

[50] Schachter, *ibid*., suggests: Without a reasonably clear general idea of its meaning, we cannot easily reject a specious use of the concept, nor can we without understanding its meaning draw specific implications for relevant conduct.

[51] Schachter, *ibid*. Schachter's article contains a useful elaboration of this definition and its implications. See also Beyleveld & Brownsword, *supra* note 45 at 665-66.

[52] The *Proclamation of Teheran* issued at the Teheran International Conference on Human Rights, 13 May 1968, UN Doc. A/CONF.32/41 states that the primary aim of the United Nations in the sphere of human rights is the achievement by each individual of the maximum freedom and dignity (para. 5).

[53] Schachter, *supra* note 49 at 853.

B. Rights to protection of intellectual property

It would be a mistake to assume that the relationship between patenting and human rights is necessarily antithetical. The role that the patent regime is presumed play in generating benefits for individuals is significant from a human rights point of view, as will be seen in the next section. In addition, international law has recognized rights to the protection of intellectual property as part of the human rights framework. The ICESCR in article 15(1)(c) recognizes the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author. Article 27 of the UDHR contains a similar guarantee. Interestingly, a strong argument in favour of including this right in the UDHR drew on an example of contributions to medical research.[54] The inclusion of this right in international human rights law instruments has not gone without criticism,[55] but its recognition and the justifications offered for intellectual property as a right[56] must be considered in any analysis. The right to protection of intellectual property, like other rights, is not absolute, and rights may have to be limited to accommodate each other where there is a conflict.

C. Rights to health and to benefit from scientific progress

Human research subjects may claim particular benefits or compensation, where materials obtained from them are used to generate a patented invention. These issues will be considered in the next section. This section will deal with the rights of all people to health and to benefit from scientific progress, regardless of any involvement as research subjects or sources of material.

The ICESCR affirms the right to health[57] in the following terms: The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable

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[54] See R. P. Claude & B. W. Issel, Health, Medicine and Science in the Universal Declaration of Human Rights (1998) 3 Health and Human Rights 127 at 138. The Dutch representative apparently supported the need for protection of intellectual property rights by using the example of Marie Curie, who had devoted her whole life to the progress of science for the good of humanity, not for a commercial venture.

[55] R. L. Ostergard, Intellectual Property: A Universal Human Right? (1999) 21 Human Rights Q. 156.

[56] See *Ibid*. at 157-65.

[57] The phrase right to health is used to refer to the health related rights recognized in this article of the Covenant and other sources (on the use of this phrase, see e.g. V. A. Leary, Implications of a Right to Health in K. E. Mahoney & P. Mahoney, eds., *Human Rights in the Twenty-first Century* (Dordrecht: Martinus Nijhoff, 1993) 481 at 484-86; B. C. A. Toebes, *The Right to Health as a Human Right in International Law* (Antwerp: Intersentia, 1999) at 16-24). The recognition of the right to health does not require states to guarantee a state of health (see e.g. Committee on Economic, Social and Cultural Rights, *CESCR General Comment 14: The right to the highest attainable standard of health*, 22nd Sess., UN Doc. E/C.12/2000/4 (2000) at para. 8-9), but does entail a set of obligations, some of which are set out explicitly in the Covenant, and others which have been identified through interpretation of the relevant provisions. See e.g. Leary, *ibid*.; Toebes, *ibid*.; *Economic and Social Rights and the Right to Health* (Cambridge, Mass.: Harvard Law School Human Rights Program, 1995); Committee on Economic, Social and Cultural Rights, *ibid*.

standard of physical and mental health. [58] *Certain specific obligations are also set out, including steps necessary for the prevention, treatment and control of epidemic, endemic, occupational and other diseases and the creation of conditions which would assure to all medical service and medical attention in the event of sickness.* [59] *The right of everyone to enjoy the benefits of scientific progress and its applications is also recognized.*[60]

The concerns raised in this area are not unique to the patenting of human materials but are especially important in this context given that the types of inventions under consideration are likely to be related to health and medical treatment. They have been discussed in more general terms as concerns relating to distributive justice,[61] *but the existence of rights to health and to benefits of research allows them to be properly considered as human rights issues.*

There are essentially three related concerns. First, the granting of patent rights may hamper research that could lead to beneficial discoveries, because scientists may not be able to conduct research without the risk of infringing on others patent rights or the cost of obtaining rights under a license. Purely experimental use of inventions is not an infringement, but the scope of this exemption may be too limited to address these concerns.[62] *This concern has been raised particularly in the context of gene patents where it is feared that patents on genes may result in a*

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[58] ICESCR, *supra* note 42, article 12(1). The UDHR, *supra* note 40, also affirms the right to a standard of living adequate for ... health ..., including ... medical care (article 25(1)).

[59] *Ibid*., article 12(2)(c), (d).

[60] *Ibid*., article 15(1)(b). Article 27(2) of the UDHR states that everyone has the right to share in scientific advancement and its benefits. For a discussion of the drafting of this article see Claude & Issel, *supra* note 54 at 137. Other UN documents also address the question of benefit from scientific progress, e.g. *Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind*, 10 November 1975, UN G.A. Res. 3384(XXX).

[61] See e.g. B. Looney, Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical and Policy Foundations of an International Agreement (1994) 26 L. & Pol y Int l Bus. 231 at 239-40.

[62] Traditionally, the exemption has covered only experiments for purely philosophical motives or for amusement, and with no commercial purpose. The *Patent Act*, *supra* note 6, does not create any exemption for research but the common law exemption is preserved by s. 55.2(6): For greater certainty, subsection (1) does not affect any exception to the exclusive property or privilege granted by a patent that exists at law ... in respect of any use, manufacture, construction or sale of the patented invention solely for the purpose of experiments that relate to the subject-matter of the patent. For discussions of the scope of the exemption, see E. R. Gold, Making Room: Reintegrating Basic Research, Health Policy, and Ethics into Patent Law in T. Caulfield & B. Williams-Jones, eds., *The Commercialization of Genetic Research: Ethical, Legal, and Policy Issues* (New York: Kluwer Academic/Plenum, 1999) 63 at 71 [hereinafter Making Room]; L. M. Kurdydyk & S. S. McDiarmid, Patent Infringement Issues Relating to Biotechnology (1993) 10 C.I.P.R. 175 at 179-88; I. P. Cooper, *Biotechnology and the Law* (St. Paul, Minnesota: West Group, 1982, revised 1999), vol. 1 at §5A.12; *Micro Chemicals Ltd.* v. *Smith Kline & French Laboratories Ltd*., [1972] S.C.R. 506.

chilling effect on further research.[63] *The counter-argument is that without the incentive that patents create, research would be even more seriously impaired by a lack of financial support. The resolution of this issue is difficult because it depends in part on the actual operation of patents as incentives for or barriers to research, which as a factual question is the subject of considerable debate.*[64]

Second, there are concerns that the exclusive rights held by patent owners will result in prohibitive costs for therapeutic applications of research, and thus lead to serious inequities of access to the benefits of research.[65] *This is not a concern unique to patents on human material but has arisen also in the case of pharmaceuticals, for example.*[66] *The rights to health and to benefit from scientific progress and its applications are to be guaranteed equally to all persons,*[67] *and this equality is threatened if the patent regime indirectly prevents equitable access. However, it could also be argued that in the absence of the patent regime, products might not be marketed and no one would receive concrete benefits from research.*[68]

Finally, there is a concern that reliance on patents as incentives for research will direct research priorities toward certain types of products (those which are likely to be patentable and to be commercially lucrative)[69] *and leave gaps in areas which may be of great importance to the general population or to disadvantaged groups within a nation or in the international community. This has led to calls for government funding in areas likely to be neglected by commercial interests.*[70]

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[63] M. A. Heller & R. S. Eisenberg, "Can Patents Deter Innovation? The Anticomons in Biomedical Research" (1998) 280 Science 698; "Making Room", *ibid*. at 65-66. A related concern is the effect of patenting on disclosure of research results; see e.g. D. Blumenthal et al., "Withholding research results in academic life science: Evidence from a national survey of faculty" (1997) 277 JAMA 1224.

[64] See "Making Room", *ibid*. at 64-65, 68.

[65] See e.g. A. L. Taylor, "Globalization and Biotechnology: UNESCO and an International Strategy to Advance Human Rights and Public Health" (1999) 25 Am. J. L. & Med. 479 at 488-89, 495-96; M. L. Bouguerra, "Genes of inequality" (September 1999) 52 UNESCO Courier 35.

[66] See e.g. P. Boulet, J. Perriens & F. Renaud-Théry, *Patent situation of HIV/AIDS-related drugs in 80 countries* (Geneva: UNAIDS/WHO, 2000). In some countries, including Canada, there are means by which patentees can be prevented from charging "excessive" prices for medicines: see *Patent Act*, *supra* note 6, s. 83.

[67] ICESCR, *supra* note 42, article 1(2).

[68] On the role of industry in making products available to the public, see T. Caulfield, "The Commercialization of Human Genetics" (1998) 21 J. Consumer Pol'y 125 at 126.

[69] *Ibid*. at 147ff.

[70] A. Attaran, "Human Rights and Biomedical Research Funding for the Developing World: Discovering State Obligations under the Right to Health" (1999) 4 Health and Human Rights 27; A. R. Chapman, M. S. Frankel & M. S. Garfinkel, *Stem Cell Research and Applications: Monitoring the Frontiers of Biomedical Research* (American Association for the Advancement of Science & Institute for Civil Society, 1999) at 20-22. I have argued elsewhere that the tendency to view government funding for research as an "investment" for which commercial

D. Research subjects, informed consent and self-determination

A number of distinct issues are raised with respect to patenting human material due to the fact that the patented inventions are derived from material obtained from human beings. The patented invention will not consist of material from an individual s body in its natural state because of the requirements for patentability, but in virtually every case there will be one or more source individuals to whom the material can be directly or indirectly traced. The right to receive some benefit from research therefore takes on a particular importance and different dimension in respect of these individuals or groups. Claims to benefit may arise in other circumstances indeed in any case where an individual feels she has contributed to the invention, through labour, participation in an experiment, etc. but in this case we are dealing with material actually taken from individuals bodies, which raises additional issues of bodily integrity.

A number of well-known and controversial cases have highlighted concerns in this area. In Moore v. Regents of the University of California,[71] John Moore sued his doctor after discovering that the doctor had, without his 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 interests in his own biological material which entitled him to a share of the profits. The court held instead that Moore would be entitled to compensation for the doctor s breach of his fiduciary duties.

Other cases have been if anything more controversial because they involved the alleged exploitation of vulnerable peoples. For example, a cell line was developed using blood taken from a member of the Hagahai tribe in Papua New Guinea and patented by the National Institutes of Health (NIH) in the United States. The NIH subsequently abandoned the patent, apparently in part because of the international controversy which ensued (although it also had minimal commercial value).[72] There have been other examples of controversial research involving populations around the world.[73] Such cases have sparked opposition to the Human

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return is expected is inimical to the fulfillment of government obligations in this regard: B. von Tigerstrom, Pharmaceutical Research, Testing and the Scientific Process: Human Rights Perspectives, Parkland Institute Fall Research Conference, Edmonton, 26 November 1999.

[71] *Moore* v. *Regents of the University of California*, 793 P.2d 479 (Cal. 1990).

[72] For a discussion of this case, see A. Pottage, The Inscription of Life in Law: Genes, Patents, and Bio-politics (1998) 61 Modern L. Rev. 740 at 740-42; K. H. Ching, Indigenous Self-Determination in an Age of Genetic Patenting: Recognizing an Emerging Human Rights Norm (1997) 66 Fordham L. Rev. 687 at 701-702.

[73] For discussion of several other examples, see Ching, *ibid*. at 687, 699-702. Genetic research in Iceland has also been somewhat controversial: see L. Nielsen, The Icelandic Health Sector Database: Legal and Ethical Considerations in Caulfield & Williams-Jones, *supra* note 62, 111; O. M. Arnardóttir, D. T. Björgvinsson & V. M. Matthíasson, The Icelandic Health Sector Database (1999) 6 Eur. J. Health L. 307.

Genome Diversity Project[74] *and raised concerns about the exploitation of individuals and populations.*

As noted above there is a general right to the highest attainable standard of health and to benefit from the applications of scientific research which must be guaranteed without discrimination. The idea that individuals and/or groups who participate as research subjects and as sources of biological material are entitled by virtue of that participation to some additional or specific benefit is increasingly well accepted, at least in theory, as an ethical obligation of researchers.[75] *To the extent that claims to benefit are based on the recognition of property rights in one s own body and biological material, there is no clear support in human rights law.*[76] *However, these claims are also based in equity, and rights to bodily integrity and self-determination may also be relevant.*

Individual autonomy and bodily integrity are protected in the context of medical treatment and research by the requirement of informed consent. This requirement is based on the principle that every competent person has the right to determine what is done with his or her own body.[77] *In Canada, this right is considered to be coextensive with an individual s rights under section 7 of the Charter (liberty and security of the person).*[78] *Informed consent requires the disclosure of any financial interest or commercial potential*[79] *of the research. However, recognition of individual rights in the consent process will ensure only that subjects are aware of commercial interests, but does not extend to a right to receive benefit or compensation.*

More extensive claims might be made using the right to self-determination. In its current

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[74] 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 criticised by indigenous peoples. See e.g. *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.

[75] See B. M. Knoppers, Status, sale and patenting of human genetic material: an international survey (1999) 22 Nature Genetics 23 at 24; L. H. Glantz *et al.*, Research in Developing Countries: Taking Benefit Seriously (1998) 28 Hastings Center Report 38.

[76] The question of whether individuals do or should have property rights in their bodies and body parts is a complex one which is beyond the scope of this paper, but has been explored elsewhere. See e.g. E. R. Gold, *Body Parts: Property Rights and the Ownership of Human Biological Materials* (Washington, D.C.: Georgetown University Press, 1996); B. M. Dickens, Living tissue and organ donors and property law: More on Moore (1992) 8 J. Contemp. Health L. & Pol y 73.

[77] *Schloendorff* v. *Society of New York Hospital* (1914), 105 N.E. 92 (N.Y.C.A.) at 93.

[78] *Fleming* v. *Reid* (1991), 4 O.R. (3d) 74 (Ont. C.A.) at 88.

[79] *Moore*, *supra* note 71 at 483. B. M. Dickens, Informed Consent in J. Downie & T. Caulfield, eds., *Canadian Health Law and Policy* (Toronto: Butterworths, 1999) 117 at 134.

formulation, however, this is a right that is recognized to belong only to peoples under international law.[80] There is as yet little consensus regarding the definition of peoples or the exact content of the right.[81] However, such collective rights may be especially relevant to indigenous peoples, given the emerging norms regarding the right to self-determination of indigenous peoples in international law[82] and the recognition of aboriginal rights in Canadian constitutional law.[83] For those who can claim this right, it might permit a greater degree of control over any research involving a particular population,[84] possibly including some rights to financial, health or other benefits. The right to self-determination of all peoples including indigenous peoples might also be understood to include the right to make collective decisions about participation in research. However, it is important to remember that the individual members of such groups would also have individual rights to autonomy which could not necessarily be overridden by collective decisions.

Other human rights issues may be raised by the targeting of certain ethnic or indigenous populations. For example, where the group is one that is subject to pre-existing disadvantage or vulnerable to discrimination, the possibility of discrimination claims should be considered. In addition, where the group is one that holds strong religious or spiritual beliefs that are inconsistent with the patenting of human or other biological material,[85] there might be

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[80] The ICCPR, *supra* note 41 and ICESCR, *supra* note 42 both state as article 1(1): All peoples have the right to self-determination. By virtue of that right they freely determine their political status and freely pursue their economic, social and cultural development. Article 1(2) of the UN Charter refers to self-determination of peoples: *Charter of the United Nations*, 26 June 1945, Can. T.S. 1945 No. 7. Regarding the restriction of the right to peoples and the difficulties of defining peoples, see e.g. *Reference re Secession of Quebec*, [1998] 2 S.C.R. 217 at para. 123; S. J. Anaya, A Contemporary Definition of the International Norm of Self-Determination (1993) 3 J. Transnat l L. & Contemp. Probs. 131.

[81] In particular, it is important to distinguish between external self-determination which may include secession or other changes to state structures, which has a much more limited scope (and would not be at issue in this context), and internal self-determination which concerns the exercise of rights within existing state structures. See *Reference re Secession of Quebec*, *ibid*., at para. 126; A. Cassese, *Self-determination of peoples: A legal reappraisal* (Cambridge: Cambridge University Press, 1995), c. 4, 5.

[82] See e.g. E.-I. A. Daes, The Right of Indigenous Peoples to Self-Determination in the Contemporary World Order in D. Clark & R. Williamson, eds., *Self-Determination: International Perspectives* (Houndmills, U.K.: Macmillan Press, 1996, 47; S. J. Anaya, *Indigenous Peoples in International Law* (New York: Oxford University Press, 1996); *Draft United Nations Declaration on the rights of indigenous peoples*, UN Doc. E/CN.4/Sub.2/1994/56.

[83] Section 35 of the Constitution recognizes and affirms the existing aboriginal and treaty rights of the aboriginal peoples of Canada.

[84] Ching, *supra* note 72 at 716ff.

[85] For example, the *Beijing Declaration of Indigenous Women*, 7 September 1995, online: http://www.ipcb.org/resolutions/beijingdec.html, article 40 calls for a stop to the patenting of life forms, which is the ultimate commodification of life which we hold sacred. See also M. J. Hanson, Religious voices in biotechnology: the case of gene patenting (1997) 27:6 Hastings Center Report 1.

allegations that patents on material derived from the group infringe their freedom of religion[86] or aboriginal rights.

E. Privacy and protection from discrimination

Modern genetic research has given rise to serious concerns about personal privacy. Genetic information is especially problematic from a privacy perspective because it may reveal otherwise hidden characteristics such as propensity to develop a certain disease, which may be the basis for discrimination.[87] The association of certain genetic traits with identifiable groups also raises concerns regarding group privacy and discrimination.

The right to privacy is recognized both in Canadian and international law. Although there is no specific right to privacy set out in the Canadian Charter, courts have recognized a right to privacy based on section 7 (liberty and security of the person) and section 8 (freedom from unreasonable search and seizure) which may apply in some situations.[88] This right receives special protection when the personal information at issue relates to an individual s health.[89] In international law, the ICCPR recognizes the right of everyone to protection of the law against arbitrary or unlawful interference with one s privacy.[90] Equality rights are also protected in Canadian law by the Charter and human rights legislation, as well as in various international law documents.[91]

There are clearly some serious concerns with respect to genetic privacy and the potential for discrimination based on genetic information. It is less clear, however, to what extent these concerns are related to patenting per se. Patents may play a role in encouraging the

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[86] Freedom of religion is protected by s. 2(a) of the *Charter* and article 18 of the ICCPR.

[87] The privacy issues raised by genetic testing and research have been extensively discussed in the literature. See e.g. I. J. Brown & P. Gannon, Confidentiality and the Human Genome Project: A Prophecy for Conflict in McLean, *supra* note 4, 215; M. A. Rothstein, Genetic privacy and confidentiality: why they are so hard to protect (1998) 26 J. L. Med. & Ethics 198; L. O. Gostin, Genetic privacy (1995) 23 J. L. Med. & Ethics 320.

[88] See e.g. *R. v. Dyment*, [1988] 2 S.C.R. 417; *R. v. Plant*, [1993] 3 S.C.R. 281; *R. v. O Connor*, [1995] 4 S.C.R. 411. For a discussion of *Charter* rights and privacy in the context of health information, see B. von Tigerstrom, P. Nugent & V. Cosco, Alberta s *Health Information Act* and the *Charter*: A Discussion Paper, Health Law Review (forthcoming).

[89] *R. v. Mills*, [1999] 3 S.C.R. 668.

[90] ICCPR, *supra* note 41, article 17. The *American Convention on Human Rights*, 22 November 1969, O.A.S. T.S. No. 36, 1144 U.N.T.S. 123, contains a similar provision at article 11.

[91] E.g. ICESCR, *supra* note 42, article 2(2); *Convention on the Elimination of All Forms of Racial Discrimination*, 21 December 1965, 660 U.N.T.S. 195.

development of certain technologies, for example for genetic tests,[92] and thus may be indirectly implicated in any misuse of information which might result. The other potential area of concern is the disclosure of genetic or other personal information in patent documents, which will become public. Information disclosed would not be directly identified with any individual, but might in some circumstances be traceable to individuals or groups, and therefore violate their privacy and leave them vulnerable to discrimination. There may also be potential conflicts between those who agree to the use of their material (either as an individual or as a group), and those (e.g. certain members of a group) who may wish to prevent disclosure to protect privacy or other interests. We need to examine what measures are required to adequately protect privacy and how privacy protection may be reconciled with respecting the autonomy of research subjects and the need to have an open patent application process.

F. Individual autonomy[93]

The EU Directive explicitly provides that the human body and processes for cloning human beings or modifying the germ line identify of human beings are not patentable.[94] Neither Canada nor the U.S. has any specific statutory provision excluding human beings from patentability.[95] Despite the absence of a statutory exclusion, the U.S. Patent and Trademark Office (USPTO) has taken the position that it will not accept a claim directed to or containing within its scope a human being because a the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. [96] The specific constitutional basis for this position is presumed to be the Thirteenth Amendment of the U.S. Constitution which prohibits slavery.[97] One possible response to this is that a patent holder does not own the invention, and thus patent rights in a

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[92] See e.g. J. Donahue, Patenting of Human DNA Sequences Implications for Prenatal Genetic Testing (1997-98) 36 J. Family L. 267, arguing that the number of available tests will grow rapidly as a result of the availability of patent rights for DNA sequences (at 268; see also 276ff).

[93] The issues in this section are discussed in greater detail in B. von Tigerstrom, Human Rights Issues in Patenting of Higher Life Forms - The Role of the *Canadian Charter of Rights and Freedoms,* paper prepared for the Canadian Biotechnology Advisory Committee.

[94] *EU Directive*, *supra* note 27, articles 5(1), 6(2)(a), (b).

[95] Australia does expressly exclude human beings from patentability, however; *supra* note 20. Statutes containing such an exclusion have been introduced in the U.S. but never enacted: *Life Patenting Moratorium Act of 1993*, S. 387, 103d Congress, 1st Session, s. 3; *Transgenic Animal Patent Reform Act*, H.R. 1556, 101st Congress, 1st Session, s. 4; *Patent Competitiveness and Technological Innovation Act of 1990*, H.R. 5598, 101st Congress, 2nd Session, s. 204.

[96] D. J. Quigg (Commissioner of the United States Patent and Trademark Office), Statement, Policy Statement on Patentability of Animals, 1077 Off. Gaz. Pat. Office 24 (7 April 1987).

[97] K. D. DeBré, Patents on People and the U.S. Constitution: Creating Slaves or Enslaving Science? (1989) 16 Hastings Const l L. Q. 221 at 228; R. E. Fishman, Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection? (1989) 15 Am. J. L. & Med. 461 at 462.

human being are not equivalent to slavery.[98] *However, this argument cannot be dismissed without determining whether the property interests of a patent holder might, although not amounting to ownership, entail sufficient control that the patent offends the prohibition on slavery or broader rights to liberty and security of the person.*

The prohibition on slavery is well-established in international law,[99] *and includes institutions and practices similar to slavery such as debt bondage and forced marriage*[100] *as well as contemporary forms of slavery such as traffic in women and children, use of children in armed conflicts and sale of organs.*[101] *Slavery is defined as the status or condition of a person over whom any or all of the powers attaching to the right of ownership are exercised.* [102]

Canada is a party to relevant conventions, and although our domestic law contains no specific prohibition on slavery, it would surely violate rights to liberty and security of the person and equality rights protected in the Charter. These Charter guarantees (and equivalent rights in international law) also cover a broader scope, proscribing infringements which might not be caught by the definition slavery. In the Canadian context, therefore, it is more useful to refer to these rights to determine what type or degree of control might offend the Charter.

The question, then, is whether and to what extent patent rights in a human being (or human material) would infringe the Charter. While this might seem a somewhat speculative question, in fact its resolution would be both important and useful. The Patent Act s provisions on patentability and patent rights could be read down to limit patents and patent rights to those consistent with the Charter. However, if the grant of patent rights does not infringe the Charter but we want to exclude certain materials from patentability or prohibit the exercise of certain patent rights, a specific prohibition will be required. In any case, a specific prohibition might be favoured to avoid uncertainty and proactively establish desired limits.

It is not the goal of this paper to attempt to conclusively determine the scope of potentially unconstitutional patents. For each potential subject matter, it must be considered whether the exercise of the usual rights of the patent holder in the absence of any other regulation or

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[98] See e.g. Fishman, *ibid*. at 474.

[99] UDHR, *supra* note 40, article 4; ICCPR, *supra* note 41, article 8; *American Convention on Human Rights*, *supra* note 90, article 6; *Slavery Convention*, 25 September 1926, 60 L.N.T.S. 253; *Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others*, 21 March 1950, 96 U.N.T.S. 271; *Supplementary Convention on the Abolition of Slavery, the Slave Trade, and Institutions and Practices Similar to Slavery*, 7 September 1956, 226 U.N.T.S. 3 [hereinafter *Supplementary Convention*]. Canada is a party to all of these except the *Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others*.

[100] *Supplementary Convention*, *ibid*., article 1.

[101] United Nations High Commissioner for Human Rights, *Fact Sheet No. 14: Contemporary Forms of Slavery* (Geneva: UNHCHR, 1991).

[102] *Slavery Convention*, *supra* note 99, article 1(1) [emphasis added].

prohibition would infringe Charter rights. The patent holder has the exclusive right to make, use and sell the invention,[103] but it must be remembered that in reality what this means is the right to prevent others from making, using or selling the invention, not necessarily an affirmative right to do those things. It has been suggested that an attempt to enforce the right to exclude others from using the invention could interfere with the patented individual s right to use him- or herself or associate with others;[104] this could be the case only if we take a very broad view of what it means to use an invention. Concerns have also been raised that the exclusive right to make the invention could interfere with individuals rights to reproductive freedom.[105] Essentially, the individual would be infringing the patent by reproducing and thus the patent holder s rights would in theory prohibit reproduction. This may seem unlikely, especially given the limited term of patents, but the potential for such conflicts should be examined.

Further questions arise as to the scope of any constitutional prohibition on patenting humans. First, what patents on human materials, as opposed to humans per se might give rise to these types of infringements?[106] 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 Opposition Division of the EPO in the following terms:

> *As for the opponents assertions concerning slavery and the dismemberment of women, these are considered to betray a fundamental misunderstanding of the nature of a patent. ... It cannot be overemphasised that patents covering DNA encoding human H2-relaxin, or any other human gene do not confer on their proprietors any rights whatever to individual human beings, any more than do patents directed to other human products such as proteins, including human H2-relaxin. No woman is affected in any way by the present patent she is free to live her life as she wishes and has the same right to self-determination as she had before the patent was granted. Furthermore, the exploitation of the invention does not involve dismemberment and piecemeal sale of women. The whole point about gene cloning is that the protein encoded by the cloned gene in this*

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[103] *Patent Act*, *supra* note 6, s. 42.

[104] Fishman, *supra* note 97 at 475-76.

[105] *Ibid*. at 475; DeBré, *supra* note 97 at 238-39; R. W. Walker, Patent Law Should Genetically Engineered Human Beings be Patentable? (1991) 22 Memphis State U. L. Rev. 101 at 110; D. L. Burk, Patenting Transgenic Human Embryos: A Nonuse Cost Perspective (1993) 30 Houston L. Rev. 1597 at 1649-50 (this last author rejects the argument as untenable for a variety of practical and doctrinal reasons). The right to make reproductive decisions is protected in Canada by section 7 of the *Charter*: *Morgentaler* v. *R.*, [198] 1 S.C.R. 30. For a comprehensive review of human rights law and reproductive freedom, see R. J. Cook, Human Rights and Reproductive Self-Determination (1995) 44 Am. U. L. Rev. 975.

[106] For practical purposes, the distinction between a patent on a human being per se and on certain materials or processes may not be important. In the *Harvard College* case, *supra* note 20, the Federal Court noted at para. 36 that even if a mouse were found to be within the realm of patentable subject-matter it would give the inventor no additional protection in this instance. The inventor has already received a patent for the creation of the plasmid and the injection thereof into the mouse oocyte.

> *case human H2-relaxin is produced in a technical manner from unicellular hosts containing the corresponding DNA; there is therefore no need to use human beings as the source for the proteins.*[107]

Although some perceive serious ethical problems with patents on human materials,[108] *from a human rights law point of view we need to consider in each case whether the nature of the invention is such that its exploitation would infringe legally recognized rights of individuals.*

The second question is, assuming that there are some constitutional barriers to patenting human beings, how would we define human beings as the subjects of this protection? This question has been raised in the context of embryos[109] *and anencephalic infants.*[110] *A human embryo or fetus is not a person in Canadian law,*[111] *but if it was determined that there was or should be a prohibition on patenting human beings or relevant processes, such a prohibition might have to extend to embryos in order to have any real effect. The EU Directive s exclusion specifically refers to the human body at the various stages of its formation and development.* [112]

The development of technology for creating transgenic animals, hybrids and chimaeras[113] *raises another definitional question: 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?*[114] *The question is not a serious one when dealing with transgenic animals such as the Harvard mouse with a very limited amount of human genetic material, but it would be quite another matter if we are faced with, for*

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[107] *Howard Florey / Relaxin*, *supra* note 24 at para. 6.3.3.

[108] Another controversial example is the patent granted by the EPO to the US company Biocyte for the use of stem cells from umbilical cord blood. An opposition to the patent was successful but on the grounds that it lacked novelty and an inventive step, not on ethical grounds. D. Butler, Patent on umbilical-cord cells rejected in Europe... (1999) 399 Nature 626.

[109] See e.g. Burk, *supra* note 105.

[110] Walker, *supra* note 105 at 106ff.

[111] *Tremblay* v. *Daigle*, [1989] 2 S.C.R. 530; *Winnipeg Child and Family Services (Northwest Area)* v. *G. (D.F.)*, [1997] 3 S.C.R. 925.

[112] *Supra* note 27, article 5(1).

[113] A transgenic animal is one that 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 containing 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. See T. A. Magnani, The patentability of human-animal chimeras (1999) 14 Berkeley Tech. L. J. 443.

[114] For a discussion of these issues, see Fishman, *supra* note 97; T. Schrecker *et al.*, Ethical Issues Associated with the Patenting of Higher Life Forms (17 May 1997) online: http://strategis.ic.gc.ca/SSG/ip01079e.html.

example, a human/chimpanzee chimaera.[115] *A patent application in the United States has sought to test these limits. Jeremy Rifkin and Dr. Stuart Newman filed a patent application at the USPTO covering the production of human-animal chimaeras that could be up to 50% human. 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.*[116] *The application was rejected in part on the basis that it included a human being within its scope and human beings are not patentable.*[117]

V. Conclusion

Further analysis will be required to resolve some of the questions raised in this paper. Resolution of these issues is important for all concerned: for government, in order to identify and comply with relevant human rights obligations; individuals, to know what rights are protected and how; and industry, investors and researchers, to have some certainty as to what activities are permissible and what patents may be obtained and exploited. A more comprehensive and detailed examination of the issues dealt with here, as well as some of those which were set aside concerning human rights implications of the technologies themselves, can lead us to the next step, which is to identify measures which may be required to protect human rights.

These measures may include modifications to the patent law regime: various options have been proposed for law reform which would alleviate some of the concerns identified here. These might include exclusions to patentability but also broader exemptions for research use, compulsory licensing, and limiting the scope or term of patents,[118] *or the application of principles such as common heritage* [119] *or public trust.*[120] *We should also consider various regulatory measures that could either prevent the development of technologies in the first place*

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[115] Increasing knowledge about the genetic and behavioural similarities between humans and non-human primates is challenging the exceptional status of human beings in law. In New Zealand, a law was introduced in 1999 which 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.

[116] E. Marshall, Legal Fight Over Patents on Life (1999) 284 Science 2067 at 2067.

[117] D. Dickson, ... as US bid to patent human-animal hybrid fails (1999) 399 Nature 626. The applicants have announced their intention to appeal the decision. The USPTO had previously released a statement saying that inventions directed to human/non-human chimera, could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement. United States Patent and Trademark Office, News Release 98-6, Facts on Patenting Life Forms Having a Relationship to Humans (1 April 1998).

[118] Making Room, *supra* note 62; Timothy Caulfield and Richard Gold, "Whistling in the Wind: Reframing the Genetic Patent Debate" (2000) 15 Forum for Applied Research and Public Policy 75.

[119] *Human Dignity and Genetic Heritage*, *supra* note 45 at 18-20; B. M. Knoppers, Sovereignty and Sharing in Caulfield & Williams-Jones, *supra* note 62, 1 at 3, 9-10.

[120] For a discussion of the public trust doctrine, see B. von Tigerstrom, The Public Trust Doctrine in Canada: Potential and Problems (1998) 7 J. of Env tl L. & Practice 379.

or regulate the exploitation of certain types of inventions.[121] *We may be able to identify areas in which development of human rights law is required to address novel situations or ensure effective protection.*[122] *Finally, some concerns may require non-legal solutions such as public education or encouraging dialogue between stakeholders. A rigorous analysis of human rights issues can help take the debate beyond should we patent or not toward a more comprehensive assessment of potential harms and benefits. This will allow a more precise consideration of possible responses.*

Further examination and discussion of human rights issues relating to patenting of human biological material should therefore provide a useful contribution to policy debate in this area. This discussion would best be pursued at both a national and international level, since international cooperation and consensus in this area will be important for Canada.[123]

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[121] See J. Black, Regulation as Facilitation: Negotiating the Genetic Revolution (1998) 61 Modern L. Rev. 621 for a useful discussion of regulation in this field.

[122] Some commentators have suggested that the existing human rights framework is inadequate to deal with concerns raised by modern biotechnology: see A. T. Iles, The Human Genome Project: A Challenge to the Human Rights Framework (1996) 9 Harvard Human Rts. J. 27; D. Bell, Human Cloning and International Human Rights Law (1999) Sydney L. Rev. 202.

[123] This point was made by Glenn Rivard in a conversation with the author (23 March 2000).