

**Human Rights Issues in Patenting of Higher Life
Forms - The Role of the *Canadian Charter of Rights
and Freedoms***

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Human Rights Issues in Patenting of Higher Life Forms - The Role of the *Canadian Charter of Rights and Freedoms*
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EXECUTIVE SUMMARY

The patenting of human materials has raised a number of human rights concerns, ranging from issues regarding benefit from research, to the rights of research subjects, to the protection of individual privacy. Some have suggested that patents on human beings or other human biological materials may directly infringe human rights and that patent rights are incompatible with the prohibition of slavery and the protection of individual liberty. A patent holder has the right to exclude any other person from making, using or selling the invention. These rights do not amount to ownership, but the patent holder's exclusive rights are limited property rights which might, in certain circumstances, fall within the definition of slavery or otherwise be contrary to recognized human rights. This paper seeks to identify whether there are any cases in which patents on human materials may result in a violation of the rights of individuals protected in the *Canadian Charter of Rights and Freedoms*, in particular the guarantee of life, liberty and security of the person in section 7, and to a lesser extent equality rights in section 15(1).

The right to reproductive autonomy falls within the scope of section 7 of the *Charter*. The patentee's exclusive right to make an invention potentially conflicts with this right and equality rights when the invention is one that can be "made" through natural reproduction: for example human beings and germ line genetic interventions. The exclusive right to use the invention probably would not, even in the case of a patent on a human being, interfere with an individual's usual activities. A patentee might attempt to prevent others' use of a human being or other human material for research or other purposes, which might violate rights under section 7 or 15(1). In certain cases a particular means of enforcing the exclusive right of use (for example an injunction affecting an individual's person) might infringe *Charter* rights. Finally, the exclusive right to sell has no application in the case of a patented human being; in addition some tissues cannot be sold under current law. However, in cases where human biological material could be sold, the patentee would have the exclusive right to sell and could prevent anyone else from doing so. The right to sell one's biological material is not as well protected under the *Charter*, although one could argue that equality rights are violated by a restriction which applies only to certain classes of individuals.

There are therefore a few cases in which the grant of a patent or the enforcement of patent rights might directly infringe an individual's *Charter* rights. The prospect of a patent on a human being raises the most serious concerns but a human being is almost certainly not patentable under current law in any case. Patents on human materials such as genes and proteins do not raise concerns about interference with individual rights although they may raise other human rights concerns.

Patent law may be modified either by legislative or judicial action to eliminate these potential conflicts with individual rights. One option for modifying patent law would be to exclude certain material from patentability. Some other jurisdictions have excluded human beings or provided general exclusions based on "*ordre public* and morality." Another option would be to avoid any restrictions on what is patentable (beyond the current criteria), but to restrict the exercise of patentees' rights where these may interfere with individual human rights. The second option might be preferable since it entails minimal interference with the patent system, except in the

case of human beings where patent rights would be problematic in many respects and an exclusion may be advisable. Any modification of the patent system will have to take account of international trade law obligations regarding patent protection.

A broader range of measures will be required to address other human rights concerns, including those relating the equitable distribution of benefits from research and resulting patents. Measures requiring further consideration may include modifications to the patent system, but also the development of other norms and regulatory mechanisms at a national and international level.

I. Introduction

The patenting of human materials has raised a variety of legal and ethical concerns, including some relating to human rights. Distinct questions involving human rights are raised by the technology and purposes underlying attempts to patent human materials. However, there are other concerns that are specific to patenting. Identifying these issues and recognizing the distinctions between them is essential, since it is only by precisely identifying potential issues that we can formulate appropriate solutions.

A. Human rights issues related to patenting of human materials

A range of human rights issues or concerns relating to patenting human materials has been identified.² First, there are concerns that patenting human materials may lead to violations of the right to health and to benefit from the applications of scientific progress. Some believe that the patent system may impede research, by restricting the exchange of information and/or by making research prohibitively expensive due to the need for researchers to acquire rights from patent holders to use research materials. There is also a concern that because of the limited monopoly that a patent creates, the cost of therapeutic applications will prevent equitable access to the benefits of scientific research. The availability of patents may also play a role in directing research interests disproportionately toward commercially profitable areas and away from others which could provide important benefits to individuals.

Second, there are also specific concerns relating to the rights of individuals used as research subjects, including claims to receive some benefit from patented inventions that may result from their participation and the protection of their rights to autonomy and physical integrity during the research itself. Individuals or groups who are used as research subjects may also have concerns about the protection of their privacy, especially relating to genetic information, and protection from related discrimination. Issues regarding collective rights may be raised where distinct groups or populations participate as research subjects.

Finally, it must be asked to what extent the grant of patent rights on certain human materials might directly infringe the liberty, security of the person or equality of any individual. It is this last question which will be the primary focus of this paper. The possibility that patents on certain human materials might constitute a direct violation of individual rights must be investigated, because it has important implications for the measures which might be required to protect rights.

B. Patenting of human materials

Before moving on to a discussion of these questions, it is important to clarify the scope of the subject matter at issue and its current status in Canadian law. "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. We will also be

² See B. von Tigerstrom, "Human Rights Issues Related to the Patenting of Human Biological Material," paper prepared for the Canadian Biotechnology Advisory Committee.

concerned with processes by which any of these are created or modified, since processes themselves may also be patented.

It has been the law in the United States³ and Canada⁴ since the 1980s that living organisms produced by human intervention may be the subject of a patent. Generally, human material will be patentable when it constitutes an invention within the meaning of the *Patent Act*⁵ and meets the usual criteria of novelty, non-obviousness and utility.⁶ These requirements narrow the scope of patentable subject matter: for example, a discovery is not patentable, nor are human materials in their naturally occurring form. However, elements of the human body such as genes and proteins may be patentable if they are isolated and purified; cell lines and hybridomas are also patentable.

Previously, higher life forms of any kind could not be patented in Canada, but a decision of the Federal Court of Appeal recently found that transgenic non-human mammals are patentable.⁷ This holding is limited to non-human animals, however: “the Patent Act cannot be extended to cover human beings.”⁸ Some reasons for this will be explored in the next section. It could also be said that human beings cannot be patentable inventions because they would not meet the utility requirement. The requirement that an invention be “useful” means that it must have some “industrial value.”⁹ This normally means that it will have some prospect of commercial exploitation (although commercial success or lack of it does not necessarily prove whether the invention is useful).¹⁰ To apply this definition to a human being would be to stretch it beyond a

³ *Diamond v. Chakrabarty*, (1980) 447 U.S. 303 (S.C.). The U.S. Patent Office had granted a patent for yeast in 1873, but later, until 1980, 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.

⁴ *Re Application of Abitibi Co.* (1982), 62 C.P.R. (2d) 81 (Patent Appeal Bd.).

⁵ R.S.C. 1985, c. P-4, s.2: “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 *Ibid.*, ss. 2, 28.2(1), 28.3.

⁷ *President and Fellows of Harvard College v. Canada (Commissioner of Patents)*, [2000] F.C.J. No. 1213 (F.C.A.) (QL) [hereinafter *Harvard College*]. 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.

⁸ *Ibid.* at para. 127.

⁹ *Northern Electric Co. et al. v. Brown's Theatres Limited*, [1939] 3 D.L.R. 729 at 749 (Ex. Ct.), aff'd [1941] 2 D.L.R. 105 (S.C.C.). Canadian Intellectual Property Office, *Canadian Patent Office Manual of Patent Office Practice* (Ottawa-Hull: Industry Canada, 1998), para. 16.02.01.

¹⁰ See H. G. Fox, *Canadian Law and Practice relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) at 149, 158-59.

reasonable interpretation.¹¹ Furthermore, an invention with an immoral or unlawful purpose, or one which is dangerous, is not useful in the sense required by the patent system¹² and proposed uses of human beings for industrial or commercial purposes would almost certainly fall in this category. Patents on human beings will nevertheless be considered below for the sake of discussion. This discussion is limited to subject matter which otherwise meets the criteria for patentability and involves human intervention similar to that for other higher life forms, such as human beings produced through cloning, or genetically modified or transgenic human beings.¹³ It should be borne in mind, however, that it is unlikely that a patent would ever be granted for a human being, even if these other conditions were met.

II. Patent rights as an infringement of individual rights

Some authorities have taken the position that patent rights relating to a human being constitute an impermissible infringement of personal liberty. The U.S. Patent and Trademark Office (USPTO) has stated that a claim “directed to or containing within its scope a human being will not be considered to be patentable subject matter” because “[t]he grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.”¹⁴ Similarly, the majority judgment of the Canadian Federal Court of Appeal in the recent decision allowing patents on higher life forms contains the following statement:

A final question is whether the Patent Act could be extended to cover human beings. In other words, could a finding that “invention” includes living organisms extend to human beings? For example, on a theoretical level, could a person whose genome has been modified by the addition of an engineered gene in order to eliminate or suppress a genetic predisposition to a disease be the subject matter of a patent?

¹¹ Thanks to Ted Yoo for articulating this point. There have been no valid patents on a fully developed human being. In December, 1999, the European Patent Office (EPO) mistakenly granted a patent that included within its scope a method of preparing a transgenic human being. The application had failed to restrict the transgenic animal to “non-human” and therefore covered humans within its scope. European Patent Office, Press Release 1/2000, “Declaration of the European Patent Office with regard to Patent No. EP 0695351 granted on 8 December 1999” (22 February 2000). The patent application was subsequently amended to exclude humans from its scope. There have recently been patents granted for human embryos, however: see *infra* note 87.

¹² Fox, *supra* note 10 at 156-57; see also *infra* note 97 and accompanying text.

¹³ This is important given that there are many misconceptions among members of the public regarding the concept of patents on human beings or other human materials. For example, it is not unusual to see references to “patents on humans” or “patents on people” when what is really meant is gene patents, and according to recent news reports, a British woman applied for a patent on herself in order to protect her genetic material. Her application stated: “It has taken 30 years of hard labour for me to discover and invent myself, and now I wish to protect my invention from unauthorised exploitation, genetic or otherwise.” See James Meek, “Poet attempts the ultimate in self-invention - patenting her own genes,” 29 February 2000, *The Guardian*, online: <http://www.guardianunlimited.co.uk/Archive/Article/0,4273,3968738,00.html>.

¹⁴ 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).

...

The answer is clearly that the Patent Act cannot be extended to cover human beings. Patenting is a form of ownership of property. Ownership concepts cannot be extended to human beings. There are undoubtedly other bases for so concluding, but one is surely section 7 of the Charter of Rights and Freedoms which protects liberty.¹⁵

A. Patenting and slavery

The specific constitutional basis for the USPTO's position has been assumed to be the Thirteenth Amendment of the U.S. Constitution which prohibits slavery.¹⁶ The legal commentators in the U.S. who have examined this statement seem unanimous in concluding it is wrong, at least insofar as it relies on the Thirteenth Amendment.¹⁷ As one put it: "the legal basis for the PTO position is flawed; there is no reason to suppose that the Thirteenth Amendment addresses the type of right conferred by a patent."¹⁸ At least two commentators have concluded that a patent on a human being is not unconstitutional at all.¹⁹

The basis on which the USPTO's position is questioned is that a patent right does not equate to ownership, therefore a patent on a human being would not constitute slavery. The patent holder has the right only to exclude others from making, using or selling the invention and does not (at least not necessarily or merely by virtue of owning the patent) own individual embodiments of the invention.²⁰ However, it would be surprising, to say the least, if the Commissioner of the USPTO misunderstood the nature of the rights granted by a patent. Clearly the USPTO must know that a patent does not equate to ownership of the invention, but understands that it does confer a "limited, but exclusive property right". The comments of the Canadian Federal Court of Appeal similarly refer to patents as a form of property, but it is unlikely that this is because the Court mistakenly believes that patents are equivalent to ownership. Therefore, the crux of the issue must lie elsewhere. We know that we are not concerned here with outright ownership of a human being, but we need to examine the rights that are granted to a patent holder and what effect they might have on individuals' rights.

¹⁵ *Harvard College*, *supra* note 7 at paras. 125-28.

¹⁶ 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.

¹⁷ Fishman, *ibid.*, at 462; DeBré, *ibid.*, at 258; D. L. Burk, "Patenting Transgenic Human Embryos: A Nonuse Cost Perspective" (1993) 30 *Houston L. Rev.* 1597 at 1647; R. Walker, "Patent Law – Should Genetically Engineered Human Beings Be Patentable?" (1991) 22 *Memphis State U. L. Rev.* 101 at 111.

¹⁸ Burk, *ibid.* at 1647-48.

¹⁹ Walker, *supra* note 17 at 111; DeBré, *supra* note 16 at 258.

²⁰ Burk, *supra* note 17 at 1648; Fishman, *supra* note 16 at 474-75; DeBré, *supra* note 16 at 231-32.

To begin with, the definition of slavery, at least in the international legal instruments that are relevant to Canada,²¹ includes more than what we might understand as ownership of a human being. 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.”²² Property is a “bundle of rights” which includes, for example, the right to possess, use or earn income from something.²³ The exclusive right to use an invention might therefore be described as one of the “powers attaching to the right of ownership.” A patent gives its owner the exclusive right to make, use and sell the invention, which is sometimes explained as being no more than the right to exclude others from making, using or selling the invention. However, the same could be said of property generally: the concept of property has been described as “a state-enforced right of exclusion over things, good (generally) against the world.”²⁴ An owner may not be able to use her property as she likes, but she still owns it and can legally prevent others from using it.

There is, of course, a difference between owning a patent on an invention and owning the product or embodiment of the invention, and the two do not necessarily go together. The key point here is that the *nature* of these rights is perhaps not as different as some would suggest. It is therefore conceivable, at least in theory, that patent rights in a human being could amount to a power of ownership sufficient to meet the definition of slavery in international law. Whether this is the case will depend on whether the patent owner can, as a result of the patent rights, exercise control over an individual and on the nature and degree of any such control. For our purposes, in the context of the *Charter*, the question of control is also central. There is no specific prohibition against slavery in the Canadian Constitution, but the *Charter* does protect individual liberty and security of the person under section 7 and equality rights under section 15(1). Therefore, we can most usefully advance the analysis by asking whether patent rights might in some cases interfere with individual liberty, security of the person, or equality, regardless of whether we would characterize this interference as a form of ownership.

B. Scope of *Charter* rights

Section 7 of the *Charter* is particularly relevant in this context because it protects individuals’ right to liberty and security of the person. The section states: “Everyone has the right to life, liberty and security of the person and the right not be deprived thereof except in accordance with the principles of fundamental justice.” The claimant must establish first that there has been a

²¹ *Universal Declaration of Human Rights*, 10 December 1948, UN G.A. Res. 3/217A [hereinafter UDHR], article 4; *International Covenant on Civil and Political Rights*, 16 December 1966, Can. T.S. 1976 No. 47, 999 U.N.T.S. 171 [hereinafter ICCPR], article 8; *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. 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*.

²² *Slavery Convention*, *ibid.*, article 1(1) (emphasis added).

²³ B. Ziff, *Principles of Property Law*, 2nd ed. (Scarborough, Ontario: Carswell, 1996) at 2.

²⁴ *Ibid.* at 5.

deprivation of life, liberty or security of the person, and second, that this deprivation is not in accordance with the principles of fundamental justice. If both of these are established, the government must justify the violation under section 1.²⁵

The liberty interest protected by section 7 includes freedom from physical restraint such as imprisonment, or requirements to submit to fingerprinting or to produce documents.²⁶ It also protects an individual's right to make decisions about personal matters of fundamental importance free from state interference.²⁷ This "narrow sphere of inherently personal decision-making"²⁸ may include matters such as one's choice of a place of residence,²⁹ decisions to consent to or refuse medical treatment,³⁰ and decisions about reproduction.³¹ Section 7 does not, however, guarantee absolute freedom from any constraint.³² Furthermore, it does not, as a general rule, include economic freedoms such as the right to engage in business or a profession,³³ nor does it cover the freedoms that are protected elsewhere in the *Charter* such as freedom of conscience, expression and association, or mobility rights.³⁴

The right to control one's own body is also protected by the right to security of the person in

²⁵ Section 1 provides that rights are guaranteed "subject only to such limits prescribed by law as can be demonstrably justified in a free and democratic society." The test for justification under s. 1 has been stated as follows: "First, the objective of the legislation must be pressing and substantial. Second, the means chosen to attain this legislative end must be reasonable and demonstrably justifiable in a free and democratic society. In order to satisfy the second requirement, three criteria must be satisfied: (1) the rights violation must be rationally connected to the aim of the legislation; (2) the impugned provision must minimally impair the Charter guarantee; and (3) there must be a proportionality between the effect of the measure and its objective so that the attainment of the legislative goal is not outweighed by the abridgement of the right. In all s. 1 cases the burden of proof is with the government to show on a balance of probabilities that the violation is justifiable." *Egan v. Canada*, [1995] 2 S.C.R. 513 at para. 182.

²⁶ *R. v. Beare*, [1988] 2 S.C.R. 387; *Thomson Newspapers v. Canada*, [1990] 1 S.C.R. 425.

²⁷ *Blencoe v. British Columbia (Human Rights Commission)*, 2000 SCC 44 [hereinafter *Blencoe*] at para. 49-52; *Godbout v. Longueuil*, [1997] 3 S.C.R. 844 at para. 66. See also e.g. *Singh v. Minister of Employment and Immigration*, [1985] 1 S.C.R. 177 at 205; *R. v. Morgentaler (No. 2)*, [1988] 1 S.C.R. 30 at 164-66 [hereinafter *Morgentaler*]; *B. (R.) v. Children's Aid Society of Metropolitan Toronto*, [1995] 1 S.C.R. 315 at para. 83.

²⁸ *Blencoe*, *ibid.* at para. 51.

²⁹ *Godbout v. Longueuil*, *supra* note 27.

³⁰ *Fleming v. Reid* (1991), 4 O.R. (3d) 74 (Ont. C.A.) at 88. According to the majority in *B. (R.)*, *supra* note 27, it may also include the right to make medical decisions for one's child.

³¹ *Morgentaler*, *supra* note 27, *E. v. Eve*, [1986] 2 S.C.R. 388.

³² *Blencoe*, *supra* note 27 at para. 54. See also *B. (R.)*, *supra* note 27 at para. 80, citing *Re B.C. Motor Vehicle Act*, [1985] 2 S.C.R. 486 at 524; *R. v. Edwards Books and Art Ltd.*, [1986] 2 S.C.R. 713 at 785-86.

³³ *Edwards Books*, *ibid.*, *Re ss. 193 and 195.1 of the Criminal Code*, [1990] 1 S.C.R. 1123, *ILWU v. Canada*, [1994] 1 S.C.R. 150.

³⁴ *Re ss. 193 and 195.1 of the Criminal Code*, *ibid.*

section 7.³⁵ Security of the person is infringed not only by harm to one's health or physical integrity, but also by a loss of control over one's body, for example regarding termination of a pregnancy.³⁶ "On this basis, security of the person would include some requirement of personal autonomy, at least with respect to medical treatment."³⁷ In addition, it protects psychological as well as physical integrity³⁸ and therefore is offended where there is, objectively, a "serious and profound effect on a person's psychological integrity."³⁹ For example, invasion of privacy, stigmatization, and disruption of family relationships may violate one's security of the person.⁴⁰ Generally speaking, however, section 7 does not protect social or economic security, or security of one's personal property.⁴¹ Finally, it does not include a generalized right to dignity, although human dignity is an important underlying value of the *Charter*.⁴²

A violation of the right to liberty or security of the person will not amount to a violation of section 7 which must be justified under section 1 of the *Charter*, unless it is contrary to the principles of fundamental justice. The principles of fundamental justice are the "fundamental principles of our legal system," both substantive and procedural.⁴³ These principles include aspects of procedural fairness and the right to a fair trial, and lack of unfairness,⁴⁴ arbitrariness,⁴⁵

³⁵ *Morgentaler*, *supra* note 27; *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519; *Fleming v. Reid*, *supra* note 30.

³⁶ *Morgentaler*, *supra* note 27.

³⁷ P. W. Hogg, *Constitutional Law of Canada*, Loose-leaf ed., (Scarborough: Carswell, 1997) at 44-10.

³⁸ *Morgentaler*, *supra* note 27 at 56, 173; *Re ss. 193 and 195.1 of the Criminal Code*, *supra* note 33 at 1177; *Rodriguez*, *supra* note 35 at 587-88; *Mills v. The Queen*, [1986] 1 S.C.R. 863; *New Brunswick (Minister of Health and Community Services) v. G. (J.)*, [1999] 3 S.C.R. 46 [hereinafter *G. (J.)*] at paras. 58-60; *Blencoe*, *supra* note 27 at para. 55-57.

³⁹ *G. (J.)*, *ibid.* at para. 60.

⁴⁰ *G. (J.)*, *supra* note 38 at 61-62; *Mills v. The Queen*, *supra* note 38 at 919-20; *R. v. Mills*, [1999] 3 S.C.R. 668 at para. 85.

⁴¹ See e.g. G.-A. Beaudoin & E. Mendes, *The Canadian Charter of Rights and Freedoms*, 3rd ed. (Toronto: Carswell, 1995) at 9-17 - 9-18, Hogg, *supra* note 37 at 44-11 - 44-13 and cases cited therein.

⁴² *Blencoe*, *supra* note 27 at para. 74-80.

⁴³ *Re B.C. Motor Vehicles Act*, *supra* note 32 at 503.

⁴⁴ *Morgentaler*, *supra* note 27.

⁴⁵ E.g. *Rodriguez*, *supra* note 35.

vagueness⁴⁶ or overbreadth.⁴⁷ In *Rodriguez*,⁴⁸ a majority of the Supreme Court of Canada held that respect for human dignity, while a principle underlying our society, is not a principle of fundamental justice; however, respect for human life is a principle of fundamental justice. The Supreme Court has also held that protection of a child's right to life and health is a principle of fundamental justice.⁴⁹ The analysis may also involve a substantive balancing of the individual's interests and the interests of society.⁵⁰

The primary focus of this paper is on section 7 of the *Charter*, but other sections may also be relevant, including in particular section 15(1) which protects the right to equality before and under the law and the equal protection and benefit of the law. There is no rigid formula for the analysis of claims under section 15(1), but the Supreme Court of Canada has recently articulated the following guidelines:⁵¹

(A) Does the impugned law (a) draw a formal distinction between the claimant and others on the basis of one or more personal characteristics, or (b) fail to take into account the claimant's already disadvantaged position within Canadian society resulting in substantively differential treatment between the claimant and others on the basis of one or more personal characteristics?

(B) Is the claimant subject to differential treatment based on one or more of the enumerated and analogous grounds?

and

(C) Does the differential treatment discriminate, by imposing a burden upon or withholding a benefit from the claimant in a manner which reflects the stereotypical application of presumed group or personal characteristics, or which otherwise has the effect of perpetuating or promoting the view that the individual is less capable or worthy of recognition or value as a human being or as a member of Canadian society, equally deserving of concern, respect, and consideration?

Some possible claims under section 15(1) will be considered at various points below.⁵²

⁴⁶ E.g. *Re ss. 193 and 195.1 of the Criminal Code*, *supra* note 33.

⁴⁷ *R. v. Heywood*, [1994] 3 S.C.R. 761.

⁴⁸ *Supra* note 35.

⁴⁹ *B.(R.) v. Children's Aid Society of Metropolitan Toronto*, [1995] 1 S.C.R. 315.

⁵⁰ See e.g. *Cunningham v. Canada*, [1993] 2 S.C.R. 143 at 152.

⁵¹ *Law v. Canada (Minister of Employment and Immigration)*, [1999] 1 S.C.R. 497 at para. 88.

⁵² However, since the major focus of this paper, in accordance with its terms of reference, is on section 7, further exploration of the equality issues raised in this context may be required.

C. Patent rights and the *Charter*

As federal legislation, the *Patent Act* is clearly subject to the *Charter*,⁵³ and if it is inconsistent with the *Charter*, is of no force and effect to the extent of that inconsistency.⁵⁴ The act of issuing a patent is also a government action to which the *Charter* would apply. Where a patentee attempts to enforce patent rights against an alleged infringer, the latter could invoke the *Charter* to argue that the patent rights infringe his or her constitutional rights.⁵⁵

In order to identify possible *Charter* violations it is essential to understand the nature of a patent and the rights that are granted to a patent holder. The significance of granting a patent on certain human material cannot be appreciated without knowing what a patent entails and assessing the effect of the patent rights. It might be argued that the mere fact of granting a patent on a human being or certain human material infringes the liberty, security or equality rights of affected individuals, either because of some psychological effect from knowing that one is potentially affected by a patent, or because the existence of a patent means that the law has a differential impact on those individuals. However, any psychological effect – even if it might reach the threshold of serious state-imposed psychological harm required to trigger section 7, which seems somewhat doubtful – can only be fully assessed in terms of what the existence of a patent actually means. Similarly, it would be difficult to determine whether there is any violation of equality rights without understanding the potential impact of a patent.

A patent gives the patentee “the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used.”⁵⁶ In essence this is the right to exclude others from making, using or selling the invention. The patent holder will not necessarily have the right to undertake these activities (they may be subject to regulation or even prohibition by law), but may prevent anyone else from doing so during the term of the patent. A patent is infringed whenever someone interferes with the patentee’s monopoly without consent.⁵⁷ It does not matter whether the infringer intended to infringe the patent or even was unaware of the patent, and the infringer need not have benefited financially from the infringement,⁵⁸ although

⁵³ *Canadian Charter of Rights and Freedoms*, Part I of the *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11, section 32(1)(a).

⁵⁴ *Constitution Act, 1982*, being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11, section 52 (1).

⁵⁵ Although this would be a private action between two private parties, the patentee would be relying on the *Patent Act* in seeking a remedy against an alleged infringer; this situation is therefore distinguishable from the case of *RWDSU v. Dolphin Delivery Ltd.*, [1986] 2 S.C.R. 573, where the party seeking an injunction was relying only on the common law. A court order in itself is not sufficient government action to attract the application of the *Charter* (*ibid.* at para. 36), but where the exercise of government action such as legislation is present and relied upon by one of the parties to produce an infringement of the rights of another, the *Charter* will apply (*ibid.* at para. 37-39).

⁵⁶ *Patent Act*, *supra* note 5, s. 42.

⁵⁷ Fox, *supra* note 10 at 349.

⁵⁸ *Ibid.* at 381-82.

purely private acts with no commercial purpose may not be infringements.⁵⁹ The remedies available against an alleged infringer include damages⁶⁰ and an injunction to prevent the use, manufacture or sale of the subject-matter of the patent.⁶¹

Reproduction as “making” an invention

The advent of patents on living organisms raises the possibility of reproduction as patent infringement. One of the exclusive rights of the patentee is to make the invention. Where the invention is a living organism, it can be made through reproduction. “To breed descendants of a patented transgenic animal without license is as much infringement as would be duplicating a patented laboratory process of inserting transgenes into an embryo. The patent system assimilates reproduction, whether natural or artificially aided, to ‘making’ a duplicate.”⁶² This is crucial to the protection of the patentee’s exclusive rights when the invention concerns a transgenic animal, because if the inventor could patent only the process by which the animals were originally produced, any person who gained possession of the animals could breed them to produce more without requiring a license or paying any compensation to the patentee of the process. The availability of patents on living organisms as products as well as the processes by which they are created is in part designed to provide this protection to the inventor.⁶³

However, when this same logic is applied to humans as inventions as opposed to non-human animals, the possibility of control over reproduction raises human rights concerns. Our society generally accepts that the reproduction of non-human animals may be controlled by humans, but human beings have the right to make reproductive decisions for themselves without interference as part of their personal autonomy, a right which is within the scope protected by section 7 of the *Charter*.⁶⁴ The concern has been raised that the grant of an exclusive right to make an invention

⁵⁹ The *Patent Act*, *supra* note 5, s. 55.2(6) states that its provisions do not “affect any exception to the exclusive property or privilege granted by a patent that exists at law in respect of acts done privately and on a non-commercial scale or for a non-commercial purpose”; however the scope of this exception is not clear. Fox, *supra* note 10 at 382 states that making a patented article even for private use is an infringement, and a patent is infringed even if the infringer gains no benefit, commercial or otherwise, from the article. Of course these factors may affect the remedies available to the patentee, however.

⁶⁰ *Ibid.*, s. 55.

⁶¹ *Ibid.*, s. 57.

⁶² L. M. Guenin, “Norms for Patents Concerning Human and Other Life Forms” (1996) 17 *Theoretical Medicine* 279 at 281. In the Harvard mouse case, Rothstein J. stated: “One might argue this simply involves the natural processes of mouse reproduction. However, such a view ignores the fact that an offspring oncomouse has the artificial oncogene sequence by virtue of its introduction into the genome of the original founder mouse. The offspring oncomouse has a particular genetic trait which would not occur in nature.” *Harvard College*, *supra* note 7 at para. 42.

⁶³ *Harvard College*, *supra* note 7 at para. 93, citing W. Hayhurst, “Exclusive Rights in Relation to Living Things” (1991) 6 *Intellectual Property Journal* 171 at 177.

⁶⁴ *Morgentaler*, *supra* note 27, *E. v. Eve*, *supra* note 31.

could interfere with an individual's reproductive freedom.⁶⁵ It may seem "perverse" to "call human birth or life an 'infringement'"⁶⁶ but a patent on a human being would make this possible, at least in theory.⁶⁷

If, by virtue of a patent, a patentee obtained the right to prevent an individual from reproducing, this would seem clearly to offend the protected right to liberty and security of the person. Imposing this constraint on some individuals likely would offend their equality rights as well, if they could establish a connection to some enumerated or analogous ground. It remains to be determined, then, what types of patents might potentially produce this result. One would be a transgenic human being, by analogy with patents on transgenic non-human animals. If the patent was on the transgenic human as a product, and not just the process, then even natural reproduction could be an infringement. Another would be a germ line genetic intervention in a human. A germ line intervention would be passed down to the recipient's offspring and thus reproduction could constitute an infringement.

Use of the invention

Transgenic non-human animals are designed and produced to be used by humans, in particular for research. It is difficult to conceptualize what "use" would mean in the context of a human being as invention. One commentator has suggested:

A patent holder has the right to exclude others from using his or her invention. But a human being is autonomous; he or she is the only person who can 'use' himself or herself through participation in activities, striving for goals and making contributions to society. The patent holder would be prevented from controlling the altered person's activities by the thirteenth amendment proscription against involuntary servitude. If the patent holder tried to prevent others from interacting with the altered person, he or she would violate the right to freedom of association, which is also constitutionally protected.⁶⁸

Another author has suggested that the exclusive right to use, if applied to human beings, could interfere with an individual's right to earn a livelihood, the right to life, liberty and property in the Fifth Amendment of the U.S. Constitution and the Thirteenth Amendment prohibition on

⁶⁵ See Walker, *supra* note 17 at 110-11; Burk, *supra* note 17 at 1649-50; Fishman, *supra* note 16 at 475; DeBré, *supra* note 16 at 238.

⁶⁶ Guenin, *supra* note 62 at 281.

⁶⁷ Some commentators have argued that the likelihood of such a conflict actually occurring is small, since in most cases the term of the patent would have expired before any affected individuals reached reproductive maturity: DeBré, *supra* note 16 at 238, n. 98; Burk, *supra* note 17 at 1649; Walker, *supra* note 17 at 111. However, this is not necessarily the case. The twenty-year term of a patent allows the possibility of natural human reproduction occurring within the term, not to mention any artificial means which might not rely on reproductive maturity.

⁶⁸ Fishman, *supra* note 16 at 475-76.

slavery and involuntary servitude.⁶⁹

As noted earlier, the idea that no one other than each individual him- or herself can “use” a human being undermines the possibility of patenting a human being as a useful invention. If we accept that a human being could be a patentable invention, it still seems unlikely that the actions of an individual in going about his or her daily life, pursuing goals and associating with other people would fall within the scope of “use” of an invention as intended in the *Patent Act*. To “use” an invention is to put it to use for its intended purpose. If someone wanted to use a patented article for some purpose totally unrelated to the purpose for which it was designed, it is difficult to see what cause the patentee would have to object. If personal activities of a human being were considered to be “use” of the invention, attempts to interfere with the personal decisions of an individual would probably violate the right to liberty. There are some limits to this, however: for example, section 7 does not, as a general rule, protect the right to pursue a certain occupation or profession. Freedom of association is protected in section 2(d) of the *Charter*, but this section has a restricted scope.⁷⁰

If human beings could be patentable inventions, by analogy to transgenic non-human animals, the likely uses for which they might be designed might include research or the provision of organs and tissues for transplant. It is conceivable that a patent holder might want to have a transgenic or genetically modified human participate in research, to test or improve the invention, and that this might fall within the scope of “use” of the invention. Any attempt to compel such participation, however, would run into several legal obstacles. The individual’s right to consent or refuse to participate in medical research is protected by the common law,⁷¹ ethical guidelines,⁷² international human rights law⁷³ and the *Charter*.⁷⁴ A patent holder clearly would not be able to require an individual to participate in research without that individual’s free and informed

⁶⁹ Walker, *supra* note 17 at 111.

⁷⁰ For example, it has not been interpreted to cover personal relationships such as associations between family members: *Catholic Children’s Aid Society of Metropolitan Toronto v. S.(T.)* (1989), 60 D.L.R. (4th) 397 (Ont. C.A.); or restrictions on trade: *Canadian Egg Marketing Agency v. Richardson*, [1998] 3 S.C.R. 157.

⁷¹ Regarding consent generally, see E. Nelson, “The Fundamentals of Consent” in J. Downie & T. Caulfield, *Canadian Health Law and Policy* (Toronto: Butterworths, 1999) 101; regarding consent for research see K. C. Glass, “Research Involving Humans” in Downie & Caulfield, *ibid.*, 375 at 381 ff.

⁷² See e.g. World Medical Association, “Declaration of Helsinki: Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects,” June 1964, 18th World Medical Assembly, online: <http://www.wma.net/e/policy>; Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada & Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, 1998), online: <http://www.nserc.ca/programs/ethics/english/index.htm>.

⁷³ See e.g. ICCPR, *supra* note 21, article 7; *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, 4 April 1997, E.T.S. No. 164, articles 5, 16 (the latter is a regional convention to which Canada is not a party).

⁷⁴ *Fleming v. Reid*, *supra* note 30.

consent. A similar analysis would apply to other medical procedures, including the taking of organs or tissues for transplant or other purposes.

A patent holder might also want to gain information from or about an individual, for research purposes, as part of the “use” of the invention. Personal information such as information about the individual’s health would be subject to the individual’s right to privacy which is protected in international human rights law⁷⁵ and under sections 7 and 8 of the *Charter*.⁷⁶ Any attempt to gain information about an individual without her consent would potentially violate these rights.

The preceding discussion deals with use by the patentee. What is granted by the patent, however, is the right to exclude others from using the invention. The patent holder might also want to prevent an individual from participating in research by a competitor, providing personal information to a competitor or from providing any biological material to a competitor as part of the right of exclusive use. While it is not difficult to conclude that a patentee cannot force an individual to participate in research or to allow tissue or organs to be removed without the individual’s consent, the question of whether the patentee could restrain the individual from engaging in these activities with others is more problematic. The common law and *Charter* rights just discussed do not necessarily include the affirmative right to receive treatment, participate in research, donate or sell biological material or disclose personal information to specific persons. Where participating in research or undertaking some other activity with someone other than the patentee was necessary for the protection of the individual’s life or health, then an attempt to prevent this would likely be an interference with security of the person. It is also possible that attempts to interfere with these actions by an individual would be a violation of the right to liberty which protects fundamental personal decisions. However, the arguments under section 7 are not as clear in this context as in the case of forced participation. The individual could further argue that enforcement of the patentee’s rights in this context would violate the right to equality in section 15(1) of the *Charter*, given that they would impose restrictions on the individual’s activities that are not suffered by others. Freedom of association might also be invoked, although likely with less success given that the scope of s. 2(d) in the *Charter* is quite narrow.⁷⁷

In some instances, patent rights relating to use may be generally unobjectionable but specific means of enforcing these rights give rise to human rights concerns. For example, there might be cases in which the use of a patented invention is related to reproduction and therefore implicates the right to reproductive autonomy. Where a patent concerns a process for some reproductive technology (e.g. human cloning) or intervention relating to an embryo or fetus (e.g. genetic

⁷⁵ E.g. ICCPR, *supra* note 21, article 17.

⁷⁶ See e.g. *R. v. Plant*, [1993] 3 S.C.R. 281; *R. v. Dyment*, [1988] 2 S.C.R. 417; *R. v. O’Connor*, [1995] 4 S.C.R. 411; *R. v. Mills*, [1999] 3 S.C.R. 668. For discussions of the protection of privacy under the *Charter* see M. Marshall & B. von Tigerstrom, “Privacy, Confidentiality and the Regulation of Health Information” in *Canadian Health Law Practice Manual* (Toronto: Butterworths, 2000); B. von Tigerstrom, P. Nugent & V. Cosco, “Alberta’s *Health Information Act* and the *Charter*: A Discussion Paper” *Health Law Review* (forthcoming).

⁷⁷ See *supra* note 70.

therapy, whether somatic cell or germ line) and parents wish to use the process for their child, issues may arise regarding the enforcement of the patentee's exclusive right to use. Generally speaking, the patentee has the right to prevent use unless a license is granted, and parents would have no special immunity. However, there would be limits to how this exclusive right could be enforced, because of the parents' reproductive rights. For example, a patentee could not require a woman to have an abortion to destroy a fetus that had been created or modified by infringing use of a patented invention. It has been suggested that the enforcement of such rights against the individual parents would not be in the patentee's interest, as illustrated in a hypothetical case:

If Mr. And Mrs. Thurston, learning of Medipulate Inc.'s patented technique for germ line manipulation, arrange with their physician for the technique but no one pays the royalty, a damage remedy may lie against the providers. We can scarcely imagine a suit by Mendipulate against Mrs. Thurston, her daughter or granddaughter, or their physicians or hospitals, complaining of the conception of a child, not to mention injunctive relief, i.e., an order for an abortion. Mere pragmatism makes clear that Mendipulate's interests require no remedy against a patient. Drug manufacturers do not sue patients who infringe by "using" an infringing drug. They sue rival manufacturers and distributors who "make" and "sell" it in quantity.⁷⁸

Similarly, an individual who had, incorporated into her body, patented biological material or material made or inserted using a patented process would be "using" the invention, in a sense. Even if this were found to be "use" within the meaning of the *Patent Act*, any attempt to stop this use would probably entail an unacceptable interference with the individual's autonomy and security of the person. However, the health service provider or manufacturer responsible for making or using the invention would be the likely target of an infringement action, not the individual, just as the above analogy to drug manufacturers and patients illustrates. Nevertheless, in certain cases an injunction against the provider might be argued to constitute a violation of an individual's rights, if the denial of access to a product constituted a threat to the individual's health or bodily integrity, for example.

Sale of the invention

Since a human being per se cannot be owned, the exclusive right to sell the invention would simply have no application in the case of a patent on a human being; the patent holder could not legally sell the invention, nor could anyone else. Would the exclusive right to sell other patented material offend any constitutional rights? Sales of tissue and of any body or body parts is prohibited by legislation in Canada.⁷⁹ However, this does not apply to regenerative tissue such as

⁷⁸ Guenin, *supra* note 62 at 304.

⁷⁹ See e.g. *Human Tissue Gift Act*, R.S.A. 1980, c. H-12, s. 10: "No person shall buy, sell or otherwise deal in , directly or indirectly, for a valuable consideration, any tissue for a transplant, or any body or part or parts of it other than blood or a blood constituent, for therapeutic purposes, medical education or scientific research, and any such dealing is invalid as being contrary to public policy." See also e.g.: *Human Tissue Gift Act*, R.S.B.C. 1996, c. 211, s.10; *Human Tissue Act*, R.S.M. 1987, c. H 180, s. 15 (2); *Human Tissue Gift Act*, R.S.O. 1990, c. H-20 (to be renamed *Trillium Gift of Life Network Act*: S.O. 2000, c. 39), s. 10, *Human Tissue Act*, R.S.N.B. 1973, c. H-12, s.

blood or skin, nor does it apply to human gametes.⁸⁰ One author raises the possibility of “the enterprising move of a patient who sells gametes that contain altered genes” that were subject to a patent.⁸¹ It is questionable whether such a sale would fall within the rubric of reproductive autonomy, and thus receive constitutional protection. Likewise, an individual probably possesses no property interest in her own biological material,⁸² and even if she does, property rights generally are not protected by section 7. It is possible, however, that an individual could make an argument that any such restriction would violate her right to equality in section 15. To the extent that individuals who were subject to a patent or contained patented material were restrained by law from selling biological material when others were not, it could be argued that this constitutes differential treatment. It would also have to be established, however, that this differential treatment was on an enumerated or analogous ground, and that it was discriminatory.

Summary

In this section we have identified a few cases where the grant or enforcement of a patentee’s exclusive rights relating to human biological material may violate the rights of individuals. If a human being were patentable, the exclusive right to make or use the invention could interfere with rights to liberty and security of the person or equality. The exclusive right to sell has no effect regarding a sale of a human being per se but might restrict an individual’s ability to sell biological material. It is questionable whether the right to sell such material would be constitutionally protected, however.

There are a few cases in which patent rights on subject matter which is patentable would also lead to potential violations. First, enforcement of patent rights relating to germ line genetic therapy could interfere with reproductive autonomy and equality rights. Second, enforcement of the exclusive right to use processes relating to reproduction or processes for intervention in an embryo or fetus (e.g. genetic therapy) could also interfere with reproductive rights, although in practice this seems unlikely. Finally, where patented biological material has been incorporated into the body of an individual, this individual’s section 7 rights could potentially be affected if a patentee tried to prevent an infringing use. Again, in practice it seems unlikely that a patentee would pursue such a remedy against an individual. This individual might also be restricted from selling biological material.

There are therefore some legitimate concerns, although many of them seem somewhat remote. It should be emphasized, however, that the majority of patents on human materials will not pose any direct threat to individual rights, although they may indirectly raise other significant human rights concerns. Patents on biological material such as isolated genes or proteins would not

8(3); *Human Tissue Gift Act*, R.S.N.S. 1989, c. 215, s. 11; *Human Tissue Act*, R.S.N. 1990, c. H-15, s. 18; *Human Tissue Gift Act*, R.S.Y. 1986, c. 89, s. 10.

⁸⁰ See M. Litman & G. Robertson, “The Common Law Status of Genetic Material” in B. M. Knoppers, T. Caulfield & T. D. Kinsella, *Legal Rights and Human Genetic Material* (Emond Montgomery, 1996) 51 at 53.

⁸¹ Guenin, *supra* note 62 at 305.

⁸² *Moore v. Regents of the University of California*, 249 Cal. Rptr. 494, rev’d in part 271 Cal. Rptr. 146 (1990), cert. denied 111 S.Ct. 1388 (1991).

entail control over any individual human beings in a manner which might infringe their liberty or other rights. The Federal Court of Appeal in the Harvard Mouse decision stated that its comments with respect to patents on human beings entailed “no finding or observation on the patentability of human genes or products or processes at the genetic level. As scientific research advances, these and other related matters will require determination by the Courts or by Parliament.”⁸³ The European Patent Office dealt with a claim that patents on genes and proteins constituted slavery in the *Relaxin* case. As the decision explains:

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 of self-determination as she had before the patent was granted.⁸⁴

In the majority of cases regarding patents on human materials, this will be the case. If no individual human being is directly affected by the patentee’s exclusive rights, there may still be other related human rights concerns (regarding access to benefits from research, for example). However, the grant of a patent in and of itself will not necessarily restrict any individual’s rights.

III. Addressing Human Rights Issues: Options for Consideration

A. Modifying Patent Law to Protect Individuals’ *Charter* Rights

One option for dealing with human rights concerns relating to patenting of human materials is to modify patent law to exclude certain subject matter from patentability, or to modify the operation of rights granted to patent holders in some cases. It is essential to remember that such reforms are not the only measures which may be used to protect human rights; some others will be briefly explored below. However, with respect to the issues we discussed in the previous section, modification of patent law may be of particular interest as an option because there are some cases in which the existence of a patent or the enforcement of patent rights may constitute a direct violation of the rights of certain individuals.

Judicial or legislative modification?

A modification of patent law such as an exclusion could occur either by legislative or by judicial action. A challenge to provisions *Patent Act* could result in a judicial modification of patent law

⁸³ *Harvard College*, *supra* note 7 at paras. 125-28.

⁸⁴ *Howard Florey / Relaxin*, [1995] EPOR 541 at para. 6.3.3. See also *Directive on the legal protection of biotechnological inventions*, Directive 98/44/EC, O.J. L 213, 30/07/1998 p. 0013-0021, [hereinafter *EU Directive*] preamble para. 20: “an invention based on an element isolated from the human body or otherwise produced by means of a technical process, which is susceptible of industrial application, is not excluded from patentability, even where the structure of that element is identical to that of a natural element, given that the rights conferred by the patent do not extend to the human body and its elements in their natural environment.”

or its operation. The sections above discussed several potential violations of *Charter* rights. However, it would remain to be seen in each case whether a court would actually find that a section of the *Charter* had been violated and that it could not be justified under section 1. The analysis will be specific to each case and thus it is not possible to make generalized predictions about the outcome. As a result, there will be a considerable degree of uncertainty if it is left to the judiciary to decide whether the operation of patent law must be modified in some cases. This approach would also impose the burden of bringing and arguing a *Charter* case on affected individuals, and would involve substantial delays, as opposed to the government taking a proactive approach in legislating any changes. In the absence of specific legislative guidance, the Commissioner of Patents has no discretion to refuse a patent when the requirements of the *Patent Act* are satisfied.⁸⁵ The courts have jurisdiction to grant what remedies may be necessary to protect *Charter* rights, but not to undertake any further modifications for policy or other reasons, or with the aim of preventing other potential violations. The Federal Court of Appeal stated in the *Harvard College* decision that questions of policy and public interest should be dealt with by Parliament.⁸⁶ A declaration of invalidity or other judicial remedy may be a blunt instrument as compared to more detailed revisions which may be possible by legislative action. Finally, it is important to remember that some subject matter will be beyond the reach of the *Charter*: for example, an embryo or fetus is not a legal person protected by the *Charter*⁸⁷ and there may be questions regarding the constitutional protection of part-human animals.⁸⁸ Therefore, if we decide that exclusions should extend to these, legislative action would be necessary.

Addressing issues through judicial action on a case-by-case basis has its disadvantages,⁸⁹ but also allows flexibility. It may be very difficult to design a legislative amendment which achieves just the desired result and anticipates all potential problems. The complexity of this area makes it difficult to define and predict when human rights issues may be raised by a patent and what the best means of protection may be. In the following sections, we will explore some of the options

⁸⁵ See *Harvard College*, *supra* note 7 at para. 29.

⁸⁶ *Ibid.* at paras. 30, 92, 117-18.

⁸⁷ *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. In early 2000, the first patent to include within its scope a cloned human embryo was granted by the British patent office. Geron Corporation received patents in January and February, 2000 relating to nuclear transfer methods and products, including human embryos at an early stage of development. Patent No. GB2318578, "Quiescent cell Populations for Nuclear Transfer," issued 19 January 2000; Patent No. GB2331751, "Quiescent cell populations for nuclear transfer," issued 19 January 2000; Patent No. GB2318792, "Unactivated oocytes as cytotblast recipients for nuclear transfer," issued 23 February 2000; Patent No. GB2340493, "Unactivated oocytes as cytotblast recipients for nuclear transfer," issued 23 February 2000. See Geron Corporation, "Geron Announces Granting of Nuclear Transfer Patents," News Release, 21 June 2000, online: www.geron.com.

⁸⁸ See e.g. Fishman, *supra* note 16; von Tigerstrom, *supra* note 2 at 19-20. On the question of defining human beings for the purposes of patent law and a legislative exclusion, see also 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>.

⁸⁹ See also B.M. Knoppers, "Reflections: The Challenge of Biotechnology and Public Policy" (2000) 45 McGill L. J. 559 at 564: a "constitutional" approach to policy development "is both costly and lengthy; furthermore it is *ad hoc* in nature."

and considerations for legislative reform.

Exclusion from patentability or modification of patent rights?

The patent system could be changed to exclude certain subject matter from patentability altogether or to limit the scope of certain patents, or to allow patenting but restrict the enforcement of patent rights, either in general terms or for specific types of patents. In order to choose between these options, we need to precisely identify the source of the problem. In some cases, the nature of the patent and the rights involved may be such that none of the patent rights should be enforceable.⁹⁰ If that is the case it is difficult to see how a valid patent could be granted. In other cases, however, only a certain patent right or even a certain means of enforcing it would be contrary to the *Charter*. In such cases, it may not be necessary or appropriate to exclude subject matter from patentability to avoid conflict with constitutional rights. Modifying the operation of patent holders' rights has the advantage of allowing the measure to be more precisely targeted to potential violations, leaving the patent system otherwise intact. The modification could occur by judicial intervention, or could be introduced by legislative amendment, within the limits of international trade law.⁹¹

Exclusion from patentability

There may be few cases where an exclusion from patentability is required as the only acceptable means of protecting rights. However, exclusions may be proposed to avoid conflicts with individual rights or for other purposes, some of which will be briefly discussed below.

An exclusion may take the form of a provision excluding specific materials from patentability, or a general provision allowing patents to be refused on certain grounds, to be applied on a case by case basis. Examples of specific exclusions include the Australian *Patents Act*, which provides that “[h]uman beings, and the biological processes for their generation, are not patentable inventions”⁹² and proposed legislation in the United States which also would have excluded human beings from patentability.⁹³ One of the U.S. bills also excluded human organs or parts

⁹⁰ For example in the case of patents on human beings: see Fishman, *supra* note 16 at 476; Burk, *supra* note 17 at 1650; Walker, *supra* note 17 at 110.

⁹¹ Both the NAFTA and TRIPS require patent protection to include exclusive rights to make, use, offer for sale or sell a patent product or product obtained directly from a patented process. *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(5); *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 28. They also restrict the issuance of compulsory licenses and require certain remedies to be available to the patentee. See C. Kent, “The Uruguay Round GATT TRIPS Agreement and Chapter 17 of the NAFTA: A New Era in International Patent Protection” (1993) 10 C.I.P.R. 711 at 723-25.

⁹² *Patents Act 1990* (Australia), s. 18.2.

⁹³ *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.

thereof.⁹⁴ Some exclusions merely reaffirm what would be the case by the normal operation of patent law: for example, mere discoveries, human materials in their natural state and human beings are not patentable because they do not meet standard statutory criteria.

The second alternative is exemplified by the European Patent Convention, which provides:

European patents shall not be granted in respect of:

(a) inventions the publication or exploitation of which would be contrary to ‘ordre public’ or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;⁹⁵

The more recent *EU Directive* incorporates both approaches. Article 5(1) provides that “[t]he 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.” The exclusion in article 5(1) also limits the scope of patents, according to article 9: “The protection conferred by a patent on a product containing or consisting of genetic information shall extend to all material, save as provided in article 5(1), in which the product is incorporated and in which the genetic information is contained and performs its function.” Article 6 then provides that “[i]nventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality” and specifies that certain inventions will be considered unpatentable on that basis, including processes for cloning human beings, processes for modifying the germ line genetic identity of human beings and uses of human embryos for industrial or commercial purposes.

In Canadian and U.S. patent law, there is no explicit exclusion based on *ordre public* or morality, although one formerly existed in Canada.⁹⁶ To a limited extent, concerns about morality can be factored into the analysis of whether something is a useful invention.⁹⁷ The proposition, discussed above, that a human being cannot be a patentable invention, can be seen as an example of the application of such an implied exclusion. One could conceive of a practical industrial purpose for a human being, but it is contrary to the legal and ethical norms of our society to create or use a human being for such a purpose.

⁹⁴ *Life Patenting Moratorium Act of 1993, ibid.*

⁹⁵ *European Patent Convention*, 5 October 1973, U.K.T.S. 1978 No. 20, article 53(a). This article was recently amended to read: “inventions the commercial exploitation of which would be contrary to “ordre public” or morality, provided that such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States.” *Act Revising the Convention on the Grant of European Patents*, 29 November 2000, article 18.

⁹⁶ The former section 27(3) of the *Patent Act* excluded inventions for “illicit” objects (repealed by the new s. 27(8) in S.C. 1993, c. 15, s. 31).

⁹⁷ See *Ex parte Murphy*, 200 U.S.P.Q. 801 (PTO Bd. App. 1977), cited in J.-C. Galloux, “La brevabilité du génome humain ou la tension entre le droit des biotechnologies et les bio-droits” in J.-L. Baudouin & S. Le Bris, *Droits de la personne: “Les bio-droits” Aspects nord-américains et européens* (Cowansville, Quebec: Yvon Blais, 1997) 309 at 322; see also B. Looney, “Should Genes be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement” (1994) 26 J. L. Pol’y Int’l Business 231 at 251.

Specific exclusions provide greater certainty, although questions of interpretation will remain⁹⁸ and they must be carefully designed. A general exclusion such as “*ordre public* and morality” is more flexible but therefore more uncertain. It leaves greater discretion to the patent office and the courts to decide when the exclusion should apply, and some question whether patent officials should be making such decisions.⁹⁹ Depending on its interpretation,¹⁰⁰ the “*ordre public* and morality” exception might be adequate. It has been suggested that human rights obligations should be the basis for interpreting this exclusion.¹⁰¹ It might be advisable to make this approach explicit in any legislative exclusion, or to draft the exclusion to more precisely address human rights concerns. Relying on implied exclusions on the basis of morality as part of the definition of an invention is the least desirable option since it provides little clarity or certainty, and a limited scope.

In the design of any exclusions, however, the restrictions of international trade law in the area of intellectual property must be taken into account. The NAFTA and TRIPS agreements specifically permit exclusions to protect *ordre public* and morality.¹⁰² Exclusions are also allowed to protect human or animal life, and it could be argued that this should extend to protection of human rights, at least security of the person. States are also permitted to exclude plants and animals, other than micro-organisms, and essentially biological processes for their production.¹⁰³ Otherwise, states are required to provide patent protection in all fields of technology.¹⁰⁴

B. Options for Addressing Other Human Rights Issues

This paper has focussed on cases in which the grant and enforcement of a patent may directly violate the *Charter* rights of some individual. As noted earlier, there are many other kinds of

⁹⁸ For example, where a “human being” is excluded, it must be determined what this should include. See e.g. IP Australia, *Australian Patent Office Manual of Practice and Procedure* (IP Australia, 1999), online: <http://www.ipaustralia.gov.au/patents/Manual>, at para. 8.5.1. See also the sources cited *supra* note 75 regarding the definition of human beings.

⁹⁹ B. Yorke, “Which Rules of Patenting are Acceptable from the Point of View of Industry?” in F. Vogel & R. Grunwald, eds., *Patenting of Human Genes and Living Organisms* (Berlin: Springer, 1994) 197 at 197-98.

¹⁰⁰ The interpretation of this exception in the European context is not settled: Galloux, *supra* note 97 at 323. It has been used as the basis for a broad “cost-benefit” analysis: see *Harvard / Onco-mouse*, [1990] EPOR 4, at para. 5; another view, exemplified in the *Relaxin* decision, suggests that it should only be applied in “rare and extreme cases” where the invention “would universally be regarded as outrageous”: *Howard Florey / Relaxin*, *supra* note 84 at para. 6.2.1. See also F.-K. Beier & R. Moufang, “Patentability of Human Genes and Living Organisms: Principles of a Possible International Understanding” in Vogel & Grunwald, *ibid.*, 205 at 214.

¹⁰¹ R. Ford, “The Morality of Biotech Patents: Differing Legal Obligations in Europe?” (1997) 6 E.I.P.R. 315.

¹⁰² NAFTA, *supra* note 91, article 1709(2); TRIPS, *supra* note 91, article 27(2).

¹⁰³ NAFTA, *supra* note 91, article 1709(3); TRIPS, *supra* note 91, article 27(3).

¹⁰⁴ NAFTA, *supra* note 91, article 1709(1); TRIPS, *supra* note 91, article 27(1).

human rights concerns relating to the patenting of human materials. Exclusions and other modifications of patent law have been proposed to address some of these concerns as well. However, the nature of these concerns may require different options. A full exploration of these options is beyond the scope of this paper, however this section will outline some avenues for further consideration.

Exclusions

Earlier we discussed the possibility of excluding certain subject matter from patentability where the grant or enforcement of a patent could entail violations of individual rights. Some have suggested an even broader use of exclusions, for example to remove the incentive for certain technologies which society may want to discourage because of ethical or safety concerns. However, there is no guarantee that removing the prospect of a patent will prevent people from developing certain types of inventions, and removing patent protection may actually make it more difficult to control use and commercialization of inventions.¹⁰⁵ Other forms of regulation may be more appropriate.

Exclusion of certain materials and processes from patent protection has also been suggested as means of ensuring access to essential materials for research. If basic research tools are patented, it may be expensive or even impossible for others to use them; furthermore, the prospect of patents may deter the sharing of information which allows research to advance. This is a human rights concern because it could lead to individuals being deprived of the benefits of research in violation of their rights to health and to benefit from scientific progress and its applications.¹⁰⁶ These concerns are most often raised within the context of patenting human genetic material.¹⁰⁷

Other modifications to patent law

“Compulsory licensing on basic research tools would prevent monopolization of early-stage technologies ... The patent holder still receives most of the advantage from having the patent – a commercial return – but cannot use the patent to block further research and development.”¹⁰⁸

¹⁰⁵ E. R. Gold, “Biomedical Patents and Ethics: A Canadian Solution” (2000) 45 McGill L.J. 413 at 420.

¹⁰⁶ *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, Can. T.S. 1976 No. 46, 993 U.N.T.S. 3 [hereinafter ICESCR], articles 12, 15(1)(b). UDHR, *supra* note 21, articles 25(1), 27(2). For a discussion of these issues, see von Tigerstrom, *supra* note 2 at 9-11 and the sources cited therein.

¹⁰⁷ There has been a great deal of writing on this subject which will not be reviewed in detail here. See e.g. Looney, *supra* note 97 at 243-46; M. A. Heller & R. S. Eisenberg, “Can Patents Deter Innovation? The Anticommons in Biomedical Research” (1998) 280 Science 698; 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 65-66 [hereinafter “Making Room”]; D. Keays, “Patenting DNA and Amino Acid Sequences – An Australian Perspective” (1999) 7 Health L. J. 69 at 73-74. The Human Genome Organization has made a number of statements regarding these concerns, including “HUGO Statement on the Patenting of DNA Sequences,” January 1995, online: <http://www.gene.ucl.ac.uk/hugo/patent>; and more recently “HUGO Statement on the Patenting of DNA sequences: In Particular Response to the European Biotechnology Directive,” April 2000, online: <http://www.gene.ucl.ac.uk/hugo/patent2000.html>, focussing on expressed sequence tags (ESTs).

¹⁰⁸ “Making Room,” *ibid.* at 72.

The question of access to materials and processes for research could also be dealt with by means of a broader research exemption, which would protect researchers from infringement actions.¹⁰⁹ Another alternative is to restrict the term of a patent.¹¹⁰ These approaches have the advantage of minimal interference with the patent system, however, any such modifications of patent law would have to take into account international trade law on intellectual property protection, or would require international negotiations to the extent that they conflict with existing law.

Another option for consideration is the integration of protections for human rights into the patent system. For example, the rights of research subjects are a particular concern when we are dealing with human materials. There are existing mechanisms in the law and ethical guidelines to ensure that researchers obtain the informed and voluntary consent of individual research subjects.¹¹¹ Compliance with these standards could be required as a precondition of a successful patent application. The *EU Directive* provides in its preamble: “if an invention is based on biological material of human origin or if it uses such material, where a patent application is filed, the person from whose body the material is taken must have had an opportunity of expressing free and informed consent thereto, in accordance with national law.”¹¹² As part of the preamble, this paragraph is not legally enforceable, but it provides a model for a provision that could be made binding. If the practical details of such a requirement could be worked out – what evidence of consent is required, for instance – there is no reason in principle why such a proposal could not be adopted. However, these concerns might better be dealt with through the development of enforcement mechanisms for the rights of research subjects, and of specific norms regarding research leading to patented inventions.

Alternatives or supplements to the patent system

Whereas the previous options would work within the patent system, other proposals would operate as supplements or alternatives to patenting. Richard Gold has suggested that an alternative statutory scheme for some human biological materials would allow consideration of non-economic values.¹¹³ These could include a variety of human rights issues, such as equitable

¹⁰⁹ There is an exemption for experimental use at common law, but it traditionally covered only experiments for purely “philosophical” motives or for amusement, and with no commercial purpose. The *Patent Act* 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 “Making Room”, *ibid.* at 71; 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.

¹¹⁰ “Making Room,” *ibid.* at 72.

¹¹¹ See *supra* notes 71-74 and accompanying text.

¹¹² *Supra* note 84, preamble, para. 26.

¹¹³ “Making Room,” *supra* note 107 at 75-76. For a further discussion and assessment of this proposal, see “Biomedical Patents and Ethics: A Canadian Solution,” *supra* note 105 at 421-26.

access to benefits. There have also been proposals for similar schemes at the international level, for example the “Human Genome Trust” which would hold gene sequences in trust and administer a licensing scheme instead of allowing genes to be patented.¹¹⁴ Such schemes could help to alleviate problems regarding impediments to research and equitable distribution of benefit. However, they contemplate exclusive control (in the hands of a board rather than a single corporate or individual patent holder), and thus could potentially entail the same kinds of intrusions into individual liberty, security and equality as are discussed above, in certain cases. It would be essential to integrate protection for individual rights into any such scheme.

Concern for equitable sharing of benefits has led to other proposals. Rules for sharing benefits with research subjects or relevant communities could supplement the patent system to ensure equitable distribution of benefits.¹¹⁵ Others have suggested that the “common heritage” principle be applied to human material (in particular the human genome) so that all human beings will benefit equitably from genetic research.¹¹⁶ These could operate as alternatives to the patent system, or as a means of managing patent rights in certain materials.

Other legislation/regulation

Some of the human rights issues identified can be addressed through statutory or regulatory measures independent of the patent system. As previously discussed, there are legal and ethical rules for the protection of research subjects, which operate regardless of whether patentable material is at issue but could incorporate specific standards to deal with patenting issues. Similarly, we should explore the application and development of legal and ethical norms for the protection of privacy in the context of patenting human materials.

The protection of human rights in this and other contexts would be strengthened by the full implementation of international human rights law commitments in Canadian law. In particular, the area of economic, social and cultural rights, including the right to health and to benefit from scientific progress, has traditionally been neglected particularly in terms of providing judicial or other effective remedies.¹¹⁷ Since these are important areas of concern in relation to patenting

¹¹⁴ Looney, *supra* note 97 at 269-71; see also Keays, *supra* note 107 at 87.

¹¹⁵ See HUGO Ethics Committee, “Statement on Benefit-Sharing,” 9 April 2000, online: <http://www.gene.ucl.ac.uk/hugo/benefit.html>; B. M. Knoppers, “Status, sale and patenting of human genetic material: an international survey” (1999) 22 *Nature Genetics* 23 at 24.

¹¹⁶ B. M. Knoppers, *Human Dignity and Genetic Heritage* (Ottawa: Law Reform Commission of Canada, 1991) at 18-20; B. M. Knoppers, “Sovereignty and Sharing” in Caulfield & Williams-Jones, *supra* note 107, 1 at 3, 9-10; Keays, *supra* note 107 at 88.

¹¹⁷ States parties to the ICESCR undertake to take steps “by all appropriate means, including particularly the adoption of legislative means” to achieve the realization of the rights in the Covenant (*supra* note 106, article 2(1)). A variety of effective measures may be required, but the provision of judicial or other effective remedies is considered essential: see e.g. Committee on Economic, Social and Cultural Rights, *CESCR General Comment 9: The domestic application of the Covenant*, 19th Sess. (1998), UN Doc. E/C.12/1998/24 at paras. 2, 3, 9; 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. 59; *The Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights*, UN Doc. E/CN.4/1987/17, Annex, reprinted in

human materials, further means of implementing these rights in Canadian law should be explored to provide greater protection.

Finally, we could explore development of specific legal instruments at the national and international level to deal with the particular issues raised in the area of patenting human materials, or a larger set of issues in biotechnology. The UNESCO *Universal Declaration on the Human Genome and Human Rights*¹¹⁸ and the European *Convention on Human Rights and Biomedicine*¹¹⁹ could be used as models. More specific provisions relating to patenting and human rights would need to be developed. The Biomedicine Convention allows for the adoption of protocols dealing with specific topics,¹²⁰ a structure which lends itself well to complex subject matter.

IV. Conclusions and recommendations

The prospect of patenting a human being raises the most serious human rights concerns. Human beings are likely not patentable in any case. However, it may be advisable to exclude human beings from patentability. Currently the Patent Office has no authority to refuse a patent because of concerns about potential human rights implications, and although some internal limits can be implied in the definition of a patentable invention, this may not offer sufficient certainty or clarity. A legislative amendment could incorporate a text similar to the *EU Directive*, which contains a general exclusion for the protection of *ordre public* and morality as well as specific exclusions, which here would include human beings. Particular attention will need to be paid to the definition of human beings and the scope of the exclusion. *Ordre public* and morality should be interpreted to encompass the protection of human rights; if not, then alternative wording which specifically refers to human rights should be developed.

Alternatively, we could rely on the courts or legislative action to prevent patentees from exercising specific patent rights that would violate the liberty, security of the person or equality of individuals. This latter approach may be preferable for other types of human materials and related processes, where allowing patenting does not necessarily entail a conflict with human rights but the enforcement of patent rights in certain circumstances could lead to human rights

(1987) 9 Hum. Rts. Q. 122 at para. 19. The Committee on Economic, Social and Cultural Rights has urged the Government of Canada to take steps to ensure that Covenant rights are enforceable: Committee on Economic, Social and Cultural Rights, *Concluding Observations of the Committee on Economic, Social and Cultural Rights: Canada*, 19th Sess., UN Doc. E/C.12/1/Add.31, para. 52.

¹¹⁸ *Universal Declaration on the Human Genome and Human Rights*, UNESCO Gen. Conf., 29th Sess., 29 C/Resolution 19 (1997).

¹¹⁹ *Supra* note 73. This Convention does not deal specifically with patenting, although it contains a general provision in article 21 stating that “[t]he human body and its parts shall not, as such, give rise to financial gain.” It is an example of an attempt to deal with human rights issues in the context of medical treatment and research in a specific regional instrument.

¹²⁰ The first, dealing with human cloning, was concluded in 1998: *Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings*, 12 January 1998, E.T.S. No. 168.

violations.

A broader range of measures will be required to address other human rights concerns, including those relating the equitable distribution of benefits from research and resulting patents. Measures requiring further consideration may include modifications to the patent system, but also the development of other regulatory mechanisms at a national and international level.