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A BRAVE NEW WORLD:

Where Biotechnology and Human Rights Intersect

Chapter 6

Human Rights and Patenting

Canada

A Brave New World: Where Biotechnology and Human Rights Intersect

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Chapter 6

Table of Contents

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Human Rights and Patenting

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6.1 Introduction

I should not like — under such circumstances, to be what I may call dispersed, a part of me here and a part of me there, but should wish to collect myself like a genteel person.[1]

A patent is a grant of monopoly rights by the state to the inventor (patentee) that allows him or her to capitalize on an invention by excluding others from making, using, selling or importing it for a limited period of time.[2] In exchange for this right, the patentee must publicly disclose a full description of the invention.

Patented inventions composed of non-living materials, such as wood or metal, rarely raise controversy with respect to subject matter. Beginning, however, in the 1980s, patent applications and grants over living materials, such as micro-organisms and human biological materials, began to attract attention and to raise ethical, moral and legal concerns.

More recently, advances in biotechnology and the completion of the Human Genome Project ("HGP") have combined to produce a dramatic rise in the number of patents issued over human materials, including human deoxyribonucleic acid ("DNA") sequences (genes). During the last decade, individuals and organizations began to voice concerns with the notion that human materials could be the subject of property rights that reside with a single owner (often a large corporation).[3]

This chapter examines the question of whether the issuing of patents in the area of biotechnology raises any human rights issues. It includes a discussion of property rights in the body and excised bodily materials, including a discussion of the common law and legislation. The chapter includes three hypothetical scenarios under which the issue of patenting and human rights is analyzed and discussed. It begins with a background section which provides a general discussion of patents and briefly explains the science and technology involved in the research and patenting of human bodily materials, including genes.

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6.2 Background

Patents

The state regulation of inventions through patents has a long and rather obscure history. Despite the uncertain origins, patents are considered to be the oldest form of intellectual property.[4] Some individuals believe that the

1 Charles Dickens, *Our Mutual Friend* (London: Penguin, 15th ed., 1984) at 127; Michelle Bourianoff, "Personalizing Personality: Toward a Property Right in Human Bodies" (1990) 69 Tex. L. Rev. 209.

2 David Young et al., *Terrell on The Law of Patents*, 14th ed. (London: Sweet & Maxwell, 1994) at 1.

3 Nuffield Council on Bioethics, *The ethics of patenting DNA: a discussion paper* (Nuffield Council on Bioethics: London, 2002) at 5.

4 The Australian Law Reform Commission, *Intellectual Property Rights Over Genetic Materials and Genetic and Related Technologies* (Canberra: Department of Communications, Information Technology and the Arts, 2004) at 41.

issuing of patents began with a 1474 Venetian decree.[5] The British patent system can trace its roots to the "Monopoly System" begun during the reign of Queen Elizabeth I.[6]

In Canada, a statutorily based patent regime existed prior to Confederation in both Upper and Lower Canada. Canada's *Constitution Act, 1867* assigned exclusive legislative authority over patents to the federal Parliament.[7] Today, Canadian patents are granted by the Patent Commissioner in accordance with the *Patent Act* for any "new, useful, and unobvious… machines, products, processes, or improvements to existing technology."[8]

Each country grants patent rights according to its own rules or scheme enacted in its domestic legislation.[9] The World Intellectual Property Organization ("WIPO") works to promote the respect, use and protection of forms of intellectual property, such as patents. WIPO is an international organization that falls under the auspices of the United Nations. One of its objectives is to ensure administrative cooperation among the Member States. In addition, international trade organizations, such as the World Trade Organization ("WTO"), have attempted to introduce some common international rules through the TRIPS Agreement regarding intellectual property that must be adhered to by Member States.

It is important to emphasize that a patent does not give the patentee an automatic right to make, use, sell, or import an invention. Other domestic legislation may require approval of the invention before it may enter the marketplace. A patent grants to the patentee the right to exclude others from doing so.[10] It could be viewed as a reward by society for the inventor's inventiveness: it could be characterized as a "carefully crafted bargain" or social agreement between the inventor and society.[11] A patent regime arguably serves the public good by encouraging the invention and distribution of inventions, as well as the disclosure and furtherance of knowledge, in exchange for the patentee's right to exclude others from using, making, selling or importing the invention for a limited period of time, usually 20 years.[12]

Biotechnology and Patents

In the past, biochemical processes and methods of agriculture were generally refused patent protection because they were considered mere discoveries. However, the marriage of biology and technology produced methods or processes that were so different from what was considered "natural" that the courts began to uphold patents over them in the 1960s and 70s.[13]

Today, there are patent applications for entire animals, such as the Harvard oncomouse, entire plants, genes incorporated into either, as well as parts of the human body, which raise novel concerns. The continuing expansion of the biotechnology industry and the subsequent development of new products, using biological processes or living organisms, raise questions as to whether certain products or processes can or should be the subject-matter of a patent.

Critics of patents over human materials argue that instead of increasing knowledge and research in society, they often result in a negative impact on research, especially patents issued for human genes and cells. In their view, patents over extracted human materials may block the access of researchers to information and research materials, and thus impede research. Other commentators, however, point out that the concern with withholding new knowledge from society is not unique to patenting but also occurs when corporations protect their research and inventions by labelling them as "trade secrets."

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5 David Vaver, *Intellectual Property Law: Copyrights, Patents and Trade-Marks* (Concord, Ontario: Irwin Law, 1997) at 1.

6 Young, *supra* note 2, at 2.

7 *Constitution Act, 1867*. 30 & 31 Victoria, c. 3. (U.K.), s. 91(22).

8 Vaver, *supra* note 5, at 113.

9 Each country issues patent rights that are only valid in that jurisdiction. For example, a Canadian patent would not apply to activity in the United States.

10 Sheldon W. Halpern, Craig Allen Nard and Kenneth L Port, *Fundamentals of United States Intellectual Property Law: Copyright, Patent, and Trademark* (The Hague: Kluwer Law International, 1999) at 252.

11 *Bonito Boats*, 489 U.S. at 149 (United States Supreme Court); Cynthia Ho, "Who Deserves the Patent Pot of Gold?: An Inquiry into the Proper Inventorship of Patient-Based Discoveries" (2002) Hous. J. Health L. & Pol'y 107, at 113.

12 E.R. Gold & T. A. Caulfield, "Human Genetic Inventions, Patenting and Human Rights" (Edmonton, Alberta, Health Law Institute, 2003) at 26.

13 Young, *supra* note 2 at 22-3.

A secondary concern is that the results of new research may be kept secret for an extended period of time while the researcher perfects the invention to a stage of development that ensures the grant of a patent.[14] One could argue, however, that such secrecy is necessary in order for the inventor to be granted a patent, i.e., it is a requirement under the *Patent Act* that the invention be "new." In addition, there is evidence that university-business joint ventures result in secrecy in university laboratories.[15] Some of these critics are scientists who consider that information regarding the human genome is communal property that should be freely available to other scientists and the public.[16] This concern has been dubbed the "tragedy of the anti-commons" by commentators.[17]

Others point out, however, that patents stimulate invention and promote the disclosure of inventions and thus knowledge, which in turn enables other inventors to learn about them and to develop improvements on the original invention, as well as alternatives. The U.K.'s Nuffield Council on Bioethics[18] described the benefits of patents as follows:

> … [patents represent] one of the most important incentives for commercial enterprises to undertake research and development, by allowing them to enjoy returns on the generation and application of knowledge. The patent system provides an incentive to invest in the production and application of knowledge by allocating benefits directly to those companies making the investments, and because it grants property rights which recognise an inventor's exclusive right to prevent others, for a fixed term, from making, using or selling an invention based on that knowledge without licence. By contrast, the inability or failure of companies to prevent others from making use of the new developments they generate is an established cause of the failure of commercial enterprises… Moreover, because patents facilitate the dissemination of knowledge, they also serve to prevent costly and wasteful duplication of the efforts of researchers.[19]

The Science

In order to fully understand the complex legal and ethical issues raised by patenting human materials, it is important to have a basic understanding of the science involved. This section briefly describes the patenting of human genes, and other human materials, such as cells, as inventions or as part of a patented process.

The term "biotechnology" was coined in 1919 to refer to the science and the methods that permit products to be produced from new materials with the aid of living organisms.[20] Common examples of early biotechnology are the use of living micro-organisms to catalyze chemical reactions to produce certain foods, such as bread and cheese, and the propagation of plants through grafting.[21] Modern or second-generation biotechnology began with Watson and Crick's 1953 discovery of the structure of DNA, the genetic material occurring in living organisms.[22] This discovery heralded a new age of research in which scientists laboured to discover how DNA functioned and how differences in DNA resulted in differences between individuals.[23]

Modern biotechnology is, for the most part, based on molecular biology and operates at the cellular and molecular levels.[24] Scientists are able to exchange genetic information between mircro-organisms, plants, and animals, including humans. In practical terms, genetic modification or engineering has resulted in products that were once only available from natural sources in limited

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14 ALRC, *supra* note 4 at 63.

15 Ned Hettinger, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics" (1995) 22 B.C. Envtl. Aff. L. Rev. 267, at 294.

16 J. Donahue, *Patenting of Human DNA Sequences — Implications for Prenatal Genetic Testing*, 36 Brandeis J. Fam. L, 1997-98, at 274.

17 E. R. Gold and T. A Caulfield, *supra* note 12, at 30.

18 Nuffield Council on Bioethics, *supra* note 3.

19 *Ibid.* at 13.

20 Tara Snell and Réal Doutre, *Biotechnology: A Reference Guide for Department of Justice Practitioners* (Ottawa: Department of Justice, 2003) at 1 citing B. Sheridan, *EU Biotechnology Law & Practice* (Isle of Wight: Palladian Law Publishing Ltd., 2001) at 3.

21 P. Reimer and B. Schwartz, "Biotechnology: A Canadian Perspective" (2001) 1 Asper Rev. of Int'l Bus. And Trade Law, para. 2, online: QL (JOUR). Ned Hettinger, "Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics" (1995) 22 B.C. Envtl. Aff. L. Rev. 267 at 274.

22 Nuffield Council on Bioethics, *supra* note 3, at 3.

23 *Ibid.*

24 Modern biotechnology began with the Cohen/Boyer Patent. It was the first process/technique for creating a transgenic involving recombinant DNA using plasmids in bacteria. Enzymes were used to insert a synthetic gene into plasmid. The bacteria had in the past had been used to incorporate its DNA into the plant. Now, however, the plasmid transferred the synthetic gene into the plant.

amounts being manufactured in large amounts at low costs. Insulin and human growth hormone are two examples of such products.[25]

Human Genes

A gene is the functional and physical unit of heredity passed from parent to offspring. Genes are units within the nucleus of a cell that are made up of deoxyribonucleic acid, more commonly known as DNA. Within the cell's nucleus, genes are organized into chromosomes, of which humans inherit a set of 23 from each parent for a total of 46 chromosomes. In interaction with the environment, chromosomes determine a person's physical and to some extent, behavioural characteristics.[26]

The Human Genome Project (the "HGP") begun in 1990 could be considered an indication of the thriving state of genetic research.[27] The intent of the project was to co-ordinate international research to identify and map all the genes in the human DNA, and to order the chemical base pairs that make up human DNA. Research was jointly undertaken by two communities of researchers: those in publicly funded bodies, such as universities and research institutes, and those working in privately funded industrial organizations, such as Celera.[28] The international consortium was led by Dr. Francis Collins of the United States ("U.S.") National Human Genome Research Institute.[29]

In 2001, two versions of the draft map of the human genome were published by the two research communities, with the data from the publicly funded research being incorporated into the results from the privately funded version. The publicly funded research had been conducted in the context of a strong commitment to the public sharing of, and access to, the data.[30] The final sequencing of the human genome was completed in April 2003. The sequence data produced by the HGP was deposited into public gene banks, while Celera and other private organizations, sought patent protection over the sequences they identified.[31]

In 2003, the human genome was estimated to be composed of approximately 30,000 protein-coding genes, and a myriad of other functional elements, such as non-protein-coding genes.[32] More recently, the International Human Genome Sequencing Consortium (made up of several pharmaceutical companies) has announced that the human genome only contains between 20-25,000 protein-coding genes. This is a far cry from the original estimate of 100,000 human protein-coding genes.[33]

The HGP resulted in an enormous increase in the knowledge and understanding of the human genome and it pushed the issue of gene patenting to the forefront of research, medicine and society. The draft of the human genome, released in 2001, allowed researchers to identify genes associated with a number of genetic based disorders and diseases. To date, over 30 genes have been pinpointed and linked to diseases such as breast, skin and colon cancer, muscle disease and Alzheimer's disease.[34]

It is interesting to note that the mapping of the human, mouse and chimp genomes have revealed that 40 to 80 per cent of the human genome is shared with the mouse,[35] while 99 per cent is shared with the chimpanzee.[36] One could argue that the human genome is not just the common heritage of humans but rather significant portions of it are

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25 Tara Snell and Réal Doutre, *supra* note 20, at 2-3, citing William P. Cunnigham et al., eds., *Environmental Encyclopedia*, First ed. (Detroit, U.S.A.: Gale Research Inc., 1994) at 99.

26 Government of Ontario, "Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare" Draft Report to the Provinces and Territories, (Toronto, 2002) at 13 [hereinafter *Charting New Territory*].

27 K. Davies, "Cracking the Genome: Inside the Race to Unlock Human DNA" (2001) at 3.

28 Nuffield Council on Bioethics, *supra* note 3, at 3.

29 ALRC, *supra* note 14, at 47.

30 Nuffield Council on Bioethics, *supra* note 3, at 3. The public sector research published the sequence in Nature (Feb. 15, 2001), while the private sector project undertaken by Celera Inc., a United States genomics company, was published in Science (Feb. 16, 2001).

31 ALRC, *supra* note 14, at 47-8.

32 Francis s. Collins, et al. (on behalf of the US National Human Genome Research Institute), "A vision for the future of genomics research: a blueprint for the genomic era" (Nature/Vol. 422/24 April 2003) at 3. Online: http://www.nature.com/nature. accessed August 2004.

33 Nature, 21 October 2004, Online: Human genome: End of the beginning, Nature 431, 915-16.

34 *Charting New Territory, supra* note 26, at 15.

35 Elizabeth Pennisi, "Sequence Tells Mouse, Human Genome Secrets" *Science Online*, Volume 298, Number 5600 (6 December 2002) p. 1863-65. Online: http//cmbi.bjmu.edu.cn/news/0212/26.htm. Accessed 28 April 2005; NIH/National Human Genome Research Institute, "The mouse genome and the measure of man" (4 December 2002). Online: http//cmbi.bjmu.edu.cn/news/0212/26.htm. Accessed 28 April 2005.

36 Cornell News, "DNA analysis for chimpanzees and humans reveals striking differences in genes for smell, metabolism and hearing" (18 December 2003). Online: http//www.news.cornell.edu/releases/Dec03/chimp.life.hrs.html. Accessed: 28 April 2005. Newswise, "Lifestyle Accounts for Differences in Chimp, Human Genome" (18 December 2003). Online: http//www.newswise.com/articles/view/502544. Accessed: 28 April 2005.

also the heritage of other species. This knowledge may also diminish the notion that the human genome is unique and/or sacrosanct.

The raw materials of nature are not patentable since they are discoveries rather than inventions. For the same reason, scientific knowledge about a naturally occurring phenomenon is not eligible for patenting: it is viewed as a mere discovery. Consequently, scientific knowledge about genetic information encoded in some naturally occurring phenomenon is not eligible for patenting and thus the gene and its information inside a human body could not be the subject matter of a patent. However, an artificial phenomenon that does not occur naturally, such as a molecule that has been isolated, identified and cloned, that encodes human genetic information may be patentable.[37]

The distinction between the invention and the discovery of a naturally occurring substance was aptly described by Richard Gold and Timothy A. Caulfield in their paper "Human Genetic Inventions, Patenting and Human Rights."[38] The authors state:

> A DNA sequence, as it exists in a human body, is not an invention. Its occurrence in that body is completely natural and is not due to a technical intervention. That sequence is not, therefore, patentable. *However, this does not mean that the same DNA sequence could not be patented in a different context.* Consider for example, the same DNA sequence extracted from its native cell and placed in a test-tube. *The sequence in that particular form owes its existence to human intervention. It is thus patentable* [as long as it meets the other criterion in the Act], The patent holder only has, in this case, the right to prevent others from making, using, selling or importing the DNA sequence in this isolated form; *the patent holder has no rights against anyone making use of the DNA sequence in its natural human host.* Nevertheless, should the person with the DNA sequence decide to have a genetic test — which involves removing that DNA sequence from its natural environment and placing it in a test-tube — that person would violate the patent.[39] [emphasis added]

One way to obtain the genetic information contained in a DNA sequence requires the use of cloning techniques. Cell samples are collected and scientists apply enzymes to break the cell apart and to separate the DNA from other chemicals in the cell. Once the DNA is removed, other enzymes are used to break the long DNA molecule into shorter sequences, such as genes, gene fragments, or genetic markers. Chemicals or electrical methods are then used to separate the pieces of DNA into strands of different lengths. These shorter sequences are taken up by vectors and transferred into bacteria which subsequently make copies of these DNA sequences. The cloned DNA is removed from the bacteria and a process known as polymerase chain reaction is used to make thousands of purified copies of the DNA.[40]

Much of the debate surrounding the patentability of human DNA sequences has centered on whether or not they are a discovery of something already existing in nature or whether they can be considered an invention. In patenting terms, the scientific knowledge concerning the genetic information has been discovered through the creation of an artificial molecule. Patent offices around the world have concluded that the genetic information is essentially part of an invention, a molecule which is human handiwork and thus patentable.[41]

This process of isolating and cloning has been the basis for granting patents over DNA sequences in the past. However, the use of computational techniques (relying on computers) to identify DNA sequences of genes is fast replacing the laboratory cloning method described above, and may in the not too distant future call into the question the eligibility for patenting of DNA sequences because of the lack of inventiveness in the computational technique.[42]

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37 Nuffield Council on Bioethics, *supra* note 3, at 27.

38 Gold and Caulfield, *supra* note 12.

39 *Ibid*, at 22-23.

40 D. Resnik, "DNA Patents and Human Dignity" (2001) 29 J.L. Med. & Ethics 152 at 154.

41 Nuffield Council on Bioethics, *supra* note 3, at 27-8.

42 *Ibid.* at 28. The *in silico* approach or technique to identifying DNA sequences is unlikely to provide the grounds for eligibility for patenting in Europe as it does not involve any laboratory work. It relies on the fact that the human DNA sequence is now available from a personal computer. The researcher simply matches an unknown human DNA sequence to a homologous, or similar, gene sequence in an animal genome where the function may already be known. The researcher then files a patent application on the human DNA sequence, in the context of a diagnostic or therapeutic use, based on the similarity of function. Although this process may not meet the test used by the European Patent Office, it will likely meet the lower threshold of inventiveness used by the United States Patent and Trademark Office.

In order to receive a patent on an invention, it must be new, non-obvious and useful. Patents on isolated gene sequences and their associated proteins have been granted since the 1980s on the basis that the protein might be a useful therapeutic at some point.[43] The patent granted the "inventor" a monopoly over the "isolated sequences, the purified protein, various vectors used to transform production organisms with the relevant sequence, and the transgenic organisms used to produce large quantities of the protein."[44] Patent law theory allowed these materials to qualify as inventions since none had previously existed in nature in their isolated or purified form (additionally, the transgenic production organisms were novel). The scope of such a patent is broad enough to allow a pharmaceutical company to bring to market (after clinical trials and research) a drug or other product based on the therapeutic protein. [45]

The scope of what is patentable continues to expand in many jurisdictions, especially the U.S. For example, patents have now been granted on partial gene sequences that might be useful in identifying a gene, and on genes that are no longer identified through protein production but through computer analysis. In 2001, the U.S. Patent and Trademark Office ("PTO") issued Utility Examination Guidelines[46] which provided standards regarding the amount of knowledge one must have about the biological significance of a sequence before it can be patented.[47] However, this has not stopped patenting from expanding further still. The U.S. now issues patents on protein co-ordinates. These patents are monopolies over the use of the measured co-ordinates in computer programs to attempt to model the interaction of the protein with other chemicals that might be candidates for therapeutics. In addition, patents have been issued in the U.S. on diagnostic sequences, including single nucleotide polymorphisms ("SNPs")[48] and expressed sequence tags ("ESTS").

Scientists working on the HGP produced and published a map of 1.42 million SNPs. SNPs are sites in the genome at which single nucleotide bases differ from person to person and appear to occur at a frequency of approximately 1 per 1900 bases.[49] Variations in DNA sequence can have a major impact on how humans respond to disease, environmental insults, such as bacteria, viruses, toxins and chemicals, as well as drugs and other therapies. SNPs are thus quite useful tools in biomedical research.[50] SNPs have value as markers for linkage or for association studies of genetic susceptibility to disease.[51] To date, SNPs maps have identified DNA sequences underlying such common diseases as cardiovascular disease, diabetes, arthritis, and some types of cancer. The hope is that the identification of disease genes and SNPs will allow scientists to target the development of new drugs and therapies.[52]

ESTs are parts or fragments of a gene.[53] Often these are patented without a description of the exact location of the original gene on the chromosome and without a description of its biological function. The patenting of these fragments has become controversial among scientists and many have argued that both SNPs and ESTs are biological research tools that should not be patentable.[54] It appears that the U.S. PTO may have recently adopted a more restrictive approach to the issuing of these patents.

Many of these patents present significant problems to the U.S. pharmaceutical industry because the materials patented are research tools useful for the development of therapeutics and new drugs. Biotechnology companies have acquired patents to many of these with the intent of supplying them under contract (licence) to pharmaceutical companies.[55] One could argue that one of the social benefits of patenting, i.e., the distribution of inventions, as well as the disclosure of knowledge and information within society, is being lost through the expansion of patentability.

Thousands of patents with claims to human DNA sequences have been filed and granted, mostly in the U.S. These include patents for genomic DNA sequences, SNPs, DNA sequences of individual mutations that give rise to

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43 John H. Barton, "Genomics Patents" at 101, in Bartha Maria Knoppers and Charles Scriver, eds., *Genomics, Health and Society: Emerging Issues for Public Policy* (Ottawa: Policy Research Initiative).
44 *Ibid.*
45 *Ibid.*
46 66 Fed. Reg. 1093 (5 January 2001).
47 Barton, *supra* note 43 at 102.
48 *Ibid.*
49 WHO Genomics and World Health at 2.4.3 page 32.
50 *Charting New Territory, supra* note 26, at 38.
51 WHO, *supra* note 49, at 32.
52 *Charting New Territory, supra* note 26, at 15.
53 *Ibid.* at 37.
54 *Ibid.* at 37-8.
55 Barton, *supra* note 43, at 103.

disease, cloning vectors, proteins and parts of proteins, and computer-assisted methods for identifying proteins or parts of proteins of similar structure. Currently, there are over 3 million genome-related patent applications filed with the U.S. PTO.[56]

Other human materials

Technology has produced new ways of using human bodily materials in research. Human materials are not only used in biomedical research but also as a component of a variety of commercial products ranging from drugs to vaccines to pregnancy test kits.[57] Many of the results of such research, especially where it has a commercial or research application, will become the subject matter of a patent.

The most common technologies employed to convert human materials, tissues and cells, into products are: cell culture technology, hybridoma technology and recombinant DNA technology.[58] Cell culture technology involves the use of human cells that continually divide and grow in culture. Most, but not all, of the established cell lines originated from malignant tissue samples.[59] Successful cell lines begin with the isolation and expansion of a single cell a process referred to as cloning.[60] The resulting cell cultures are used in many types of commercial and non-commercial research. They can be used as a biological factory to produce a substance and to test drugs or the toxicity of various chemical compounds.[61] These cell cultures are often the subject matter of a patent.

Hybridoma technology uses hybridomas which are special types of hybrid cells created by the fusion of two different types of cells, a type of tumour cell called a myeloma and a B lymphocyte cell.[62] The B lymphocyte cell is isolated from the spleen or lymph node tissue (part of the body's immune system), which has been injected with the specific foreign substance of interest to the researcher. The B lymphocyte is a specialized type of white blood cell that produces one specific kind of antibody in response to the injection. When the B lymphocyte is fused with the immortal myeloma cell, the resulting hybridoma continuously multiplies in culture and secretes a single specific type of antibody. The supply of large amounts of specific antibodies is important for research, medicine and commerce. They can be used in diagnostics and for prophylactic or therapeutic regimens in humans. [63]

The third type of technology is referred to as DNA recombinant technology (also referred to as genetic engineering). Donor DNA is cut by enzymes into fragments, one of which contains the sequence of interest. These fragments are joined with vector DNA (vectors can be bacterial, viral, phage or eukaryotic DNA or combinations of these DNA) to become recombinant DNA molecules. The recombinant molecules are then introduced into host cells. The host population containing the cloned gene can be expanded and the cloned gene used to identity, isolate and scrutinize scarce biological compounds.[64]

There are three major sources of human tissues and cells for research: patients, healthy volunteers and cadavers. Specimens obtained from patients can be both normal and atypical, but most are obtained as "leftovers" from diagnostic or therapeutic procedures.[65]

Human reproductive materials, including sperm, ova, and *in vitro* embryos are also the subject matter of research, and some of these materials have been considered patentable. Embryonic Stem cells derived from human *in vitro* embryos are viewed as potentially valuable research materials and have been the subject of patents in the U.S. and elsewhere.[66]

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56 Johnathan Kahn, "What's the Use? Law and Authority in Patenting Human Genetic Material" (2003) 14 Stan. L. & Pol'y Rev. 417 at 421-2.

57 Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells — Special Report*, OTA-BA-337 (Washington, DC: U.S. Government Printing Office, 1987) at 23.

58 *Ibid.* at 31.

59 *Ibid.* at 33.

60 *Ibid.* at 34.

61 *Ibid.* at 35.

62 *Ibid.* at 35-8.

63 *Ibid.* at 38; Maureen s. Dorney, "Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation against the right of Informed Consent" at 3.Online: http://www.law.berkley.edu/journals. Accessed August 2004.

64 *Supra* note 57, at 43-4.

65 *Ibid.* at51.

66 In April 2003, the UK PO issued a practice note setting out its position re the patentability of cells from the human embryo. The UK PO will not grant patents for processes for obtaining stem cells from human embryos since it views such processes as excluded from patentability by virtue of the EPC *Directive*. In addition, it will not grant patents over human totipotent cells since they have the potential of developing into an entire human being. However, the PO will issue patents over human embryonic pluripotent stem cells derived from further division of the totipotent cells and which do not have the potential for developing into an entire human body. The PO considers that there embryonic pluripotent stem cells fall neither within articles 5(1), 6(1) or 6(2)(c) of the *Directive* (Boult Wade Tennant bulletin (European Patent and Trade Mark Attorneys, Patenting Stem Cells in Europe, August 2004) http://www.boult.com/information/BulletinPrint.cfm. Accessed March 14, 2004).

6.3 Property Rights in the Human Body

At first glance, it may appear that there is no connection between the subject of property rights in the body and the question of patenting and human rights. One can argue, however, that on closer examination the principle of human dignity may be the connector. This possible connection is further explored in the following discussion.

Patents over human materials essentially grant to the inventor intellectual property rights in the invention and in any extracted human materials which form part of the invention. Concerns have been expressed by human contributors of biological materials that they rarely receive a benefit from such contributions nor are they permitted to benefit by selling their biological materials in the marketplace. If inventors are able to commercialize products based on or containing donated human materials, and possibly realize substantial profits, why can an individual donor not commercialize and realize a profit from the sale of his or her excised materials, or benefit from his or her donation? The answers may lie in the commonly held Western view of the body as being inseparable from the soul and personhood.

Early philosophical writings by Plato and others on the significance of the physical body considered it an impediment: it was seen as a temporary tomb in which the soul was forced to reside.[67] This view of a split between the soul and the body was widened by the writings of more recent philosophers, such as Rene Descartes.[68] In the field of bioethics, philosopher H. Tristram Engelhardt espouses that personhood goes with consciousness, with the brain and not the body.[69] Engelhardt considers the human body to be the quintessential example of property and believes that human beings have a right to trade commercially in the body. Persons should be free to consent to do what they wish with their body.[70]

Other early philosophers, such as Aristotle, considered the body and soul as two aspects of a single entity.[71] This view is reflected in the Jewish and Christian traditions. Both traditions embraced the notion that the fleshly body is entwined with the soul.[72] Paul Ramsey, a Christian theologian, captured this view with the following statement "Persons are either embodied souls or ensouled bodies."[73] In his view, the body is a "sacredness" in the biological order and thus commercialization of the body would be seen as "morally repugnant."[74]

In Western culture, the most prevalent view of the human body is that found in the Jewish and Christian religious traditions. According to this view, the body is bound up with the soul: the body houses the soul and thus the very essence of the person. The secular notion that the human body and human dignity are linked makes commercialization of the body or its products repugnant to many North Americans and Europeans.

One might argue, however, that this viewpoint has not always been reflected in the common law, since there are situations where the law recognizes a limited property right in the human body. On the other hand, one could argue that it is precisely because the body is considered as an object of rich moral significance that the law and society consider it as "property," solely to ensure that certain legal remedies are available for offences committed against it.[75]

In order for property to be recognized in an object, not all the elements or rights that make up property have to be present.[76] The common law, for example, grants to immediate family members a limited property right, in the nature of control, in the body of a deceased relative.[77] This right does not permit the family members to sell the

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67 Thomas H. Murray, "On the Human Body as Property: the Meaning of Embodiment, Markets and the Meaning of Strangers" (1987) 20 U. Mich. J.L. 1055 at 1063.

68 *Ibid.* at 1064.

69 *Ibid.* at 1067.

70 *Ibid.* at 1068-69.

71 *Ibid.* at 1069.

72 *Ibid.* at 1069-70.

73 *Ibid.* at 1070.

74 *Ibid.* at 1071.

75 *Ibid.* at 1063.

76 Horore identified eleven elements or rights that constitute property. They include the right to: possess, use, manage, draw an income from, transmit or destroy, enjoy protection from expropriation, dispose of the interest on death, hold the property forever, residual or reversionary interests, and two other features: liability to seizure for debts and prohibition on harmful use. (A.M. Honore, "Ownership," *in Oxford Essays in Jurisprudence*, A.G.guest ed. (1961) at 107. Bruce Ziff, *Principles of Property Law* (Scarborough: Carswell Thomson Publishing, 1993) at 2.)

77 *Lubin v. Sydenham Hosp.*, 181 Misc. 870, 42 N.Y.S.2d 654 (N.Y. Sup. Ct. 1943).

body or its parts, rather it provides them with the necessary control to dispose of the body according to the wishes of the deceased. It also provides the family members with the right to claim compensation for emotional distress in those situations where the corpse has been mistreated.[78] Additional examples abound where the common law recognizes limited property rights in the body. The tort of appropriation of name or likeness and the tort of battery are examples of common law remedies that recognize limited property rights in the body. Canada's *Criminal Code* includes the offences of battery and assault, indicating the importance society and Parliament place on an individual's control over the integrity of their body.

The common law has also recognized ownership rights over the body's reproductive materials, such as sperm and *in vitro* embryos.[79] In addition, there are limited property rights granted in legislation. For example, every Canadian province has a statute that allows individuals to make a gift of parts of their body during their lifetime (*inter vivos*) and after death (*causa mortis*).

In the pivotal American case of *Moore v. The Regents of the University of Southern California et al*,[80] the courts were asked whether an individual who had unknowingly contributed parts of his body to researchers who subsequently used them to create a profitable patented cell-line, named the Mo cell-line, could successfully sue the researchers for the tort of conversion.[81] A majority of the California Court of Appeal found that Mr. Moore could sustain a cause of action for conversion, since in its view individuals had the "essence of a property interest — the ultimate right of control" with regards to their own body.[82]

On appeal, the California Supreme Court was split five members to two. The majority held that Mr. Moore did not have a cause of action for conversion, since he had no ownership interest in his excised cells.[83] He did, however, have the basis for an action in negligence against the physician since he had not obtained Mr. Moore's informed consent to the removal and donation of his excised cells and tissues for research purposes.[84]

One of the two dissenting opinions, written by Justice Mosk, noted that under the laws of California, property is a broad concept. In his view, Mr. Moore was seeking fairness and equity to some share in the profits that defendants made and expected to make from his cells. He wrote "… no one can question Moore's crucial contribution to the invention — an invention named, ironically, after him: but for the cells of Moore's body taken by defendants, there would have been no Mo cell line."[85]

The irony evident in the *Moore* decision is that while researchers and the biotechnology industry are at liberty to make potentially large profits by mining, refining and patenting human materials, the source or individual donor of the raw materials is not able to sell their bodily materials in the marketplace and is not required by law to receive a benefit back from the patentee.

6.3.1 The Principle of Human Dignity

Many writers have expressed concern that the recognition of property rights in the body would negatively impact human dignity. The worth of individuals would be seen in terms of their commercial value in the marketplace rather than in terms of their inherent worth, which is "neither given by the state nor vulnerable to political whim, totalitarian or majoritarian, either within or beyond national borders."[86]

Human dignity, while not a free-standing constitutional right, can be described as a fundamental principle[87] or a constitutional value that underlies many of the rights in the *Canadian Charter of Rights and Freedoms*[88, 89] The concept of

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78 *Supra* note 67, at 1062-63.

79 *Hecht v. Superior Court*, 16 Cal. App. 4th 836; 20 Cal. Rptr. 2d 275; 1993 Cal. App. LEXIS 638; 93 Cal. Daily Op. Service 4531; 94 Daily Journal DAR 7656, No. B073747 (Court of Appeal of California); *Davis v. Davis* (1992), 842 S.W.2d 588 (Supreme Court of Tennessee).

80 *Moore v. The Regents of the University of California et al.*, No. B021195 (QL) (Court of Appeal of California) July 21, 1988 [hereinafter referred to as *Moore CA*]; *Moore v. the Regents of the University of California et al.*, No. S006987 (QL) (Supreme Court of California) July 9, 1990 [hereinafter referred to as *Moore SC*].

81 The tort of conversion is an action for the wrongful conversion of something to one's own use (Shorter Oxford English Dictionary, 3rd Edition).

82 *Moore CA, supra* note 80 at 8.

83 *Moore SC, supra* note 80 at 14.

84 *Ibid.* at 5.

85 *Ibid.* at 29.

86 Lorraine E. Weinrib, "Human Dignity as a Rights-Protecting Principle" (Ontario Bar Association, CLE, 3rd Annual Charter Conference, October 2004) at 3.

87 *Blencoe v. British Columbia (Human Rights Commission)*, [2000] 2 S.C.R. 307, at para. 97.

dignity is likely implicated in any issue involving human rights since it is considered intrinsic to every human being, and is one of the values and principles essential to a free and democratic society.[90]

The notion of human dignity can be considered from two different viewpoints, i.e., objective and subjective. Objective dignity is said to encompass "unconditional and incomparable worth… [an] unchanging, supreme value that inheres in every human being."[91] Dignity is a constant and is not dependent on the person's circumstances or the respect shown to him or her by others in society.

Subjective dignity, on the other hand, is a personalized, individual sense of self-worth. This sense of dignity is not concerned with an abstract ideal of equal concern and respect, but with "the individual's own perception of self-worth."[92] It is dependent on whether the individual has a sense of self-worth as a human being or whether they feel worthless: it is a conception of self-respect.[93] It is specific to the particular individual. When the Supreme Court of Canada undertakes an analysis that includes human dignity, for example, when deciding a question of discrimination, it considers the impact of a government action on both subjective and objective dignity.

Would an individual's feelings of self-respect or self-worth be diminished if the state granted property rights in the body or bodily materials? Is the body sacred, housing an individual's essence or personhood, or is it nothing more than an impediment? Would a right to commercialize the body affect an individual's physical or psychological integrity of empowerment? Does the grant of a patent over excised bodily materials offend human dignity?

For many individuals, the existence of a legal market for body cells or parts would diminish human dignity. The body and the person are so intimately connected that affronts to the physical body would be affronts to the person. The notion that an individual could be reduced to and viewed as a conglomeration of marketable parts and materials would impact on their subjective feelings of self-worth and self-respect, and on their objective view of human beings as possessing incomparable and priceless worth.

For others, the fact that human materials are taken and used to produce patentable products sometimes resulting in significant profits for inventors and biotechnology companies would also diminish the concept of human dignity. The government grant of patent rights assigning to the patentee intellectual property rights over the product would be troubling.

There are still others, who view the body as separate and distinct from personhood and who would find nothing wrong with property rights in the body. Property rights in the body would not diminish human dignity, which is accorded to the person who inhabits the body, but not the body itself. For these persons, the body is morally insignificant and lacking in any intrinsic dignity. In fact, these individuals may consider it offensive that one segment of society can profit by using bodily materials in an invention, while the donor of the raw materials has no right to a share in that profit.

6.3.2 Discussion

The common law has evolved to recognize individual quasi-property rights in the body. Despite, however, the opportunity presented by *Moore*, *supra*, the common law has declined to evolve further and grant rights to alienate the body for valuable consideration, such as money, or to be compensated for bodily materials taken without consent.

Researchers and corporations routinely claim intellectual property rights over human materials that they have invented. If the Patent Commissioner determines that the invention meets the requirements for a patent, he or she must issue a patent granting the patentee the right to exclude others from using, making or selling the invention. The right to exclude others from using an object is considered by some to be the essential right that an individual must possess in order to categorize an object as

88 *Canadian Charter of Rights and Freedoms*, enacted as schedule B to the *Canada Act 1982*, (U.K.) 1982, c. 11 [hereinafter referred to as the *Charter*]

89 Dierk Ullrich, "Concurring Visions: Human Dignity in the Canadian Charter of Rights and Freedoms and the Basic Law of the Republic of Germany" (2003) 3.1 Global Jurist Frontiers 1 at 25.

90 *R. v. Oakes*, [1986] 1 S.C.R. 106 at 163.

91 Sophia Moreau, "The Wrongs of Unequal Treatment" (2004) 54 U of T L.J. 291 at 295.

92 *Ibid*. at 313.

93 *Ibid*.

property. Clearly, these biological materials/inventions are property.

Although a patent represents intangible property, one could argue that because it grants the patentee exclusive use of the invention, for example, an isolated DNA sequence in the field of biotechnology, it provides the patentee with aspects of a tangible property right in the subject matter of the patent. This is especially the case where the "invention" differs very little from the raw materials. Concerns have been expressed by authors and in government reports that with respect to human genes, the scope of patentable subject matter is constantly being expanded and in many cases, critics have argued that the usefulness or biological function of the invention is unknown at the time of patenting.[94] Others, however, have pointed out that "usefulness" remains a necessary criterion in order to receive a patent.

In the U.S., patents are issued for protein co-ordinates, SNPs, such as the BRCA diagnostic sequence (for breast cancer), and ESTs. These patented biological materials may be more appropriately characterized as research tools. Protein co-ordinates may have little or no independent value and yet can be the subject of a patent. Their real economic value derives from a final product, e.g. a pharmaceutical that is developed with the aid of the research tool.[95]

The expanding scope of patentability in the U.S. suggests a contradiction in the law. The law refuses to grant individuals property rights in their bodily materials and yet allows pharmaceutical and biotechnology companies intellectual property rights over these materials, despite the fact that some of the patented materials require very little in the way of inventivenss or differ very little from the naturally occurring material in the body. In the past, the granting of property rights in bodily materials could be explained by applying John Locke's theory of property. The inventor, using raw materials, such as human cells, applies his physical and mental labour to produce or create a product. The inventor, as a human being, has an inalienable right to self-ownership and it is this right combined with the inventor's physical and mental labour that gives him or her a right of property in the finished product. The theory is that the finished product is different from the raw materials, i.e., the excised human materials. The inventor has no property rights over the human materials in the donor's body. The state's grant of intellectual property rights, in the form of a patent, is only with respect to the finished product and not the bodily materials occurring in the human body.

John Locke's theory of property may no longer fully explain intellectual property rights over all biological inventions. For example, the use of computational techniques to identify DNA sequences requires minimal physical or mental labour to produce a patentable invention. As noted earlier, some American critics suggest that the criterion of usefulness necessary to obtain a patent is no longer as strictly applied resulting in patents being granted for inventions despite the fact that its use is not always clear when the patent is issued. If these criticisms prove valid, the rationale for allowing inventors to acquire property rights over excised human materials may be questionable. Moreover, if inventors can attain property rights in human materials with little to no labour, the strength of the argument that individuals cannot be assigned property rights in their own excised bodily materials because they have not contributed physical or mental labour would be diminished.

The continued successful commercialization of inventions composed of human materials by the biotechnology industry, with no benefit back to the respective donors, may itself come to be regarded as an affront to human dignity. Donors may increasingly feel exploited as sources of raw materials and may experience feelings of diminished self-respect and self-worth. Litman and Robertson raised similar concerns with respect to human dignity.[96] They hypothesized that by disallowing individuals exclusive control of their bodies and any excised materials, respect and human dignity would both be diminished.[97] This may be in part what the Court of Appeal in *Moore*, *supra*, was concerned with when it observed that the right to one's own genetic

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94 Barton, *supra* note 43 at 102; *Charting New Territory*, supra note 26, at 37.

95 Barton, *ibid* at 102-03.

96 Moe Litman and Gerald Robertson, "The Common Law Status of Genetic Materials," in Bartha Maria Knoppers, Timothy Caulfield and T. Douglas Kinsella, eds., *Legal Rights and Human Genetic Materials* (Toronto: Edmond Montgomery Publications Ltd., 1996).

97 *Ibid.* at 60.

materials and the power to control excised bodily tissues protects both human privacy and dignity.[98]

6.3.3 Conclusion

Although there is no human right to property in the body, the fact that quasi-property rights are granted in the body to preserve its moral significance may indicate that the door to this possibility has not been closed. Notions of moral significance of the person and human dignity are closely connected. The fact that corporations can mine, refine and patent parts of the human body in order to reap possible profits, coupled with the fact that the donor has no legal mechanism to force the recognition of his or her contribution, may be considered by many as an affront to their human dignity. Individual donors may be left feeling exploited; their only significance being as a source of raw materials.

There is no legal obligation on the patentee to recognize the contributor of materials, either through a share in the profits or a benefit back to the community. The balance is clearly weighted in favour of industry. Property rights in the human body or a human right to property in the body may be one way of righting the balance.

Others may dismiss this position by arguing that the community does receive a benefit back in the form of inventions and in the case of biomedical research, in the form of possible cures for disease. For persons and communities who have sacrificed their time and resources to donate bodily materials and raise money for biomedical research that results in very profitable inventions, more recognition may be justified.

An argument could be made that in order to preserve human dignity, the law may have to evolve to ensure that donors of human bodily materials receive a "benefit back" in those instances where the product proves to be of commercial value. This solution, while not granting persons unlimited property rights in the human body, would ensure that inventors and donors are treated equally. Both would be recognized by society for their valuable contribution to increased knowledge and to inventiveness that has the potential to provide cures to many debilitating human diseases.

Unjust enrichment and the tort of conversion may provide the most compelling legal basis on which the donor may to stake a claim to a share of the patentee's profits. To succeed at either, the courts would have to recognize limited property rights in the human body and its excised cells and tissues. A strong argument could be made that recognition by the common law of property rights in the human body would not be precedent setting. Individuals already possess a number of the elements indicative of such a property right, for example, the right to control, which is arguably the strongest indicator of property rights in an object.

6.4 Patents and Human Rights

To date, there have been no allegations that patenting infringes human rights. Some academics have made statements to that effect, but a thorough analysis of the assertion has been lacking. In an attempt to rectify the situation, this section of the chapter provides three hypothetical scenarios to assist in an analysis to determine whether the patenting raises and engages human rights.

The discussion begins by setting out: (1) international law and principles, (2) the law in other jurisdictions, (3) Canadian law, and (4) academic commentary.

6.4.1 International and Regional Instruments

International Trade Agreements

TRIPS

Canada is a member of the WTO and thus must comply with the provisions of the 1995 WTO agreement on the *Trade-Related Aspects of Intellectual Property Rights*[99] ("TRIPS"). Member States must comply with the articles in TRIPS, which set out the rules regarding different types of intellectual property, including copyright, trademarks, industrial designs, and patents.

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98 *Moore CA, supra* note 80.

99 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex IC, Legal Insturments-Results of the Uruguay Round, vol. 31, 33 I.L.M. 81 (1994) [hereinafter referred to as "TRIPS"].

Article 27, paragraph (1), of TRIPS provides that patents are available for an invention that meets the basic criterion of newness, inventiveness and industrial application. Members may not discriminate with respect to the grant of patents over technology, unless it is in accordance with one of the possible exemptions. TRIPS provides Members with the ability to exclude from patentability inventions that may violate *ordre public* or morality, as follows:

> 27.2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

The TRIPS Council is authorized to monitor compliance with the obligations of each Member State and it provides procedures for dispute settlement. When TRIPS took effect, developed countries, including Canada, were given one year to ensure that their laws and practices were compliant. The WTO regularly reviews Members' trade policies to ensure compliance with all trade agreements. In the event of a dispute between Members with respect to compliance, the Dispute Settlement Body would establish a panel to consider the case and if the offending Member refused to comply with a ruling, it has the power to authorize retaliation, including trade sanctions.

NAFTA

Canada signed the *North American Free Trade Agreement* (the "NAFTA") in 1994, along with the U.S. and Mexico. For the purposes of NAFTA, the three nations become a free trade zone for the conduct of business, including IP. Article 1709:2 of the NAFTA provides any one of the three Member States the option of excluding an object from patentability on the basis of *ordre public* or morality.

International Human Rights Instruments

The United Nations (U.N.) human rights instruments do not directly address questions of patenting. The instruments instead provide general principles that can be referred to for guidance.

Article 12 of the *International Covenant on Economic, Social, and Cultural Rights*[100] recognizes the right of everyone to the enjoyment of the highest attainable standard of physical and mental health and sets out the steps to be taken by States to allow individuals to realize the right. Article 12 states:

> 12.1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
>
> a. The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
>
> b. The improvement of all aspects of environmental and industrial hygiene;
>
> c. The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
>
> d. The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The United Nations' Committee on Economic, Social and Cultural Rights provided guidance as to the interpretation of article 12 in its General Comment No. 14.[101] The General Comment noted that "[h]ealth is a fundamental right indispensable for the exercise of other human rights."[102] In article 7 of the General Comment, the Committee noted

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[100] *International Covenant on Economic, Social and Cultural Rights*, 16 December 1966, 993 U.N.T.S. 3 (entered into force 3 January 1976) [hereinafter referred to as "the ICESCR"]. The *Universal Declaration of Human Rights* provides in article 27 (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits and in article 27(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

[101] General Comment No. 14 (2000), Distr. GENERAL E/C. 12/2000/4, 11 August 2000.

[102] *Ibid.* at article 1.

that the right to health is not to be understood as a right to be healthy, but rather it is composed of freedoms and entitlements. The Committee cautioned that the right to health does not impose upon States Parties an obligation to ensure that every citizen experiences good health and is never sick. Many of the factors influencing a person's health are beyond the State's control, such as genetic factors and lifestyle choices. Rather, the right to health should be understood as a right to enjoy a "variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health."[103]

Article 15.1 of the ICESCR provides:

> 15. 1. The States Parties to the present Covenant recognize the right of everyone:
>
> - To take part in cultural life;
> - To enjoy the benefits of scientific progress and its applications;
> - 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.

As noted in both chapters 2 and 3, there is not an abundance of literature and commentary with respect to either the rights of individuals or the State's obligations under article 15.1. In 2001, the Committee on Economic, Social and Cultural Rights, as a follow-up to its day of general discussion, adopted a statement on intellectual property and human rights.[104] The objective of the statement was to "… identify some of the key human rights principles derived from the ICESCR that are required to be taken into account in the development, interpretation and implementation of contemporary intellectual property regimes."[105]

In the statement, the Committee was careful to distinguish between human rights and legal rights in intellectual property regimes. It stated:

> The fact that the human person is the central subject and primary beneficiary of human rights distinguishes human rights, including the right of authors to the moral and material interests in their works, from legal rights recognized in intellectual property systems. Human rights are fundamental as they derive from the human person as such, whereas intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits. In contrast with human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While intellectual property rights may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas human rights are dedicated to assuring satisfactory standards of human welfare and well-being, intellectual property regimes, although they traditionally provide protection to individual authors and creators, are increasingly focused on protecting business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for under article 15 of the Covenant does not necessarily coincide with what is termed intellectual property rights under national legislation or international agreements.[106]

The statement provides grounds for making a distinction between fundamental human rights and an author's or inventor's intellectual property rights, and for assigning more significance and weight to those rights that arise from the human person. With respect to the purpose of intellectual property regimes, the Committee stated that "… intellectual property is a social product and has a social function" which should "serve the objective of human well-being."[107]

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[103] *Ibid.* at articles 8 and 9.
[104] U.N. Press Release, Committee on Economic, Social and Cultural Rights Adopts Statement on Intellectual Property and Human Rights, 27th Session, 26 November 2001.
[105] *Ibid.* at para. 2.
[106] *Ibid.* at para. 6.
[107] *Ibid.* at para. 4.

The Committee identified a number of human rights principles that deserve attention when adopting intellectual property regimes. For instance, the Committee stressed that equality rights must be protected and particular attention must be paid to disadvantaged individuals and groups.[108] The Committee also stressed the importance of participation in decision-making by those who would be affected by intellectual property regimes.

With respect to States Parties' ability to fulfil their obligations relating to rights enunciated in the ICESCR, the Committee stated:

> The Committee wishes to emphasize that any intellectual property regime that makes it more difficult for a State party to comply with its core obligations in relation to health, food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the State party.[109]

In relation to international cooperation and assistance, the Committee stressed that "[i]t is essential that intellectual property regimes facilitate and promote development cooperation, technology transfer and scientific and cultural collaboration."[110] The Committee suggested that intellectual property regimes need not be identical and encouraged the formulation of special and differential treatment for developing countries.[111]

The Committee prepared a draft General Comment on article 15.1(c) which it shared with experts in August 2004 and considered during its 33rd session in November 2004. The Committee did not adopt the draft during the recent session since it is still under review.

At least one academic, Dr. Audrey Chapman, has written extensively about article 15. She noted that the ICESCR is the major international human rights instrument that addresses the issue of balancing the rights of inventors and creators with the broader interests of society.[112] However, for a number of reasons, these rights and corresponding duties have not been well developed. She speculated that economic globalization and increasing privatization and commercialization of science have made it difficult to achieve the balances required by article 15.[113]

Despite the fact that more than 130 countries are signatories to the ICESCR and thus are legally obligated to comply with the provisions, Chapman noted that policy makers and legislators for the most part fail to include human rights considerations in their "decision-making on intellectual property regimes, and instead rely primarily on economic considerations."[114] She referred to the work of C.G. Weeramantry, who wrote in the early 1980s about the implications of unfettered technological advance. In his view, the speed of technological change in society has resulted in a situation where today technology leads, rather than is shaped by, governmental policy. Furthermore, shifts in power have occurred, particularly the concentration of power in transnational corporations and the ability of these corporations to find a common interest with personnel in government departments at the expense of the democratic process. This results in major decisions regarding the use of technology often being made at the highest legislative and executive levels, to which public interest groups have little access.[115]

Dr. Chapman suggested that the balancing required under article 15 imposes a higher standard for evaluating patent applications, namely an approach that considers whether the proposed invention is consistent with the inherent dignity of the human person and with central human rights norms.[116]

But, what are the human rights norms or principles that should be considered by the State under article 15? Chapman suggested that article 15.1(b), contains three human rights components: (1) a right of access to beneficial scientific and technological developments, (2) a right of choice in determining priorities and making decisions about major scientific and technological developments,

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108 *Ibid.* at para. 8.
109 *Ibid.* at para. 12.
110 *Ibid.* at para. 15.
111 *Ibid.*
112 A.R. Chapman, "A Human Rights Perspective on Intellectual Property, Scientific Progress, And Access to the Benefits of Science" (1998) at 1. Online: http://www.wipo.org (accessed on 18 June 2004).
113 *Ibid.* at 3.
114 *Ibid.* at 2.
115 C.G. Weeramantry, *The Slumbering Sentinels: Law and human rights in the wake of technology* (Ringwood, Victoria, Australia and Harmondsworth, Middlesex, England: Penguin Books, 1983) chapter 10.
116 Chapman, *supra* note 112 at 2.

and (3) a right to be protected from possible harmful effects of scientific and technological development on both individual and collective levels.[117] For example, a right of access to beneficial scientific and technological developments implies at a minimum the freedom and opportunity to benefit from scientific advancement "without discrimination on the basis of race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status."[118]

Article 15.1(c), imposes on States Parties an obligation to protect the moral and material interests of authors and inventors. Dr. Chapman noted, however, that it grants States Parties broad discretion in establishing a system for conferring intellectual property protection.[119] This discretion could be used to design patent systems or regimes which do take into account human rights. She suggested that the right to intellectual property as a universal human right is different from the economic interests that result from traditional intellectual property law.[120] In order to respect human rights norms, the subject-matter of the intellectual property rights and the system of patent protection must be consistent with the following principles:

1. Intellectual property rights must be consistent with the understanding of human dignity in the various international human rights instruments and the human rights norms defined therein;

2. Intellectual property rights related to science must promote scientific progress and access to its benefits;

3. Intellectual property regimes must respect the freedom indispensable for scientific research and creative activity; and

4. Intellectual property regimes must encourage the development of international contacts and cooperation in the scientific and cultural fields.[121]

In Dr. Chapman's view, a human rights approach imposes requirements on the State to undertake "a very rigorous and desegregated analysis of the likely impact of specific innovations, as well as an evaluation of proposed changes in intellectual property paradigms… it calls for particular sensitivity to the effect on those groups whose welfare tends to be absent from the calculus of decision-making about intellectual property…"[122]

It is her opinion that, from a human rights perspective, intellectual property should be viewed as a social product with a social function.[123] The *ordre public* or morality clauses contained in the *European Patent Convention* and the *Directive 98/44/EC* on Biotechnology are one means of ensuring that intellectual property rights are consistent with international human rights norms.[124]

> The Preamble to the 1997 UNESCO *Declaration on the Human Genome and Human Rights* emphasizes that research on the human genome "should fully respect human dignity, freedom and human rights."[125] Article 2 states:
>
> a. Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.
>
> b. That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.[126]

Article 4 provides that the human genome in its natural state should not give rise to financial gain. The *Declaration* has not, however, had much effect in practice with respect to what can and cannot be patented in most developed countries.[127]

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117 *Ibid.* at 2 and 9.
118 *Ibid* at 9.
119 *Ibid.* at 13.
120 A.R. Chapman, "The Human Rights Implications of Intellectual Property Protection" (2002) JIEL 861.
121 *Supra* note 112 at 13.
122 *Ibid.* at 10.
123 *Supra* note 120 at 4.
124 *Supra* note 112 at 13.
125 *Universal Declaration on the Human Genome and Human Rights*, 11 November 1997, UNESCO, 29th Sess., (adopted unanimously and by acclamation). Under international law, a Declaration is not binding on state parties but rather a sign of support for the principles contained therein. For more information see chapter 1 *supra*.
126 *Ibid* at article 2.
127 S. Thambisetty, "Study Paper 10: Human Genome Patents and Developing Countries" Background Paper, Commission on Intellectual Property Rights at 13, [hereinafter *Study Paper 10*]

Article 8, paragraph (j), of the U.N. *Convention on Biological Diversity* ("CBD") provides that State Parties must encourage the equitable sharing of benefits arising from the use of indigenous and local knowledge tied to biological diversity.[128] The Human Genome Organization's ("HUGO") Ethics Committee has stated that the concept of benefit sharing developed under the CBD should be extended to human genetics research, such that commercial entities devote a percent of their net profits to healthcare infrastructure or humanitarian efforts.[129] The rationale for "benefits back" being the commonality of the human genome and as well, reasons of compensatory, procedural and distributive justice.[130]

Regional Instruments

THE EUROPEAN UNION

In 1997, the Committee of Ministers of the Council of Europe concluded the *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*.[131] It is legally binding on those State Parties that are signatories. The *Convention* provides that States "shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine."[132]

The *Convention* was intended to preserve human dignity, rights and freedoms, through a series of principles and prohibitions against the misuse of biological and medical advances. It declares that the interests of human beings must come before the interests of science or society.[133] Canada is not a party to the *Convention*; however it does have observer status. Although the *Convention* could not form the basis of a complaint in a Canadian court, it could be introduced to inform the courts of how an intergovernmental organization in Europe has dealt with these issues.

The objective of the *Convention* is found in article 1:

> Parties to this Convention shall protect the dignity and identity of all human beings and guarantee everyone, without discrimination, respect for their integrity and other rights and fundamental freedoms with regard to the application of biology and medicine.

The *Convention* states that the interests of human beings are paramount to the interests of science or society (article 2). Article 21 provides:

> **Article 21** — Prohibition of financial gain on human beings
>
> The human body and its parts shall not, as such, give rise to financial gain.

The Committee of Ministers authorized the publication of an Explanatory Report[134] to the *Convention*. The *Report* noted that article 21 is based on the foundational principle of human dignity. It stated that organs and tissues, including blood, should not be purchased and sold or "give rise to financial gain for the person from whom they have been removed or for a third party, whether an individual or a corporate entity such as, for example, a hospital."[135] However, the *Report* clarified that article 21 does not prohibit the sale of "a medical device incorporating human tissue which has been subjected to a manufacturing process as long as the tissue is not sold as such."[136] Furthermore, it noted that article 21 does not prevent a person from whom an organ or tissue has been removed from receiving compensation, which is distinguishable from remuneration since it only reimburses the person for expenses incurred in donation or any loss of income.

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128 U.N. *Convention on Biological Diversity*, Rio de Janeiro, 5 June 1992, available at www.biodiv.org.

129 HUGO Ehtics Committee, "Statement on Benefit Sharing" available at http://www.gene.ucl.ac.uk.hugo/beneti.html; Gold and Caulfield, *supra* note 12, at 44.

130 HUGO, *ibid.*

131 Council of Europe, *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* (DIR/JUR (96) 14) (Strasbourg: Directorate of Legal Affairs, November 1996). Online: http://conventions.coe.int/Treaty/EN/Treaties/Html/164.htm. Accessed 2004 [hereinafter referred to as "the *Convention*"].

132 *Ibid.*

133 *Ibid.* at article 2.

134 Explanatory Report, 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, ETS No. 164. Online: http://conventions.coe.int/Treat/en/Reports/Html/164.htm. Accessed September 2004 [hereinafter *Report*].

135 *Ibid.* at section 132.

136 *Ibid.* at section 132.

The sale of hair and nails is exempted from article 21 since the *Report* does not consider this activity to be an affront to human dignity. Finally, the *Report* noted that the issue of patents was not considered in connection with this provision and the provision *should not* be interpreted as acknowledging the patentability of biotechnological inventions.

The European Union has adopted its own patent system and rules concerning the grant, enforcement, and definition of patentable subject matter. Member States are bound by these rules, as well as certain international intellectual property and trade agreements. Furthermore, many of these States are signatories to the *European Patent Convention.*[137] The EPC established the European Patent Office ("the EPO") and assigned it responsibility for the granting of patents in each of the signatory countries.

In 1998, the Council of the European Union and the European Parliament adopted *Directive 98/44/EU*[138] in order to bring a measure of harmonization to the European patent system. The *Directive* establishes a set of rules concerning the patentability of biological materials within Member States.[139] The *Directive* clarifies the patentability of certain human and other biological materials for Member States of the European Union.[140] The EPO, as an independent body, is not bound by the *Directive*. However in 1999, certain articles of the *Directive* were incorporated into the EPC rules following a decision of the Administrative Council of the EPC.[141]

It provides that the same general principles of patent law (i.e. only inventions that are new, non-obvious, and have an industrial application are patentable) apply to biological material.[142] Biological material, such as human DNA, that is structurally identical to that found in nature is still patentable as long as it is in a different form than found in nature.[143] The process of isolating and purifying human DNA thus makes it patentable subject matter under the *Directive's* rules. Article 5 states:

1. 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.

2. 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 if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

Article 6 of the *Directive* also contains an *ordre public* and a morality exception for biotechnology patents. In addition, it lists inventions (including processes) that are deemed to be violations of *ordre public* or morality, including cloning human beings, modifying the human germ line genetic identity, and using human *in vitro* embryos for industrial or commercial purposes. Article 6 states:

1. Inventions shall be considered unpatentable where their commercial exploitation would be contrary to ordre public or morality; however, exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation.

2. On the basis of paragraph 1, the following, in particular, shall be considered unpatentable:

   a. processes for cloning human beings;

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137 *Convention on the Grant of European Patents*, done at Munich, 5 October 1973 [hereinafter referred to as "the EPC"].

138 *Directive 98/44/EU of the European Parliament and of the Council*, 6 July 1998. Online: http://europa.eu.int/eur-lex/en/lif/dat/1998/en_398L0044.html [hereinafter referred to as the *Directive*]

139 Non-Member States of the European may also fall under the *Biotech Directive* as a result of membership in the EPC or the European Free Trade Association. E.R. Gold & A. Gallochat, "The European Directive on the Legal Protection of Biotechnological Inventions: History, Implementation, and Lessons for Canada" (2001) The Canadian Biotechnology Advisory Committee Project Steering Committee on Intellectual Property and the Patenting of Higher Life Forms, online: http://cbac-cccb.ca/epic/internet/incbac-cccb.nsf/vwGeneratedInterE/h_ah00128e.html (date accessed: 13 February 2004) [hereinafter referred to as the *Directive*].

140 Non-Member States of Europe may also fall under the *Directive* as a result of membership in the *European Patent Convention* or the European Free Trade Association.

141 See, for example, EPC rules 23b, 23c, 23d and 23e.

142 *Ibid.*

143 *Directive*, *supra* note 138, at article 3(2).

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.

The "*ordre public*" clause provides the basis for concerned citizens to challenge individual patents on the grounds that issuance would be morally offensive.[144] Recently, the EPO announced that it found an invention involving the cloning of a fused human and pig cell to be contrary to morality.[145]

The EPC also allows for third party opposition whereby any person has nine months following the grant of the patent to file an objection. This procedure has been used by public interest interveners, such as Greenpeace.[146] Recently, several public interest groups commenced an opposition proceeding challenging a 1991 EPO grant of a patent covering the synthetic human gene that codes for the human female hormone "relaxin" and another for the hormone itself. The Opposition Division Board, however, upheld the patents and rejected the groups' arguments that the invention lacked novelty and that patenting genes is ethically unacceptable.[147]

The non-binding provisions[148] of the *Directive* also address the ethical issue of informed consent. Recital 26 provides:

> Whereas 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.

Lastly, the *Directive* contains two review mechanisms to ensure that it conforms with ethical considerations related to biotechnological innovations.[149] First, the European Commission must make periodic reports to the European Council and the European Parliament on the ethical and research implications of the *Directive*. Second, a group of ethicists will engage in a continuous review of the basic ethical aspects of biotechnology including those in relation to patent law.[150]

6.4.2 The Law in Other Jurisdictions

This section reviews the law respecting the patenting of human bodily materials in three other countries, i.e., the U.S., the UK and Australia. These countries were chosen because they each have a vigorous research and intellectual property sector, and each one has attempted to deal with the issues relating to the patenting of biological materials. Relevant case law from each country has been selected for review to illustrate how the courts have addressed these difficult issues and how they have reshaped the common law to keep pace with changes in biotechnology and social attitudes.

The U.S.

The foundation for patent law is article 1, section 8, clause 8 of the *United States Constitution*. This provision empowers Congress:

> To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries… To make all Laws which

144 J. Chambers, "Patent Eligibility of a Biotechnological Invention in United States, Europe, and Japan: How Much Patent Policy is Public Policy?" (2002) 34 The Geo. Wash. Int'l L. Rev. 223 at 233 [hereinafter *Patent Eligibility of a Biotechnological Invention*].

145 *Directive*, *supra* note 138 at 9. See also Q. Schiermeiser, "Germany Challenges Human Stem Cell Patent Awarded 'By Mistake'" (2000) 404 Nature 3-4.

146 Canadian Biotechnology Advisory Committee, Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee (June 2002) at 7. Online: http//cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html. Accessed June 2004 [hereinafter referred to as the Report].

147 T. Caulfield, K. Cherniawsky & E. Nelson, "Patent Law and Human DNA: Current Practice" in B Knoppers, T. Caulfield & T. D. Kinsella eds., *Legal Rights and Human Genetic Material* (Toronto: Emond Montgomery Publications Limited, 1996) 115 at125.

148 Europe's obligations under TRIPS require that this provision be non-binding. As discussed earlier, TRIPS provides that the only permissible criteria for patentability of an invention are that the invention is new, non-obvious, and has an industrial application, and that the invention is fully disclosed to the public.

149 *Directive*, *supra* note 138, at 4.

150 *Ibid.*

> shall be necessary and proper for carrying into Execution the foregoing Powers and all other Powers vested by this Constitution in the Government of the United States, or in any Department or Officer thereof.[151]

In 1790, Congress passed the first *Patent Act.*[152] The current Act has undergone several subsequent amendments, the most recent being in 1995 and it is codified in Title 35 of the United States *Code*. In the U.S., patent rights do not exist unless they are granted by the federal government. Patents are granted by the U.S. PTO only after an examination is carried out on the patent application and the alleged new invention. If it appears, after examination, that the applicant is entitled to a patent under the law, the Commissioner must grant a patent.[153]

The Act defines the term "invention" as an "invention or discovery."[154] Inventions are patentable if they are a "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof… "[155] In addition, to being patentable, they must be non-obvious, and fit within statutorily defined subject matter.[156] Furthermore, the application for a grant of patent must fully disclose and describe "the claimed subject matter so that a person having ordinary skill in the relevant art could make and use the invention."[157]

In 1996, the *Patent Act* was amended by introducing a limited statutory defence to claims of infringement asserted against medical practitioners or health care entities in relation to their undertaking of a "medical activity."[158] The phrase "medical activity" is defined as the performance of a medical or surgical procedure on a body, including a human body, organ or cadaver, or an animal used in medical research directly related to the treatment of humans (35 USC §287(c)(2)(A), (E), (F)). The U.S. medical treatment defence is the only one of its kind in the patent laws of developed nations.

Certain activities are, however, excluded from the defence. One of the excluded activities is the practice of a process in violation of a biotechnology patent. Although the phrase "biotechnology patent" is not defined, it would include the use of isolated genetic materials.[159] There have been recent proposals to extend the scope of the medical treatment defence. One such proposal was contained in the since lapsed Genomic Research and Diagnostic Accessibility Bill 2002. It provided an extension of the definition of medical activity to include the performance of a genetic diagnostic, prognostic, or predictive test.[160] The co-sponsor of the Bill stated that it would have exempted medical practitioners using genetic diagnostic tests from patent infringement remedies.[161]

Case law

Diamond v. Chakrabarty[162] is the landmark 1980 American case dealing with the patentability of the products of biotechnology. Although *Chakrabarty* did not deal with the patenting of human bodily materials, it did determine the scope of the phrase a "composition of matter," in the U.S. *Patent Act,* which is relevant to the patentability of animal and human materials.

In *Chakrabarty*, both the patent examiner and the PTO Board of Appeals rejected a patent application for an invention on the basis that it was a living thing and thus not patentable subject matter under section 101 of the *Patent Act*. The question before the U.S. Supreme Court was whether a live, genetically-engineered micro-organism qualified as either a "manufacture" or a "composition of matter" in the context of the *Patent Act*. A five-person majority of the Court decided that such a micro-organism was patentable under the Act.[163]

Chakrabarty, a microbiologist, made three different patent claims: (1) process claims for the method of producing the bacteria, (2) claims for the inoculum comprised of a carrier material floating on water, such as straw, and the new

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151 U.S. Const. art. 1, s.8, cl. 8.
152 *U.S. Patent Act*, as amended, 35 USC §§ 1-376.
153 Sheldon W. Halpern, Craig Allen Nard and Kenneth L Port, *Fundamentals of United States Intellectual Property Law: Copyright, Patent, and Trademark* (The Hague: Kluwer Law International, 1999) at 231.
154 *Supra* note 152, at s. 100.
155 *Ibid.* at s. 101.
156 *Ibid.* at ss. 102 and 103.
157 *Supra* note 153 at 189.
158 ALRC, *supra* note 14, at 607.
159 *Ibid.* at 607-08.
160 Genomic Research and Diagnostic Accessibility Bill 2002 (HR 3967) (US) s.3.
161 ALRC, *supra* note 14, at 608-09.
162 *Diamond v. Chakrabarty*, 447 U.S. 303 (U.S. Supreme Court) [hereinafter referred to as *Chakrabarty*].
163 *Ibid.* at 1.

bacteria, and (3) claims to the bacteria themselves.[164] The patent examiner allowed the first two claims but rejected the patent claim for the bacteria itself on the basis that micro-organisms are products of nature and that living things are not patentable subject-matter under section 101 of the Act.[165] Section 101 of the *Patent Act* states:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Chakrabarty appealed the examiner's decision to the PTO Board of Appeals. The Board concluded that, since Congress had extended patent protection to certain asexually reproduced plants in the 1930 *Plant Patent Act*, section 101 of the *Patent Act* was not intended to cover living things such as laboratory created bacteria.[166]

The case was appealed to the U.S. Supreme Court. It considered the question before it to be one of statutory interpretation of section 101 within the context of the Act. The Court noted that "composition of matter" has been construed in accordance with common usage to include "all compositions of two or more substances and… all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."[167] A majority of the Court noted that the legislative history of the *Patent Act* supports a broad construction, and cited from the 1952 Committee Reports on recodifying the Act where Congress stated its intent that statutory subject matter "include anything under the sun that is made by man."[168]

The majority was quick to point out, however, that there are limits to what can be patented under section 101. It noted that the courts have held that the laws of nature, physical phenomena, and abstract ideas are not patentable. A new mineral discovery in the earth or a new plant discovered in the wild is not patentable, neither would have been Einstein's discovery that $E=mc^2$. Quoting from case law, Burger C.J., writing for the majority, noted that these discoveries are "manifestations of… nature, free to all men and reserved exclusively to none."[169]

In the majority's opinion, the living genetically altered micro-organism clearly qualified as patentable subject-matter. The majority noted that the micro-organism was not a naturally occurring organism, but rather was a manufacture or composition of matter a product of human ingenuity with a distinctive name, character and use. The invention had the potential for significant utility, i.e., the breaking down of crude oil.[170]

The argument that living things are not patentable under the *Patent Act* because Congress passed the 1930 *Plant Patent Act* and the 1970 *Plant Variety Protection Act* to specifically patent plants was rejected by the majority. Chief Justice Burger noted that two factors had led to the view that plants were not patentable under the *Patent Act*. First, in 1889, the PTO rejected a patent claim on a fibre found in a plant fearing that it would lead to patents on the trees of the forest and the plants of the earth, which would be unreasonable and impossible. Second, it was considered impossible to provide a sufficient written description of plants to satisfy the requirements of the *Patent Act*.[171]

The majority concluded that there is nothing in the language or the history of the 1939 and 1970 statutes to suggest they were enacted because section 101 of the *Patent Act* was not capable of including living things. Burger C.J. noted that it is Congress and not the courts that define the limits of patentability, but once Congress has spoken:

> … it is the province and duty of the judicial department to say what the law is… we perform our duty in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose."[172] Chief Justice Burger noted that in this case there is no ambiguity

164 *Ibid.* at 3.
165 *Ibid.* at 3.
166 *Ibid.*
167 *Ibid.* at 4.
168 *Ibid.*
169 *Ibid.*5.
170 *Ibid.*
171 *Ibid.*
172 *Ibid.* at 7.

> since the subject-matter statutory provisions were drafted in broad language to fulfil the constitutional and statutory objective of furthering the progress of science and the arts in order that society may realize the attendant social and economic benefits.[173]

Burger C.J. made reference to the risks and fears raised by the petitioner with respect to the granting of patents on living genetically altered organisms. He noted that the Court has been asked to weigh these concerns in making its decision regarding patentability. He wrote:

> … we are without competence to entertain these arguments — either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives… the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[174]

In the majority's view, the risks and concerns raised about patenting genetically altered living materials were matters for Congress and Congress, as the elected body, is responsible for investigating, balancing the competing interests, and amending the statute if necessary.

Ex parte Allen[175] followed on the heels of *Chakrabarty*, *supra* and *Ex parte Hibberd*,[176] in which the Board of Patent Appeals concluded that non-naturally occurring man-made multicellular plants were patentable under section 101 of the Act. *Ex parte Allen* dealt with whether a non-naturally occurring genetically altered strain of polyploidy oysters (a living multicellular organism) was patentable under section 101 of the Act. The Board of Patent Appeals held that it was patentable, but unfortunately the Board's decision remains unpublished.

Shortly after the decision in *Ex parte Allen*, *supra*, the PTO issued a notice which stated that:

> The Patent and Trademark Office now considers nonnaturally occurring non-human *multicellular living organisms, including animals*, to be patentable subject matter within the scope of 35 U.S.C. 101… An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law… *A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution.* Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection… Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. [emphasis added]

This statement of policy by the PTO was challenged by nine plaintiffs, including the Animal Legal Defence Fund, on the basis that the new rule or policy had been issued in a manner that contravened the public notice and comment requirements. The case, *Animal Legal Defence Fund v. Quigg*,[177] was dismissed by the Court of Appeals for the Federal Circuit on the basis that the plaintiffs lacked standing.

Amgen v. Chugai[178] dealt with appeals and cross appeals involving issues of patent validity, infringement and inequitable conduct regarding two patents. Amgen Inc., owned the patent over purified and isolated DNA sequences that encode erythropoietin ("EP"), as well as host cells

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173 *Ibid.*
174 *Ibid.* at 8.
175 *Ex parte Allen*, 2 U.S.P.Q. 2d (BNA) 1425 (P.T.O. Bd. App. & Int. 1987).
176 *Ex Parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (Bd. Pat. App. & Int. 1985).
177 *Animal Legal Defence Fund v. Quigg*, 932 F.2d 920; 1991 U.S. App. LEXIS 7884; 18 U.S.P.Q. 2D (BNA) 1677.
178 *Amgen v. Chugai*, 927F. 2d 1200; 1991 U.S. App. LEXIS 3481; 18 U.S.P.Q. 2D (BNA) 1016 (U.S. Court of Appeals for the Federal Circuit).

transformed or transfected with a DNA sequence.[179] EP is a protein consisting of 165 amino acids which stimulates the production of red blood cells and thus is a useful therapeutic for the treatment of persons with anaemia or blood disorders resulting from defective bone marrow.[180]

One of the issues before the U.S. Court of Appeals was whether Amgen's patent was valid or whether there had been a prior invention.[181] In reaching its decision, the Court made the following classic statement:

> [a] gene is a chemical compound, albeit a complex one.[182]

Commentators suggest that this is the more appropriate way to treat DNA for purposes of patent law rather than to view it as a source or presenter of information.[183]

The U.S. PTO has issued patents over human DNA sequences, human cell lines, viruses, embryos, fœtuses, embryonic stem cells, animal cell lines (combining animal and human genes), multi-cellular transgenic animals, and human-animal chimeras.[184]

Reports to Government

In 1987, the U.S. Office of Technology Assessment issued a report entitled *New Developments in Biotechnology: Ownership of Human Tissues and Cells*.[185] The Report was requisitioned by two committees of the House of Representatives. It analyzed the economic, legal and ethical rights of the human contributors of tissues and cells, and of the researchers and physicians who obtain these materials and undertake research to turn them into commercially valuable products.[186]

The Report pointed out that any biomedical research and development using human materials rarely results in a profit-making product. In addition, any final product is most likely the culmination of human materials derived from "several individuals."[187] A calculation of the contribution made of any one individual to the final commercial product would be at best speculative.[188]

With respect to property rights, the Report noted that a patent issued by the U.S. government assigns exclusive rights to the patent holder and thus, the patent itself is considered personal property. The Report examined the various elements or property interests in the human body currently recognized by the law, such as the sale of replenishable bodily materials. It concluded that since no area of law definitively sets out the rights of individuals who donate bodily materials for academic or commercial research and since neither the common law nor legislation specifically addresses these questions, it is up to the judiciary to "handle emerging legal questions" by reference to principles and precedents developed for other circumstances, including the law of cadavers, the law of organ transplantation and the law of blood and semen sales.[189]

In 2004, the U.S. President's Council on Bioethics released a pre-publication version of its report entitled, *Reproduction and Responsibility: The Regulation of New Biotechnologies*.[190] The Report focused on biotechnology and assisted human reproduction, human genomic knowledge, and human embryo research. It contained a set of policy recommendations with respect to biotechnology for the U.S. President, but fell short of recommending federal oversight and regulation of these activities, in part because of the very controversial nature of the issues and the lack of consensus in American society.[191]

The Report noted that to date patents have been issued in the U.S. for modified human tissue and cell lines, as well as human DNA molecules. In the view of the authors, the grant of a patent created "a quasi property right" and the

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179 *Ibid.* at 1-2.
180 *Ibid.* at 2.
181 *Ibid.* at 4.
182 *Ibid.*
183 R. Stephen Crespi, "Patenting and Ethics: A Dubious Connection" (2001–02) 5 Bio-Science L. Rev., at 75.
184 Cyril R.Vidergar, "Biomedical Patenting: Permitted, But Permissible?" (2002) 19 Santa Clara Computer & High Tech. L.J. 253, at 261; see also Stacy Kincaid, "Oh, The Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research" (2003) 30 Pepp. L. Rev. 553, at 561.
185 U.S. Office of Technology Assessment, *New Developments in biotechnology: Ownership of Human Tissues and Cells* (Washington, D.C.: U.S. Government Printing Office, 1987).
186 *Ibid.* at iii.
187 *Ibid.* at 55.
188 *Ibid.*
189 *Ibid.* at 86-7.
190 President's Council on Bioethics, *Reproduction and Responsibility: The Regulations of New Biotechnologies* (Pre-Publication Version) (Washington, D.C.: President's Council on Bioethics, 2004).
191 *Ibid.* at xvii.

notion that a person might own a part of another person raised "deep worries."[192] The Report also made reference to the positive aspects associated with a patenting regime, especially the fostering of continued research, which has the potential to ultimately benefit the public. It recommended that Congress permanently amend the patent laws to prohibit the patenting of human embryos, or a human organism at any stage of development, and that Congress enact restrictions on the patenting of human gametes. It made no recommendations, however, regarding the patenting of other human bodily materials.[193] (Note that none of the recommendations have been implemented.)

The UK

In the UK, a patent application can be made to the national patent office ("PO") and/or to the EPO, by virtue of the UK's membership in the European Patent Organization. If the applicant only seeks patent protection in the UK, then he or she is only required to apply under the UK *Patents Act 1977* (as amended by the *Patents Act 2004*).[194] If, however, the applicant desires patent protection in a number of European countries, then it may be more efficient to apply to the EPO for a European patent.[195]

The UK *Patents Act* states in section 1 that to be patentable an invention must be new, involve an inventive step, be capable of industrial application, and not otherwise excluded under subsections 2 and 3. These subsections exclude from patentability: (1) a discovery, (2) an invention which would encourage offensive, immoral or antisocial behaviour, and (3) any variety of plant or animal or any biological process for the production of animals or plants (excluding micro-biological processes or their products). The phrase in section 1(2) "among other things" has been interpreted to mean that the list of excluded subject matter is not exhaustive and can be added to through case law.[196]

The *European Patent Convention*[197] has been ratified by the UK. A European patent is generally to be treated in the UK, or any other signatory to the *Convention*, in the same manner as a patent granted under domestic patent legislation. In effect, a European patent creates a series of parallel national patents, which are treated as if they originated from each national patent office of the designated state.[198] The *Convention* established the European Patent Organization which administers the EPO and an Administrative Council. The task of the European Patent Organization is to grant European patents through the EPO, which is supervised by the Administrative Council.

To be patentable under the *Convention*, an invention must be new, capable of industrial application, and involve an inventive step (article 52). Article 52 lists those items that are not considered inventions, including discoveries and presentations of information. In addition, surgical methods for treating the human or animal body, as well as therapy and diagnostic methods performed on the body are not patentable as inventions. However, substances or compositions used in these methods are patentable.

At the time of writing, the UK's *Human Tissue Bill* is currently before the House of Lords. Section 1 of the Bill would authorize certain activities related to the body of a deceased person or to excised bodily materials from a deceased or a living person, such as storage and use. In order to undertake certain activities, such as research using bodily materials, the researcher would have to obtain a licence and ensure that the proper consents have been obtained (s. 16(2)(c) and (e) and Schedule 1, Part 1, s. 6). The Bill would establish the Human Tissue Authority which has responsibility for licensing, preparing codes of practice and enforcing the Bill.

Section 32 of the Bill prohibits commercial dealings in human material intended for transplant. The Bill does not, however, contain any provisions to explicitly prohibit the payment of consideration in exchange for human bodily materials donated for research purposes. Furthermore, there does not appear to be another statue in the UK that expressly prohibits the payment for donations of human materials for research purposes.

Case law

In 1926, *Commercial Solvents v. Synthetic Products*[199] approved the first grant of a UK patent for a bacteriological

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192 *Ibid.* at 160.
193 *Ibid* at 181 and 202.
194 *Patents Act 1977*, c. 37, as amended by the *Patents Act 2004*, c. 16.
195 Young, et al., *supra* note 2 at 32.
196 *Ibid.* at 16.
197 *European Patent Convention*
198 Nuffield Council of Bioethics, *supra* note 3, at 15.
199 *Commercial Solvents v. Synthetic Products* (1926), 43 R.P.C. 185 [hereinafter referred to as *Commercial Solvents*].

process which used live bacteria to produce acetone.[200] Although *Commercial Solvents* confirmed the validity of a patent over a bacteriological process, the UK PO continued to refuse to grant patents for living organisms themselves, such as plants or bacteria.

In *General Electric Co., Ltd.'s Application,*[201] the Superintending Patent Examiner rejected an application for a patent over a process for artificially inducing mutations in micro-organisms using electric shock treatment. The rationale being that the process resulted in "artificial mutants of living organisms not specifically associated with manufacturing processes" and thus the process claimed was not considered an invention within the meaning of s. 101 of the UK *Patents Act*.[202] In reaching his decision the Superintending Patent Examiner wrote:

> I feel that the [Patent] Office, on the whole, has acted liberally in construing "manufacture" to include living matter, even though of a low order… I feel… that this should be the limit of construction of "manufacture" in this field, for I think that it is straining the term too far to include therein artificial mutants of living organisms not specifically associated with manufacturing processes.[203]

The appeal was dismissed by the Patents Appeal Tribunal. In reaching its decision, the Tribunal observed:

> This appeal illustrates one more facet of the difficult problem of the content of the expression "manner of manufacture" and is in part made more difficult because of the employment in the process of living organisms. A long established Patent Office practice has prevented the acceptance of claims directed to the treatment of the more advanced forms of life, a practice applied substantially by rule of thumb methods, derived from a time when the many gradations of living forms were not as fully appreciated as is now possible… In consequence Hearing Officers have apparently been disposed to seek some dividing line by which a division between higher and lower forms of living matter could be drawn with precision and thus to render the "rule" more convenient of application.[204]

In the Tribunal's opinion, there was no advantage in adopting any other test than what is provided in the Act. The Tribunal held that the process disclosed was not a manner of manufacture and thus was not patentable.[205]

The approach of the UK PO had been that a "manufacture" could not include living things or methods involving the treatment of living organisms. In 1973, however, the High Court in *American Cyanamid v. Berk Pharmaceuticals, Ltd*.[206] held that the subject-matter of the patent, a process using mutant strains of Streptomyces aurerfaciens to produce the antibiotic tetracycline, was an invention under the Act. The Court was urged to adopt the position that the *Patents Act* was not of "sufficient breadth" to cover a process involving a micro-organism and if such protection was to be granted over this process, it was up to Parliament to pass new legislation.[207] The Court, however, rejected that argument and held that the process at issue was a process intimately associated with trade and manufacture.[208] The UK PO has since issued patents over microbacterial strains, mutants and isolates of naturally occurring strains.

Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.[209] dealt with questions of patent infringement and patent validity under the UK *Patents Act* and the EPC. In 1984, a patent was granted to Kirin Amgen for:

> … a DNA sequence for use in securing expression in a prokaryotic or eukaryotic host cell of a polypeptide product having at least part of the primary structural configuration of that of a erythropoietin to allow

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200 *Re Application of Abitibi Co.* (1982) 62 C.P.R. (2d) 81 at 3 (Patent Appeal Board and Commissioner of Patents) [hereinafter referred to as *Abitibi*].
201 *General Electric Co. Ltd.'s Application* [1961] R.P.C. 21 (Superintending Patent Examiner) [hereinafter *General Electric*].
202 *Ibid.* at 23.
203 *Ibid.* at 22-23.
204 *Ibid.* at 25.
205 *Ibid.*
206 *American Cyanamid Co. v. Berk Pharmaceuticals Ltd.*, [1973] F.S.R. 487 (High Court of Justice — Chancery Division) [hereinafter referred to as *American Cyanamid*].
207 *Ibid.* at 512.
208 *Ibid.* at 513.
209 *Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.* [2002] EWCA Civ. 1096 (Supreme Court of Judicature Court of Appeal (Civil Division) (Lexum) Online: http://www.courtservice.gov.uk/judgmentsfiles/j1329/Kirin_v_Hoechst.htm. [hereinafter referred to as *Kirin*]

> possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells and to increase haemoglobin synthesis or iron uptake.[210]

As noted in the U.S. case *Amgen, supra*, EP is a protein that serves to regulate the body's production of red blood cells, which transport oxygen from the lungs to every tissue in the body. The inventor identified and located the nucleotide sequences that codes for human EP and, using genetic engineering techniques (recombinant DNA technology), produced substantial amounts of EP.[211] EP is important for use in both diagnosis and the treatment of human blood disorders. The U.K. and EPC patent was granted over both the process and the product.[212]

One of the issues before the Court of Appeal concerned the manner in which the inventor's work had been patented. The Court referred to article 5 in the *Directive* which states:

1. 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.

2. 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 if the structure of that element is identical to that of a natural element.

3. The industrial application of a sequence or a partial sequence of a gene must be disclosed in the patent application.

The Court noted that the EPO allows claims for products defined in terms of a process of manufacture; however, the product still must meet the criterion of patentability. Hoechst maintained that to be valid, the invention must be new and, in the case of a product-by-process claim, the claim can only be new if the product itself is new. In this case, Hoechst argued that the product was an "old article."[213]

The Court noted, however, that the *Directive* permits claims to biological elements as long as they are "isolated or otherwise produced by means of a technical process even if the structure of that element is identical to that of a natural element."[214] In the Court's view, the *Directive* clearly intended to cover biological elements such as polypeptides produced by a process. The Court of Appeal concluded that the patent was valid and had not been infringed.

Reports to Government

In July 2002, the Nuffield Council on Bioethics (the "Council") issued a discussion paper entitled, *The ethics of patenting DNA: a discussion paper*.[215] The Council was jointly funded by the UK Medical Research Council, the Nuffield Foundation and the Wellcome Trust. In 2000, it convened a group of experts (academics, lawyers, ethicists) to discuss the various ethical and social issues related to patenting DNA with the objective of producing a discussion paper, conclusions and recommendations, and ultimately fostering further discussion.[216] The *Paper* provides a detailed review of the patent system, explains human DNA and patenting, provides case studies, undertakes a discussion of the issues, and arrives at conclusions and recommendations to modify the patent system and to mitigate, what the authors considered, the "deleterious effects of patents" already granted.[217]

The *Paper* concludes that, with respect to the patenting of human genes, there is an insufficient degree of both "inventiveness" and "utility" to warrant the grant of a patent. In the future, the granting of patents over genes should become the exception rather than the norm.[218] The Council notes that the description of an association between a gene and a human disease is in reality a discovery. It writes that:

> … allowing property rights to be asserted over all uses, or even all diagnostic uses, of DNA sequences in relation to diagnostic tests gives inventors too great a

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[210] *Ibid.* at 18.
[211] *Ibid.* at 4.
[212] *Ibid.* at 15.
[213] *Ibid.* at 20.
[214] *Ibid.* at 22.
[215] Nuffield Council on Bioethics, *supra* note 3.
[216] *Ibid.* at v.
[217] *Ibid.* at 69.
[218] *Ibid.* at 69-70.

> monopoly in the light of the contribution and inventiveness of their product, may hamper innovation and may not, in fact, satisfy the legal criterion for patenting … [and] if left unchanged, will have a deleterious effect on the development and use of such tests.[219]

The Council recommends that the U.S. PTO, the EPO and the Japan Patent Office examine ways to more stringently scrutinize patent applications over DNA sequences for use in diagnosis.[220] It also recommends that these three patent offices consider limiting the scope of product patents, which assert rights over naturally occurring DNA sequences, to only the uses specified in the patent claims.[221] The Council also recommends that the granting of patents over gene fragments or partial sequences (such as an SNP or an EST) as research tools be discouraged.[222]

Australia

The *Australian Constitution* grants authority over intellectual property, including patents, to the Commonwealth Parliament. Pursuant to this authority, Parliament enacted the *Patents Act 1990* (Cth) and the *Patents Regulations 1991* (Cth) to govern patenting.

The Act establishes a Commissioner of Patents who has authority to grant a patent, upon application and examination by the Patent Office ("PO"). IP Australia, a branch of the Department of Industry, Tourism and Resources, has developed a *Patent Manual of Practice and Procedure* (the *Manual*) to assist patent examiners in applying the Act and Regulations. An applicant can apply for either a standard or an innovation patent. The latter form of patent would be granted for inventions and would have to meet the requirements of the TRIPS Agreement.[223]

Under section 18 of the *Patents Act 1990*, an invention may be patented if it: (1) is a manner of manufacture, i.e., appropriate subject-matter for a patent, (2) is novel, (3) involves an inventive step, (4) is useful, and (5) has not been secretly used in Australia prior to filing for patent protection. Section 18(2) excludes from patentability both human beings and the biological processes for their creation. This section has not yet been judicially interpreted and thus its scope remains uncertain.[224] The *Manual*, however, provides that the following are included in section 18(2): (1) human beings, fœtuses, embryos or fertilized eggs, (2) methods of *in vitro* fertilization or cloning methods for creating a human being, and (3) wholly biological processes (beginning with fertilization and ending with birth) to create a human being. The *Manual* also provides that section 18(2) does not apply to human genes, tissues and cell lines and thus they can be patented. Whether section 18(2) applies to human stem cell lines and stem cell technologies is not clear and this has been the subject of debate.[225]

Standard patents may be granted for plants and animals and for the biological processes that result in their creation.[226] Section 18(4) provides that microbiological products and processes are patentable.

An application for a standard patent can be refused where the Commissioner of Patents considers it would be contrary to law (s.50 (1) (a)). The *Manual* suggests that the Commissioner's discretion under this provision should be exercised only in the clearest of cases, and only where the "use" of the patent would be unlawful and there is no alternative lawful use described in the application.[227]

In Australia, genetic materials and related technologies are currently treated as "inventions" for which patent protection can be granted under the Act. The term "invention" is defined in the Act as:

> Any manner of new manufacture the subject of letters patent and grant of privilege within section 6 of the Statute of Monopolies, and includes an alleged invention.

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219 *Ibid.* at 70.
220 *Ibid.*
221 *Ibid.* at 73-4.
222 *Ibid.* at 71.
223 ALRC, *Final Report* (Genes and Ingenuity: Gene Patenting and Human Health) (Sydney: The SOS Printing Group Pty Ltd., 2004) at 94-96.
224 *Ibid.* at 177.
225 *Ibid.*
226 *Ibid.* 176.
227 *Ibid.* at 177-8.

On July 13, 2004, the Australian Deputy Commissioner of Patents decided a patent application for a culture medium and a method of growing pre-blastocyst human embryos.[228] The Deputy Commissioner rejected the claim to the method of growing pre-blastocyst human embryos on the basis of section 18(2) of the *Patents Act 1990.* It excludes human beings and their biological processes for generation from patentability.[229]

The applicant argued that a human being was created at fertilization and since the method claimed was subsequent to fertilization, it was not subject to section 18(2) of the Act.[230] The Deputy Commissioner considered that the method of generation claimed by the applicant was one step on the path to generating a human being. The term "process" in section 18(2) applies to biological processes from fertilization to birth as long as it is related to the generation of a human being. These processes include: fertilizing an ovum, cloning at the 4-cell stage by division and cloning by replacing nuclear DNA (reproductive cloning).[231]

Case law

The Australian courts have held that to determine the meaning of "invention," a policy-oriented approach should be adopted. In *National Research Development Corporation v. Commissioner of Patents*,[232] the issue before the Commissioner was whether a process for killing weeds could be considered an "invention" for the purposes of the *Patents Act 1990*. The High Court noted that in determining whether a process or a product is patentable, it would be a mistake to limit one's thinking that manufacture was limited to the notion of producing only tangible goods either by hand or machine. Instead, the Court noted that the word "manufacture" is not intended to be literally applied to a question of patentability, but is simply a "general title" in the Statute of Monopolies for the entire category under which all grants of patents made in accordance with principles of patent law must be subsumed.[233]

The Court held that the correct question to ask was whether this is a proper subject of letters patent according to the principles developed for the application of section 6 of the *Statute of Monopolies*. This, in the Court's view, was a very different question. A review of those principles demonstrated that what comes within the term "manufacture" has evolved over time. The Court cautioned against giving the term an exact meaning:

> To attempt to place upon the idea [manufacture] the fetters of an exact verbal formula could never have been sound. It would be unsound to the point of folly to attempt to do so now, when science has made such advances that the concrete applications of the notion which were familiar in 1623 can be seen to provide only the more obvious, not to say the more primitive, illustrations of the broad sweep of the concept.[234]

The Court concluded that for an "invention" to be a "manner of manufacture," it must belong to the useful arts rather than the fine arts, it must provide a material advantage and its value to the country must be in the field of economic endeavour.[235] With respect to the case before it, the High Court concluded that it was dealing with "a process producing its effect by means of a chemical reaction" resulting in a weed-free, or comparatively weed-free condition of the farm land and as such, it is properly described as a process.[236] The Court allowed the appeal and held that the process is properly the subject-matter of a patent under the Australian *Patents Act 1990*.[237]

The distinction between an invention and a discovery has arisen in the area of patent applications over genetic sequences. IP Australia's *Manual* noted that it is not possible to distinguish between a discovery and an invention. This issue first arose with respect to patent applications for micro-organisms. In *Ranks Hovis McDougall's Application*,[238] the Commissioner of Patents had to decide whether a genetically altered micro-organism

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228 Decision of A Deputy Commissioner of Patents regarding Patent Application 44916/99 in the name of Luminis Pty and Fertilitescentrum AB, and a proposed direction under s. 107 to delete certain claims, Issued 13 July 2004.
229 *Ibid.* at 1.
230 *Ibid.* at 1-2.
231 *Ibid.* at 9-10.
232 *National Research Development Corporation v. Commissioner of Patents* (1961) R.P.C. 135.
233 *Ibid.* at 142.
234 *Ibid.*
235 *Ibid.* at 146.
236 *Ibid.* at 147.
237 *Ibid.*
238 *Ranks Hovis McDougall's Application* [1976] 46 AOJP 3915 [hereinafter referred to as *Ranks Hovis*].

was a discovery or an invention. In holding that the micro-organism was an invention, the Commissioner noted:

> An objection that a claim to a new microorganism, being something living, is not a manner of manufacture is based, in my opinion, on too restricted a view of the meaning of manufacture in section 6 of the Statute of Monopolies.[239]

Since the decision in *Ranks Hovis*, the Australian PO has granted patents on newly created micro-organisms.[240]

The courts in Australia have had few opportunities to consider whether genetic materials and technologies fall within "manner of manufacture." IP Australia's *Manual* provides that the building blocks of living matter, including human DNA, which have been identified and copied from their natural source and reproduced synthetically as unique materials for a specific industrial use are not to be considered as discoveries for the purposes of the Act.[241] The *Manual* also provides guidance on the difference between a discovery and an invention in the case of gene patents:

> The discovery of a micro-organism, protein, enantiomer or antibiotic in nature can be claimed in its isolated form or as substantially free of (perhaps, unspecified) impurities. Also, a gene can be claimed as the gene *per se* (as long as the claim does not include within its scope the native chromosome of which the gene forms part) or as the recombinant or isolated or purified gene.[242]

Reports to Government

In 2002, the Australian government, concerned with the rapid advances in human genome research and genetic and related technologies, referred a number of questions to the Australian Law Reform Commission ("the ALRC") for inquiry and report. The terms of reference required the ALRC to, for example, examine and report back on "… the impact of current patenting laws and practices including licensing related to genes and genetic and related technologies on the conduct of research and its subsequent application and commercialisation."[243]

The ALRC's report, entitled *Genes and Ingenuity: Gene Patenting and Human Health* (the "Final Report"), was submitted to Parliament on August 31, 2004. In preparing the Final Report, the ALRC undertook extensive public consultations through the release of an "issues and discussion" paper for public comment.

The Final Report is quite comprehensive, covering topics that range from an overview of the history of patents to the patentability of genetic materials and technologies to challenging and enforcing patent rights. The terms of reference asked the ALRC to suggest changes that might be required of the Australian patent regime to address any problems, "… with the aim of encouraging the creation and use of intellectual property to further the health and economic benefits of genetic research and genetic and related technologies."[244]

In chapter 22 of the Final Report, the ALRC notes that there is some evidence that gene patents may, in the future, have an adverse effect on healthcare. The concern is that the exclusive licensing of patents over medical genetic tests will result in adverse effects with respect to cost, access, quality of the test, and innovation with regards to the development of new or improved testing techniques.[245]

The Final Report considers that one of the single most important concerns is the effects on research of patents on genetic materials or technologies that are used as research tools.[246] This is especially the case with respect to patents over research tools such as ESTs and SNPs and other isolated genetic materials. Some research tools may be categorized as "foundational" or "upstream" research tools. The following statement included in the Final Report captures the concern with patents over foundational research tools:

> The area covered by these patents is at the cutting edge of research. The owners have the power to limit or extend the amount of research done. By their selectivity

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239 *Ibid.* at 3918.
240 *Abitibi*, *supra* note 200, at 5.
241 ALRC, *supra* note 223, at 129.
242 *Ibid.* at 129.
243 *Ibid.* at 9-10.
244 *Ibid.* at 28-29.
245 *Ibid.* at 605.
246 *Ibid.* at 355.

> in granting licences, they may slow, or even halt, the discovery of further beneficial mechanisms.[247]

The Final Report recommends changes to the PO practice with respect to some research tools, such as ESTs. In addition, if these problems cannot be resolved by exercising current remedies, reform options to the address the impact of these patents would have to be undertaken. The Final Report notes that problems could be addressed through the use of the compulsory licensing and Crown use and acquisition provisions of the *Patents Act 1990*.[248]

Proposal 13-1 of the Final Report states that principles and guidelines should be developed by the Australian Research Council and the National Health and Medical Research Council to ensure that the public interest in encouraging commercial exploitation of inventions is balanced with the public interest in the wide dissemination of important research tools.[249]

6.4.3 Canada

The *Patent Act*

Section 91(22) of the *Constitution Act, 1867* assigns Parliament the exclusive legislative authority for "Patents of Invention and Discovery." In 1870, the federal government passed it first *Patent Act*. It authorized the creation of the Patent Office ("PO"), which is an agent of Industry Canada. The PO is part of the Canadian Intellectual Property Office ("CIPO"). The CIPO is responsible for patents and other forms of intellectual property, including trade-marks and copyright.[250]

Canadian patents may be granted by the Commissioner of Patents for new inventions (process, machine, manufacture, composition of matter), or any new and useful improvement of an existing invention. In order to be patentable, the invention must be new (first in the world), useful (functional and operative), and non-obvious to someone skilled in that area.[251] Patents will not be granted for a scientific principle, a method of doing business, a computer program or a method of medical treatment.[252] The Commissioner will not grant a patent for a "higher" life form, such as a seed, whole plant or animal. Since 1982, however, the Commissioner has granted patents over "lower" life forms, such as micro-organisms, fungi and single cells.

The *Patent Act*, unlike the EPC, the European *Directive*, and the UK *Patents Act*, does not contain an *ordre public* and morality exception to patentability. Previous versions of the Canadian Act contained a provision which exempted from patentability inventions for illicit objects. It was removed as part of a package of legislative amendments intended to bring the statute into compliance with the provisions of the NAFTA.[253] As a result, Canadian patent law does not provide the Patent Commissioner with discretion to exempt on the basis of morality.[254] The Act does, however, require that the grant of a patent be in accordance with the law. Section 40 provides that where the Commissioner is of the view that an applicant is not "by law" entitled to be granted a patent, he or she must refuse the application.

Case law

In 1982, the Canadian PO faced a similar claim to that considered by the U.S. Supreme Court in the 1980 case of *Chakrabarty*, *supra*. In *Abitibi*,[255] the Commissioner of Patents was asked to grant a patent over a genetically engineered life form, i.e., a mixed fungal yeast culture system.

In *Abitibi*, the Patent Appeal Board noted that the patent examiner had granted a patent to Abitibi Co. for the process biodegrading spent sulfite waste liquor from the manufacture of wood-pulp, but had refused to grant a patent for the product a microbial culture system acclimatized to spent sulphite liquor and having five principal fungi components. The application for a patent over the product was rejected because "living or viable matter" was not considered patentable since it could not be

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247 RNA-mediated interference is the inhibition of expression of specific genes by double stranded RNA (ds RNA): E Milward and others, *Submission P46*, 20 October 2003; ALRC at 357.
248 ALRC, *supra* note 223, at 372.
249 *Ibid.* at 375.
250 Canadian Intellectual Property Office, *A Guide to Patents* (Hull, Quebec: Canadian Intellectual Property Office, 2000) at 3.
251 *Ibid.* at 3.
252 *Ibid.*
253 The wording of the previous provision exempting products from patentability under the *Patent Act* was: "an invention that has an illicit object in view."
254 *Supra*, note 146, at 6.
255 *Abitibi*, *supra* note 200.

considered either a "manufacture" or a "composition of matter" under section 2 of the Act.[256]

The Appeal Board reviewed the relevant case law from other jurisdictions dealing with the patenting of living materials. The long-standing approach of the PO had been that living materials were not patentable. The decision in *Chakrabarty*, *supra*, however, was now seen as casting uncertainty on that position, since the U.S. Court concluded that the terms "manufacture" and "composition of matter" could extend to micro-organisms as products of "human's ingenuity having a distinctive name, character and use."[257]

The Appeal Board noted that technological advances have led patent offices around the world to alter their interpretation of statutory subject-matter in order to adapt to the new industrial realities. The Board recommended that the patent examiner's objections to patentability of fungi products be withdrawn. It recognized that the decision would have far reaching impacts, extending patentability to:

> … all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced en masse as chemical compounds… and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.[258]

The Board observed that there were no reasons for distinguishing between life forms when deciding the issue of patentability. It did, however, note that whether higher life forms, such as animals and plants, should be patented is debatable. In any event, it doubted whether an inventor of a higher life form could reproduce it at will and in a consistent fashion, since more complex life forms tend to have less consistency between individual members. If, however, an inventor was able to achieve consistency and all the other criterion of patentability were met, then the Appeal Board could not see why such an invention should be treated any differently.[259]

In *Pioneer Hi-Bred Ltd. v. Canada (Commissioner of Patents)*,[260] the Supreme Court of Canada was asked whether a new variety of soybean plant was patentable. The PO Examiner had refused Pioneer Hi-Bred's application for a patent over the plant, the pod and the seed. The reasons for refusal were based on the Examiner's view that the new plant did not fit within the definition of "invention" in section 2 of the *Patent Act* and on the PO practice of considering as non-patentable a process and a product that is a new genetic strain or variety of plant or animal.[261] Pioneer Hi-Bred appealed to the Patent Appeal Board which upheld the Examiner's decision and noted that the new plant variety did not qualify as a "manufacture."[262]

The Federal Court of Appeal ruled against Pioneer Hi-Bred finding that the new plant variety did not fit within the term "invention" in section 2 of the Act and that Pioneer Hi-Bred had not met the disclosure requirements of the Act.[263] The Supreme Court examined whether a new variety of soybean produced through artificial cross-breeding qualified under the *Patent Act* as an invention. The Court stated that the real issue is whether a form of life can be patented.

Pioneer Hi-Bred argued that the level of human intervention required to create this new plant variety allowed it to qualify for patent protection. The Court disagreed, holding that since the intervention by Hi-Bred did not in any way alter the soybean reproductive process, which follows the laws of nature, the process could not be the basis for a patent. Furthermore, the Supreme Court agreed with the Court of Appeal that Hi-Bred's depositing of seeds was not sufficient to satisfy the requirements of disclosure under the Act. Finally, the Court noted that since the *Patent Act* does not contain any provisions relating to biotechnological inventions and new forms of life, the new soybean plant variety is not currently patentable.[264]

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256 *Ibid.* at 2-3.
257 *Ibid.* at 5.
258 *Ibid.* at 6.
259 *Ibid.* at 6-7.
260 *Pioneer Hi-Bred Ltd, v. Canada (Commissioner of Patents)* (1989) 25 C.P.R. (3d) 257 (Supreme Court of Canada) (Lexis — CPR) [hereinafter referred to as *Pioneer*].
261 *Ibid.* at 3.
262 *Ibid.*
263 *Ibid.* at 4.
264 *Ibid.* at 9.

In *Harvard College v. Canada (Commissioner of Patents)*,[265] the Supreme Court of Canada was asked to determine whether the words "manufacture" and "composition of matter" in s. 2 of the *Patent Act* were broad enough to include higher life forms. Harvard College applied for a Canadian patent on both the process used to create its oncomouse and on the mouse itself. The Patent Examiner issued a patent for the process but refused to issue a patent for the oncomouse, on the basis that it was not an invention under the Act. Harvard College appealed the Examiner's decision to the Commissioner of Patents, who upheld the decision. The Trial Division of the Federal Court dismissed the College's appeal. The Federal Court of Appeal, however, allowed the College's appeal. The Commissioner of Patents appealed the decision to the Supreme Court of Canada.[266]

The five member majority of the Supreme Court considered that the key to the patentability of biological materials, including human materials, was to be found in the Act's definition of "invention." Using the principles of statutory interpretation, the majority considered that the terms "manufacture" and "composition of matter" were not capable of including animal and plant life."[267]

Justice Bastarache, writing for the majority, was of the view that the oncomouse could not easily be considered either a 'manufacture' or a 'composition of matter'."[268] These terms, used to define "invention," were not broad enough by the majority to include higher life forms. In the majority's view, human and animal life were more that mere compositions of matter. Furthermore, the majority opined that a patent over a higher life form would represent a significant increase in the scope of patent rights because higher life forms reproduce on their own, without human intervention, and any patent would thus be extended to the progeny. This increase in scope would not have been in keeping with the scope of patent rights granted in other fields.[269] The majority concluded that Parliament did not therefore intend the patenting of higher life forms.

An alternate view of the legislative scheme respecting patentability is found in the dissent. It interpreted the legislative scheme as permissive rather than restrictive. Justice Binnie, writing for the dissent, pointed out that Parliament, in 1993, indicated that value judgements have no place in decisions regarding patentability when it did not take the opportunity to amend the *Patent Act* to grant discretion to refuse patents on the basis of *ordre public* or morality. If an invention meets the criterion of patentability, i.e., useful, non-obvious and novel, the Commissioner must grant a patent. Justice Binnie noted that all of the distinctions or "proposed dividing lines" between different life forms for the purpose of determining whether a "composition of matter" is an invention and thus patentable, are misguided. Neither the Act nor the jurisprudence respecting patentability contemplated or provided a distinction between higher and lower life forms. Thus the distinction was merely an "invention of the PO," to narrow the definition of 'invention' to reflect policy positions.[270] This view of the legislative scheme confirmed that decisions respecting patentability made on the basis of morality or ethics have no place under the Act.

The dissent considered that section 40 of the Act was the only provision under which the Commissioner was granted discretion to reject a patent application. Binnie J. noted that the phrase "by law" in section 40 refers to more than just the *Patent Act* and would presumably include other legislation, as well as the *Charter* and the common law. He pointed to the common law principle that people cannot own other people to resolve the question of whether a human being could be considered as a patentable "composition of matter" for the purposes of the Act. If that principle was not sufficient, he suggested relying on sections 7 and 15 of the *Charter.* In his view, this question would not even arise under the *Patent Act* since it is addressed by these other laws.

The dissent held that:

> … the extraordinary scientific achievement of altering every single cell in the body of an animal which does not in this altered form exist in nature, by human

[265] *Harvard College v. Canada (Commissioner of Patents)* [2002] SCC 76, Online: LEXUM, <http://www.lexum.umontreal.ca/csc-scc/cgi-bin/disp.pl/en/pub/2002/vo14/html/2002scr4> [hereinafter referred to as *Harvard Mouse*].
[266] *Ibid.* at 2.
[267] *Ibid.* at para. 120.
[268] *Ibid.* at para. 155.
[269] *Ibid.* at para. 170.
[270] *Ibid.* at para. 47.

> modification of the genetic material of which it is composed, is an inventive 'composition of matter' within the meaning of section 2 of the *Patent Act*.[271]

Justice Binnie noted, however, that a patent does not give the inventor *carte blanche* to practice the invention free from government imposed regulatory controls.[272] The dissent considered that the oncomouse was patentable subject matter.[273]

It is interesting to note that both the majority and minority in *Harvard Mouse* observed in *obiter* that a fertilized, genetically altered mouse egg would be patentable subject matter.[274] The majority considered it an invention under the *Patent Act*, while the dissent would presumably have found it to be patentable subject matter unless otherwise excluded under section 40.

The case of *Monsanto Canada Inc. v. Schmeiser*[275] involved questions of patent infringement and scope. In 1993, Monsanto was granted a patent for genetically engineered genes and for cells containing those genes which when inserted into plants, such as canola, increased their tolerance to herbicides containing glyphosate. Fields planted with canola seed containing the patented gene could be sprayed with glyphosate herbicides, which killed any weeds, while leaving the canola plants undamaged. Farmers wishing to grow Roundup Ready Canola had to obtain a licence from Monsanto. Under the licence, the farmer could use the seed to plant a single crop and could sell that crop for consumption, but only to a purchaser authorized by Monsanto. The farmer could not sell or give the seed to a third party, or save the seed for replanting or inventory.[276]

Mr. Schmeiser never purchased Roundup Ready Canola. His farm was located in an area of Saskatchewan in which five farmers had switched to Monsanto's genetically modified canola. In 1998, Monsanto obtained a court order to conduct tests on Mr. Schmeiser's canola crop. The results showed that 95 to 98 percent of his 1,000 acres of canola crop was composed of Roundup Ready plants. Mr. Schmeiser claimed that the seeds had simply blown onto his land from the adjacent farms. The seeds grew into plants from which he collected the seeds and used them to replant his fields the following year.

The trial judge found that Monsanto's patent was valid. With respect to patent infringement, the trial judge found that Mr. Schmeiser knew or ought to have known that he had saved and planted seed containing the patented gene and cell, and he had sold the resulting crop. In other words, Mr. Schmeiser had infringed Monsanto's patent. The Federal Court of Appeal confirmed the trial court's finding with respect to Mr. Schmeiser's infringement of the patent, but did not comment on the patent's validity.[277]

The case was appealed to the Supreme Court of Canada. A five member majority of the Court adopted an expanded view of the *Patent Act's* legislative scheme with respect to questions of infringement. It is interesting to note that the majority in *Monsanto* was composed of some of the same members who had been part of the dissent in *Harvard Mouse*. The majority identified the following issues: (1) whether Mr. Schmeiser's acts of saving, planting, harvesting and selling the crop containing the patented gene and plant cell constituted a "use" of Monsanto's invention contrary to the *Patent Act*, and (2) whether Mr. Schmeiser used the patented invention in commercial or business interests.

The majority decision was coauthored by Chief Justice McLachlin and Justice Fish. The majority stated that it would decide the case by applying the established principles of patent law to the facts before it.[278] At the outset, the majority noted that it was not concerned with the scope of the patent granted to Monsanto nor with questions as to the wisdom of patenting genetically modified cells and genes, rather those were matters falling within the purview of Parliament. Although the majority expressly stated that its decision was not with respect to the scope of Monsanto's patent,[279] its approach of applying patenting principles established in the manufacturing

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271 *Ibid.* at para. 8.
272 *Ibid.* at para. 4.
273 *Ibid.* at para. 115.
274 *Ibid.* at paras. 3 and 162.
275 *Monsanto Canada Inc. v. Schmeiser* [2004] 1 S.C.R. 902. Online: http://www.lexum. Umontreal.ca/csc-scc/cgi-bindisp.pl/en/rec/html/2004scc034.wpd.htm. [hereinafter referred to as *Monsanto*]
276 *Ibid.* at para. 11.
277 *Ibid.* at 2.
278 *Ibid.* at paras. 2 and 3.
279 *Ibid.* at para. 2.

context to biological materials arguably had the effect of expanding the scope of the patent for the purposes of infringement. The majority applied the following principle:

> [W]here a defendant's commercial or business activity involves a thing of which a patented part is a significant or important component, infringement is established. It is no defence to say that the thing actually used was not patented, but only one of its components.[280]

By applying this principle to the facts of the case, the majority found that Mr. Schmeiser's unlicensed collecting, saving, planting of the seed (containing the altered gene), and his harvesting of the resulting crop (containing the patented gene and cell) to his advantage constituted "use" and thus an infringement of Monsanto's patent.[281] Monsanto's patent covered processes, including the method of regeneration, the chimeric genes, and the modified cells. Monsanto was not seeking a patent over the whole plant. The majority noted that "… a defendant infringes a patent when the defendant manufactures, seeks to use, or uses a patented part that is contained within something that is not patented, provided the patented part is significant or important."[282]

In this case, the majority found that the patent covered the cells and genes that compose the entire plant. Thus, infringement through use is possible where the patented invention is part of, or composes, a broader unpatented structure or process. This expansive rule was based on the principle, established in the patent and manufacturing context, of ensuring that a patentee cannot be deprived, even in part or indirectly, of his or her legal right to the full enjoyment of the monopoly. The application, by the majority, of this patent rule/principle to biological materials could be viewed as expanding patent protection from unlicensed use to a higher life form, i.e., a plant, when it is substantially composed of a patented invention, i.e., patented cells.[283]

Schmeiser had argued that the application of Monsanto's patent should be narrowly construed based on the majority decision in *Harvard Mouse* since the plants reproduce on their own, through the laws of nature. Propagation of the plant without a licence cannot therefore be a use by others because the plants are living things growing and reproducing without human intervention. The majority rejected this argument, noting that although other jurisdictions have adopted provisions to distinguish between unpatentable naturally occurring DNA sequences in the human body from patentable isolated DNA sequences, Parliament has not enacted a comparable statutory scheme to narrow the scope of patent construction.[284]

The majority stated that the restrictive approach adopted by the courts in the UK to exclude from patentability the naturally occurring form of DNA sequence in the body's cells was based on a regulatory scheme for which there was no equivalent in Canada.[285]

A final view of the Act's legislative scheme respecting infringement can be found in the partial dissenting opinion written by Justice Arbour. The dissent considered that the central issue was whether a patented product (the gene or the cell) extended patent protection to the unpatentable object into which it was incorporated, i.e., the canola plant.[286] It is interesting to note that three of the four person dissent in this case had formed part of the majority in *Harvard Mouse*, *supra*. It comes then as no surprise that the dissent advocated a restrictive approach to the scope of the patent for infringement purposes. The dissent narrowed the scope of Monsanto's patent by limiting its application solely to the laboratory.

In Justice Arbour's view, the patent over the chimeric gene and cell did not extend patent protection to the unpatentable plant which contained them.[287] The dissent

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[280] *Ibid.* at para. 78.

[281] One could argue that *Monsanto*'s majority decision, by applying patent principles developed in the manufacturing context, extended patent protection from unlicensed use to a higher life form, i.e., an unpatented plant substantially composed of genetically altered patented cells.

[282] *Monsanto, supra* note 275, at para. 42.

[283] Three of the five member majority in *Monsanto, supra*, formed the dissent in *Harvard Mouse, supra*. In that case, the dissent disapproved of the PO's distinction between lower and higher life forms for the purposes of patentability. It advocated following the approach to patentability set out in the *Patent Act*. One might argue that the majority in *Monsanto* by extending patent protection to an entire plant is in fact signalling an end to the PO's distinction between higher and lower life forms.

[284] *Monsanto, supra* note 275, at para. 89.

[285] *Ibid.* at para. 89.

[286] *Ibid.* at para. 156.

[287] *Ibid.* at paras. 138 and 139.

considered that a patent would be invalid if the claim encompassed subject matter that was not patentable, in this case, a whole plant.[288] Monsanto's claims were found to be valid because they fell short of claiming patent protection over the whole plant, i.e., a higher life form incapable of patent protection.[289] The difficulty being that the plant can propagate without human intervention.

The dissent considered that the patent claim over the plant cell ceased to apply once the cell containing the chimeric gene was placed in growth medium to begin regeneration in the laboratory.[290] Arbour J. acknowledged the difficulties encountered in trying to fit self-replicating biological materials within the confines of the *Patent Act* and considered that they warranted adopting a novel approach.[291] The dissent restricted the scope of the patent, for infringement purposes, by holding that it was valid only for the genetically modified chimeric genes and cells in the laboratory, prior to regeneration.[292]

The dissent concluded that Mr. Schmeiser had not infringed Monsanto's patent by saving, planting, or selling seed from the plant, since the patent did not extend to the plant itself.[293] Despite this restriction, Justice Arbour noted that the patentee would still control the use of the seed and could prohibit the saving of seeds from the plants through the licensing powers granted to them under the Act.[294]

Reports to Government

THE STANDING COMMITTEE ON HEALTH

In 2001, the House of Commons Standing Committee on Health, while reviewing the proposed *Assisted Human Reproduction Bill*, recommended in its report back to Parliament that: "The *Patent Act* be amended to prohibit patenting of humans as well as any human materials."[295] This recommendation was not adopted by Parliament.

THE CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE

The Canadian Biotechnology Advisory Committee (the "CBAC") is an arms-length advisory group to the federal government. It is composed of scientists, academics, physicians, ethicists, and stakeholders. The mandate of the CBAC is to provide advice to the government on policy issues associated with the ethical, legal, social, regulatory, economic, scientific, environmental and health aspects of biotechnology.

In 2002, the CBAC released its report, entitled *Patenting of Higher Life Forms and Related Issues*.[296] The key issue addressed by the *Report* was whether Canada should permit the patenting of plants, seeds, and animals. It also examined the patenting of biological material generally.[297] The *Report* provided the federal government with thirteen recommendations. In arriving at its recommendations, the CBAC consulted with key non-governmental organizations, scientists and industry, as well as with the public through roundtable discussions held across the country in the spring of 2001 and through written input.[298]

The *Report* observed that in Canada there could be existing legal limits on a patentee's ability to exploit their invention, especially where that invention may pose risks to human or animal health or to the environment. Some of these legal limits are found in competition law, criminal law, the *Assisted Human Reproduction Bill* and in regulations governing product safety.[299] The position of the PO is that patents will not be granted for "higher life forms," which it describes as "multi-cellular differentiated organisms (plants, seeds and animals)."[300] This position is primarily what led to the challenge in *Harvard Mouse*, *supra*.

The *Report* suggested that questions of the patentability of higher life forms, such as the human body, should be dealt with by Parliament. In the CBAC's view, a patent on the human body would indicate a lack of appropriate respect for the subject-matter of the patent: it would engage the universal principle of basic human dignity. The *Report* emphasized one aspect of the principle of

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288 *Ibid.* at para. 138.
289 *Ibid.*
290 *Ibid.* at para. 130.
291 *Ibid.* at para. 154.
292 *Ibid.* at paras. 138 and 139.
293 *Ibid.* at para. 162.
294 *Ibid.* at para. 163.
295 House of Commons Standing Committee on Health, *Assisted Human Reproduction: Building Families* (2001), recommendation 34.
296 CBAC, *supra* note 296.
297 *Ibid.* at 2.
298 *Ibid.* at 6.
299 *Ibid.* at 7.
300 *Ibid.* at 10.

human dignity human beings are not commodities. It suggested that even if the granting of a patent on a human being was not a violation of human rights, the patentee's "exclusive right to make, use or sell an invented human would almost certainly violate the *Canadian Charter of Rights and Freedoms* and the Ca*nadian Human Rights Act*."[301]

With respect to the rights of the inventor to patent protection, the Report noted that this position ignores the real purpose of patent rights. Patent rights are best viewed as tools to achieve public good. The CBAC quoted Mr. Justice Jackson of the U.S. Supreme Court who in 1945 stated:

> The primary purpose of our patent system is not reward of the individual but the advancement of the arts and sciences. Its inducement is directed to disclosure of advances of knowledge which will be beneficial to society; it is not a certificate of merit, but an incentive to disclosure.[302]

If Canada decided to issue patents over higher life forms, the *Report* recommended that Canada's *Patent Act* be amended to prohibit the patenting of human bodies at all stages of development. This exemption would, however, only apply to patents claimed over the whole human body. The *Report* was careful to point out that such an exemption would still permit the granting of patents for sperm, ova, organs, human genes, cell lines and stem cells, since it is unlikely that such a patent would grant the patentee complete control over a human body containing that sequence or cell. However, it cautioned that this issue has never been addressed under the law.[303]

The *Report* recommended that higher life forms, i.e., plants, seeds and non-human animals, that meet the patentability criterion of new, useful and non-obvious be recognized as patentable.[304] However, this recommendation must be read together with the other recommendations in the *Report*, since they place limitations on patents for biological inventions, including protections for farmer's privilege, innocent bystanders, research and experimental use exceptions. The CBAC's rationale for imposing such limits was the unique reproductive nature of biological inventions and the fact that they can contain personal information. An unrestricted patent in a higher life form would grant to the patentee rights that could inhibit other useful activities, such as other research.[305]

The *Report* discussed the social and ethical considerations that arise when researchers and clinicians obtain biological materials from individuals. It recommended that the federal and provincial governments in Canada develop policies and practices that encourage the sharing of benefits reaped from research involving genetic material. The *Report* stated:

> … we recommend that… the benefits of medical and pharmaceutical research based on human genetic material (including its commercial exploitation) be shared with the groups or communities who provided the material. All bodies (public, private and corporate) involved in funding research and/or establishing guidelines or codes of conduct for the ethical conduct of research should ensure that benefit-sharing is addressed.[306]

In addition, the *Report* recommended that the PO issue guidelines on the patentability of biological materials.[307] A few of the CBAC's recommendations were implemented by the government, but none of the major recommendations discussed above have been implemented to date.[308]

In 2004, the CBAC issued an advisory memorandum to the federal government entitled "Rationalizing Patent Law in the Age of Biotechnology."[309] One of the stated

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301 *Ibid.* at 13.

302 *Sinclair & Carroll Co., Inc., v. Interchemical Corporation* 325 US 327 (1945) at 330-31 in Canadian Biotechnology Advisory Committee, *Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee* (June 2002) at 12, Online: http//cbac-cccb.ca/epic/internet/incbac-cccb.nsf/en/ah00188e.html. Accessed June 2004.

303 *CBAC*, *supra* note 296, at 12.

304 *Ibid.* at 16.

305 *Ibid.* at 16.

306 *Ibid.* at 23.

307 *Ibid.* at 26.

308 CIPO's Annual Report includes service standard and performance information (CBAC recommendation 11) while the PO Manual of Patent Office Practice is being updated in an on-going manner, as per CBAC recommendation 10.

309 Canadian Biotechnology Advisory Committee, "Rationalizing Patent Law in the Age of Biotechnology" (Ottawa: CBAC, 2004). Online: http://www.cbac-cccb.ca.

purposes of the memorandum was to alert the government to issues of immediate importance and to provide recommendations to assist decision-makers in developing an effective course of action. The CBAC recommended:

> The Federal Government should move quickly to review the *Patent Act* in light of the combined effects of the decisions of the Supreme Court of Canada on the patentability of the "Harvard mouse" and on the extent of the rights of a patent-holder of a modified cell in the recently-decided *Monsanto Canada Inc. v. Schmeiser* case.

The CBAC memorandum restated the same twelve recommendations found in the CBAC's 2002 report.

The Provinces

In 2002, the province of Ontario released its report entitled *Genetics, Testing & Gene Patenting: Charting New Territory in Healthcare*.[310] The Ontario Report was endorsed by all the provincial and territorial premiers at their meeting in January 2002. It referenced the Standing Committee's recommendation to amend the *Patent Act,* but did not endorse it.[311] The Report recommended instead a comprehensive review of the Act and put forward a number of suggested amendments, including the introduction of an opposition period, additional infringement protection for healthcare providers, tightening utility requirements and restricting broad-based patents.[312] It noted that genetic materials are unique and can have multiple research uses. It suggested that granting patents over "concepts" or general, non-specific utilities in the area of genetic materials could be problematic since it can eventually impede research and development. The Ontario Report recommended tightening the scope of patents granted for genetic material by requiring that specific uses of sub-gene and stem cell patents be identified in the application and patent grant.[313]

It also recommended the addition of a provision to the Act, similar to an *ordre public* and morality provision, to limit patents on processes or procedures that are deemed contrary to Canadian morality or ethics. In addition, it recommended the addition to the *Patent Act* of an exclusion from patentability medical diagnosis using genetic materials.[314]

The Report also recommended replacing the current 'methods of medical treatment' exclusion from patentability, created by the common law, with a provision stating that a patentee cannot bring an action for infringement against a medical practitioner for providing medical services, including both treatment and diagnosis, to patients.[315] It noted that adopting this approach, similar to that provided by a recent amendment to the U.S. *Patent Act*, would protect medical practitioners while still allowing the full patenting of genetic testing technologies.[316]

6.4.4 Academic Literature and Commentary

There is scant literature on the topic of human rights and patents over human bodily materials and the literature that does exist is mostly from the U.S.

Cyril R. Vidergar explores issues arising from the patenting of human materials in an article entitled, *Biomedical Patenting: Permitted, But Permissible?*[317] Vidergar is concerned that the lack of provisions in the U.S. *Patent Act* exempting human or human-derived materials from patentability may eventually cause Congress to legislate to ameliorate any potential threats to human dignity and autonomy.[318] He views bio-piracy (the taking of genetic material without a subject's knowledge) as impacting on constitutionally guaranteed rights under the 13th and 14th amendments, since it results in non-consensual commodification. He concludes that persons residing outside the U.S. are similarly protected from biological commodification under international laws and human rights treaties, such as the U.N. *Convention on Biological Diversity*, to which the U.S. is a signatory.[319] Vidergar notes, however, that despite these treaties and laws, the U.S. patent regime protects property right's claims to human materials derived without consent outside U.S. jurisdiction. He is concerned that there is no forum that

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310 Charting New Territory, *supra* note 26,
311 *Ibid.* at iii and 31.
312 *Ibid.* at iii.
313 *Ibid.* at xi.
314 *Ibid.* at xii.
315 *Ibid.* at 51.
316 *Ibid.* at 51.
317 Vidergar, *supra* note 184.
318 *Ibid.* at 266.
319 *Ibid.* at 268-69.

would allow for the redress of what he terms "these potential violations of human autonomy."[320]

He is also concerned with the effect biomedical patents may have on healthcare. For example, the inventor of a cell line that contains a particular gene may prevent others from similarly isolating an expression of that gene. Patentees may also charge exorbitant licensing fees for the use of their biomedical inventions, thus limiting the patients who can access a patented treatment or diagnostic to only those with a certain income level.[321]

Stacey Kincaid writing in *Oh, The Places You'll Go: The Implications of Current Patent Law on Embryonic Stem Cell Research*,[322] notes that in the U.S. a patent has been granted (Patent 6,200,806) to the University of Wisconsin's Wisconsin Alumni Research Foundation (the "WARF") over a method of isolating embryonic stem cells, as well as the stem cells themselves. She notes that this patent is the only one of its type in the world. The WARF has also applied for patents in Europe.[323] The isolated and patented stem cells have subsequently been developed into six distinct types, including: blood, liver, muscle, nerve, bone and pancreas cells.[324]

Kincaid refers to concerns with stem cell patents as essentially "ethical" and concludes that they arise because of the moral or special nature of the human embryo from which they were derived. She notes that some critics oppose the granting of these patents because they are patents over "life." She concludes, however, that these objections are largely "political in nature."[325]

R. Stephen Crespi provides a critique of the UK Nuffield Council Report (discussed earlier), in *Patenting and Ethics: A Dubious Connection*.[326] He notes that the Council believes that gene patents should be considered differently from other patents because of the issue of "ownership."[327]

In Crespi's view, the Council's Report erroneously equates a gene patent with gene ownership. He notes that a researcher who invented novel biological material would own it, regardless of whether he held a patent over it or not. Patent rights are different than ordinary property rights. A patent gives the patentee a right to exclude others from making, selling or using his or her invention for a time period fixed by law. In a legal action for patent infringement, the patentee does not assert that he or she owns the defendant's material, unlike a case of theft. If the defendant is found to have infringed the patent, he or she would most likely be required to pay damages to the patentee by, for example, an accounting of profits. This penalty for patent infringement is not in any way related to ownership of the infringing material."[328]

In the context of genes, Crespi notes that a person with a patent over DNA "owns" only the right to petition the court to stop other's unauthorized use of the isolated form of the claimed DNA.[329]

Crespi also discusses the Nuffield Report's assertion that "genes are essentially just information" and thus "the issue of patenting them [is] very different from that involved in the isolation of other chemical compounds."[330] In Crespi's view, this categorization of DNA would not stand up to legal analysis. He makes reference to the American case of *Amgen v. Chugai*[331] for the "classic statement" from the Court that "a gene is a chemical compound, albeit a complex one."[332]

There is no shortage of academic commentary highlighting moral and ethical concerns with the practice of patenting human genes. Some commentators start from the position that the human genome is the "common heritage of humanity."[333] This position is supported by the UNESCO *Declaration on the Human Genome and Human Rights*. Patents on human gene sequences are criticized because they are thought to grant exclusive rights over this common heritage to a limited number of entities.[334]

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320 *Ibid.* at 269.
321 *Ibid.* at 269-70.
322 Stacey Kincaid, *supra* note 184.
323 *Ibid.* at 572-73.
324 *Ibid.* at 573.
325 *Ibid.* at 578.
326 Crespi, *supra* note 183.
327 *Ibid.* at 72.
328 *Ibid.*
329 *Ibid.*
330 *Ibid.* at 75.
331 *Amgen v. Chugai* (1989, 1991), 13 *US Patent Quarterly* 2d 1737 to 1797 and 18 *USPQ* 2d 1017 to 1031.
332 Crespi, *supra* note 183, at 75.
333 For a full discussion see B. M. Knoppers, "Status, Sale and Patenting of Human Genetic Material: An International Survey" (1999) 22 Nature Genetics 23.
334 *ALRC*, *supra* note 4.

Other commentators are concerned that allowing patents on human genes will engender a lack of respect for human dignity. Patents, by bringing the human body and its parts to the market, lead to the commodification and objectification of the human body. Commodification and objectification have been described as:

> Commodification refers to the association of something or some practice with attitudes that ordinarily accompany a certain subset of commercial transactions. Objectification similarly refers to the act of treating someone, or something, as a commodity, but what is disturbing is not so much the exchange of money as it is the notion that a subject, a moral agent with autonomy and dignity is being treated as if it can be used as an instrument for the needs or desires of others without giving rise to ethical objections.[335]

The central concern being that the patenting of human biological materials, along with the associated transformation of these into routine objects of commerce, leads to a change in people's attitudes toward life and living organisms.[336]

There are some commentators who argue from a property perspective. For them, genes can be conceptually divided into two distinct entities: the DNA sequences themselves, and the genetic information they contain. The legal status of these two entities has not yet been settled in law. It is thought that the characterization of genes as either property, human beings, or some other legally recognized entity, will have enormous implications.[337] "These include symbolic and psychological implications that go to the very root of how human beings view themselves."[338] If genetic material is characterized as part of or as an extension of the human being from which it originated, then the law pertaining to persons could be held to regulate and protect the material. On the other hand, if the genetic material is characterized as property, then the law of property would most likely be found to regulate and protect it.[339]

It has been argued that patents over genes are incompatible with respect for an individual's self-determination (the right to make choices about how to live) because they grant ownership rights over parts of human beings.[340] Furthermore, self-determination is fundamentally linked to self-ownership (the right to choose how one's body is used) and thus granting a patent over genetic material is likened to allowing parts of people to be owned by others.[341] This argument has been criticized for confusing intangible intellectual property rights, in the form of patents, and physical property rights.[342]

6.4.5 Discussion

Under the *Patent Act*, the Commissioner must grant a patent if the "invention" meets the criterion of newness, non-obviousness and usefulness. In *Harvard Mouse*, *supra*, the five person majority upheld the PO's distinction between higher and lower life forms for the purposes of patentability, despite the fact that no such distinction exists in the Act.[343]

The dissent rejected the distinction and would have allowed the patent over the oncomouse.

A more recent case suggests that the members of the Supreme Court remain divided in their approach to questions of patentability and infringement with respect to biological materials. The majority in *Monsanto, supra*, held that the patent only applied to the chimeric gene and the plant cells into which the gene was inserted. However,

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335 T. Schrecker & a. Wellington, "Patenting of Biotechnological Innovations Concerning Animals and Human Beings" at 31.

336 *Ibid.* at 33.

337 M. Litman & G. Robertson, *supra* note 96, at 51.

338 *Ibid.*

339 *Ibid.* at 51-52.

340 Resnik, *supra* note 40, at 155-159 (quoted in *ALRC*, *supra* note 4, at 52).

341 *ALRC*, *supra* note 4 at 53-54. The authors also note at page 54 that this argument has been criticized.

342 *Ibid.*

343 One can argue, however, that the line between higher and lower life forms can be seen to have evolved in the case law. Beginning in *Abitibi, supra*, the Patent Appeal Board espoused that all new life forms produced en masse as chemical compounds and in such large numbers that "any measurable quantity will possess uniform properties and characteristics" would be patentable. The Board expressed doubts that an inventor of a higher life form could reproduce it at will and in a consistent manner. However, if he or she could, then it might be patentable. In *Pioneer Hi-Bred, supra*, the Court rejected a patent application for a new variety of soybean plant on the basis that the inventor had not altered the plant's reproductive process, it still followed the laws of nature, and thus the process could not be patented. Finally, in *Harvard Mouse, supra*, the Court majority opined that a patent over a higher life form would represent a significant increase in the scope of patent rights. Not only would the patent rights apply to the patented invention but also to its progeny since higher life forms reproduce on their own without human intervention. The scope of patent rights would not be consistent with rights granted in other fields.

since the gene and cells were in every part of the plant, any uses made of that plant would infringe the patent. As a result of the decision, the entire plant (a higher life form) is effectively protected from unlicensed use by the patent over its composite cells and genes. The dissent would have restricted the patent solely to uses in the laboratory since the plant, a higher life form, is capable of propagating on its own.

The Courts decision in *Monsanto, supra,* arguably means that Harvard's oncomouse, which is substantially composed of patented genetically altered genes, would also be protected from unlicensed use. As a result of *Monsanto* and *Harvard College*, higher life forms, although not patentable subject matter, would be the subject of patent protection from the unlicensed use of the plant or oncomouse.

If in the future, the Canadian courts reversed and adopted a more expansive approach to the scope of patentability, and rejected the distinction between higher and lower life forms, concerns with the inability to exempt certain biological materials from patentability under the *Patent Act* might force the issue before Parliament.

6.4.5.1 Could the grant of a patent over excised bodily materials raise any human rights issues?

Advances in biotechnology in the area of science and medicine will continue to push the existing boundaries of patentability and will most likely result in patented inventions using human materials in ways not yet contemplated. It is possible that some of these patented inventions will raise human rights issues, especially if the patent limits a person's autonomy and self-determination.

It is possible to grant a patent for the process of isolating and characterizing a human cell, such as a liver cell. No one else, including the donor, could use or patent that particular cell, arguably even for a different use, without first obtaining a licence from the patentee. Could the grant of such a patent raise any human rights issues?

The following hypothetical is used to illustrate some of the issues that may arise. The hypothetical may be considered by some as mere "science fiction," but in fact much of the science described is within the realm of possibility today.

> Jane Doe fully and freely consents to donate her liver cells for research purposes. The researcher successfully isolates and uses Jane's cells to invent a cell line with the potential to develop cures for individuals with cirrhosis of the liver. The researcher applies for and is granted a patent over the process (isolation, characterization and expression) and over the resulting cell line. Five years later, Jane Doe develops serious liver disease. Her physician would like to isolate Jane's liver cells and have a personalized cure developed for Jane.

Her physician requests a licence from the patentee in order to use the patented process to successfully isolate Jane's cells, but the patentee refuses to grant the requisite licence.[344] If her physician proceeds, without a licence, the patentee has a right under the *Patent Act* to bring an action in court against the physician and possibly against Jane for patent infringement. In addition, the patentee may seek an injunction restraining Jane and her physician from using the patented process (sections 54(1) and 57(1)(a) of the *Patent Act*). Jane and her physician believe that the inability to use the patented process to successfully isolate her cells to possibly create a life-saving therapy engages Jane's human rights.

***Relief under the* Patent Act**

Under section 19, a government may seek authorization from the Patent Commissioner to use the patented invention, which includes a patented process. However, the authorization to use obtained by the government under section 19 is not transferable. Moreover, the government must establish that it made attempts in the past, over a reasonable period of time, to obtain authority to use the patented invention from the patentee, unless it establishes

[344] Under section 19(1) of the *Patent Act*, the Patent Commissioner on application by the federal or a provincial government may authorize the use of a patented invention by that government. The Commissioner would have to be satisfied that the applicant (government) made efforts to obtain authority from the patentee to use the invention (s. 19.1), unless it is a case of national emergency or extreme urgency or is a public non-commercial use (s. 19.1(2)). The commissioner's decision under these sections may be appealed to the Federal Court (s. 19.2). Section 65 of the Act sets out a similar provision, however, three years must have passed since the grant of the patent before it can be relied on. After the requisite three years, the Attorney General of Canada or any person interested may apply to the Commissioner alleging that the patentee has abused his or her exclusive rights granted under the patent and seek relief under the Act.

that the use is required because of national emergency or extreme urgency or where the use required is a public non-commercial use (s. 19.1). It is possible that the government could make a good argument that Jane's case is one of "extreme urgency" and thus succeed in obtaining a licence from the patentee.

In addition, under section 65 of the Act, the Attorney General of Canada or any person may apply to the Commissioner alleging that the patentee has abused his or her exclusive rights and ask for relief under the Act, but only after the expiration of three years from the date on which the patent was issued. This provision presents a less attractive option for Jane and her physician because they must wait the requisite three years to apply.

Finally, under the research exemption, a researcher could be commissioned by Jane to study the patented process without first obtaining a licence from the patentee. The researcher would hopefully be able to design his or her own method of successfully isolating the cells and creating a cure for Jane. The research exemption presents another option, but once again it requires time to study the patented process and hopefully to succeed in inventing an equally successful one.

A Human Rights Challenge

Jane believes that the ability of the patentee to prevent her from accessing a possible cure engages her right to health, liberty and security of the person. Jane could look to international human rights instruments for relevant human rights standards.

With respect to a right to health, the most relevant human rights instrument is the ICESCR, specifically articles 12 and 15. Article 12 provides a fundamental right to the enjoyment of the highest attainable standard of health. It contains the most important recognition of the right to health in an international convention.[345] The U.N. Committee's Commentary on article 12 suggests that the right to health contains both freedoms and entitlements. The freedoms include the right to control one's health and body, and the right to be free from interference.[346] These articles and any relevant commentary could be put before the Canadian courts to inform their interpretation of the *Charter* and of the *Patent Act*.

In addition, the ICESCR provides a right to benefit from scientific progress in article 15, paragraph (1)(b). Committee Commentary on this article suggests that the fundamental human rights of the person should prevail over the rights of the patentee set out in article 15, paragraph (1)(c). As noted earlier, there is scant academic literature or commentary on this provision. The Committee of the ICESCR is currently preparing a draft Commentary to assist States Parties in their interpretation of the article.

The Committee of the ICESCR has made it clear in the past that there is a distinction to be made between fundamental human rights and intellectual property rights, which are the product of instrumental and temporary regimes created by the State. One could argue that article 15 imposes an obligation on States to adopt an approach to intellectual property rights which ensures the primacy of human well-being. Fundamental human rights which are timeless should trump intellectual property rights, which are generally of a temporary nature and which can be revoked, licensed or assigned to someone else.

An argument could be made that an exception to infringement should be recognized to allow Jane and her physician to use the patented process to extract and isolate her liver cells, without a licence, on the basis of medical necessity. The patent is preventing Jane from accessing a possible medical cure that would possibly enable her to enjoy the highest attainable standard of health: she is unable to submit to a personalized cure that could return her to optimum health.

6.4.5.2 Could the grant of a patent over a process for isolating excised human materials engage any human rights under the *Charter*?

***The* Charter**

The *Charter* provides Canadians with certain guaranteed rights and freedoms. It applies to all government actions such that legislation and regulations must be *Charter* compliant. This includes all levels of government in

[345] Virginia A. Leary, "Implications of a Right to Health" in *Human Rights in the Twenty-First Century: A Global Challenge*, edited by Kathleen E. Mahoney and Paul Mahoney (Dordrecht, The Netherlands: Martinus Nijhoff Publishers, 1993) at 488.

[346] U.N. Committee on Economic, Social and Cultural Rights, *General Comment No. 14* (2000), Dstr. General E/C.12/2000/4 11 August 2000.

Canada: federal and provincial (including municipal), and would most likely include the actions of a government or Crown agent, depending on the circumstances.

In those instances where the government action has been found to infringe a *Charter*-protected right or freedom, the government must establish that the infringement is prescribed by law and must justify the infringement under section 1 of the *Charter*, which states:

> s. 1 The *Canadian Charter of Rights and Freedoms* guarantees the rights and freedoms set out in it subject only to such reasonable limits prescribed by law as can be demonstrably justified in a free and democratic society.

Section 1 allows the government to justify an infringement of individual rights as being a reasonable limit in a free and democratic society on the basis of broader societal concerns or objectives, where the infringement is prescribed by law.

The most relevant human rights interests raised by the hypothetical are those provided in section 7 of the *Charter*. It states as follows:

> s. 7. Everyone has 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.

Under section 7, the government may deprive a person of his or her right to life, liberty and security of the person, but only where the deprivation is in accordance with the principles of fundamental justice. The principles of fundamental justice operate to qualify the rights in section 7. The Supreme Court of Canada has held that the principles of fundamental justice are found in the tenets of the legal system and are legal principles about which there is a high degree of societal consensus.

If the courts find that the government deprivation is not in accordance with the principles of fundamental justice, the inquiry may end there without the court going further and asking whether the government could justify the deprivation under section 1 of the *Charter*. The courts may consider that the infringement of section 7 is so egregious that it could not be justified under section 1. On the other hand, the courts may look to the government for arguments justifying its limit on a guaranteed human right. The onus is on the government under the section 1 inquiry to establish that the deprivation or limit is prescribed by law and is justified in a free and democratic society.

The two inquiries are based on different considerations. The Supreme Court has noted:

> … despite certain similarities between the balancing of interests in ss. 7 and 1, there are important differences, Firstly, the issue under s. 7 is the delineation of the boundaries of the rights and principles in question whereas under s. 1 the question is whether an infringement may be justified… Secondly, it was affirmed that under s. 7 it is the claimant who bears the onus of proof throughout. It is only if an infringement of s. 7 is established that the onus switches to the Crown to justify the infringement under s. 1. Thirdly, the range of interests to be taken into account under s. 1 is much broader than those relevant to s. 7… [b]ecause of these differences, the nature of the issues and interests to be balanced is not the same under the two sections.[347]

In the past, section 7 was viewed as applying solely in the criminal and quasi-criminal law context. The Supreme Court of Canada, however, has held that the rights under section 7 are not confined solely to these areas of the law.

In *B. (R.) v. Children's Aid Society of Metropolitan Toronto*,[348] the Supreme Court of Canada held that the liberty interests of the parents were engaged under section 7 of the *Charter* when the state intervened under statute to grant wardship of a child to the Children's Aid Society in order that the child could receive a blood transfusion.

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[347] *R. v. Malmo-Levine; R. v. Caine*, [2003] 3 S.C.R. 571, at para. 97.

[348] *B. (R.) v. Children's Aid Society of Metropolitan Toronto*, [1995] 1 S.C.R. 315 [hereinafter referred to as *B(R)]*

Lamer C.J. stated in *New Brunswick (Minister of Health and Community Services) v. G.(J.)*[349] that:

> … s. 7 is not limited solely to purely criminal or penal matters. There are other ways in which the government, in the course of the administration of justice, can deprive a person of their s. 7 rights to liberty and security of the person, i.e., civil committal to a mental institution.[350]

In *Blencoe v. British Columbia (Human Rights Commission)*,[351] the Supreme Court building on its decisions in *B(R)* and *G(J)*, stated that "… there is no longer any doubt that s. 7 of the *Charter* is not confined to the penal context."[352] It may be engaged in non-criminal law cases where the state action directly engages the justice system and its administration.[353]

In *Chaoulli v. Quebec (A.G.)*,[354] three members of the Supreme Court held that s. 7 was engaged despite the fact that the case considers issues arising outside both the criminal justice system and the administration of justice.[355] It remains to be seen whether this broadening of the application of s. 7 outside the criminal and administration of justice context by three members of the Court continues or will be restricted to circumstances similar to that of *Chaoulli.*

With respect to the hypothetical, the first question is whether there is a government action that could deprive Jane of her section 7 right to life, liberty and/or security of the person.

An argument could be made that there is government action. Patents are granted by the Commissioner of Patents who is appointed by the Governor in Council and who exercises the delegated powers and perform the duties conferred on him or her by the Act. The Commissioner acts in reliance to a statutory power, i.e., the *Patent Act*, and thus the *Charter* would most likely apply to the Commissioner's actions, including his or her decisions regarding patents. Peter W. Hogg notes that the *Charter* will apply to:

> … actions taken by the cabinet, by individual ministers and by public servants within the departments of government,… including Crown corporations and public agencies that are outside the formal departmental structure, but which, by virtue of a substantial degree of ministerial control, are deemed to be "agents" of the Crown.[356]

One could argue that the grant of a patent by the Commissioner under the *Patent Act* is an action that is subject to the *Charter*. However, the act of issuing a patent to an inventor for a process to isolate human cells is unlikely to engage any *Charter* rights. The patent only applies to the process of successfully isolating Jane's cells.

Arguably, problems arise for Jane only in those instances where the patentee refuses to grant a licence to allow her physician to use the patented process to isolate her liver cells. Is the patentee's decision not to issue a licence to Jane's physician subject to *Charter* scrutiny?

One might argue that the patentee's decisions with respect to licensing are not controlled by government.[357] On the other hand, could an argument be made that the patentee's licensing decisions are government since they are made in reliance on a statutory power and thus subject to the *Charter*?

The grant of a patent under the Act provides the patentee with exclusive rights to use, make or sell the invention. In addition, the Act provides that if the invention is made, used or sold without the permission of the patentee (in the form of a licence-to-use), the patentee may apply to court for damages relating to patent infringement. Although the statute provides certain rights to the patentee and a remedy when those rights are infringed, any licensing decisions on the part of the patentee are not

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349 *New Brunswick (Minister of Health and Community Services) v. G.(J.)*, [1999] 3 S.C.R. 46 [hereinafter referred to as *G(J)*].

350 *Ibid.* at para. 65

351 *Blencoe, supra* note 87.

352 *Ibid.* at para. 45.

353 *Ibid.* at para. 46.

354 *Chaoulli v. Quebec (A.G.)*, [2005] SCC 35 [hereinafter referred to as *Chaoulli*].

355 *Ibid.* at para. 153.

356 Peter W. Hogg, *Constitutional Law of Canada*, Loose-leaf Edition (Scarborough: Thomson Carswell, 1997) at 34.2(e).

357 The *Patent Act* provides for government intervention in a patentee's licensing decisions but only where the government can establish that the patentee has abused the exclusive rights granted under the patent and only three years after the grant of patent (sections 65 and 66 of the *Patent Act*).

made in reliance on a statutory power. The patentee's licensing decisions are not for the most part subject to government control (only when the patentee has abused his or her patent rights may s. 65 of the Act be engaged). The patentee's licensing decisions are *not made* on the basis of a delegated statutory authority.

In the hypothetical, Jane's inability to successfully isolate her liver cells results directly from the patentee's refusal to issue a license to Jane and her physician. The patentee is arguably a private entity whose licensing decisions are for the most part free of government control. In conclusion, Jane could likely not challenge either the government or the patentee on the basis of a deprivation of a *Charter* right.

The analysis and conclusion, however, would be different if the patent was held by a government department. In that case, the refusal to grant a licence could be characterized as a government action, which would be subject to *Charter* scrutiny.

Under the hypothetical, there may be one successful argument that Jane could make regarding the *Charter*. Although the decision by the private patentee respecting the granting of licences to use a patented invention would not likely be considered government action, a court ordered injunction, one of the remedies available in a dispute between private parties under the *Patent Act*, may be found by the courts to be government action subject to *Charter* scrutiny.

Peter W. Hogg suggests that, based on Supreme Court jurisprudence, if the court order was issued to resolve a matter between two private parties, and if it was based solely on the common law, it would *not* be considered government action and thus the *Charter* would not apply. However, if the court order was issued in a purely private dispute that was governed by statute law, then the *Charter would* apply to the order.[358]

If Jane and/or her physician decided to proceed and infringe the patent by undertaking an unlicensed extraction and isolation of her cells, the patentee could exercise his or her statutory rights in court, and seek damages and an injunction. The court-ordered injunction is one remedy available under, and governed by, the *Patent Act* for the resolution of private disputes. The injunction could be considered government action subject to *Charter* scrutiny.

Jane could argue that the courts must, prior to issuing an injunction, first subject it to *Charter* scrutiny. She could argue that the injunction would prevent her and her physician from devising a possibly lifesaving medical therapy and thus would engage her *Charter* right to liberty and to security of the person.

In *R. v. Morgentaler*,[359] Chief Justice Dickson, writing for himself and Justice Lamer, stated:

> … that state interference with bodily integrity and serious state-imposed psychological stress, at least in the criminal law context, constitute a breach of security of the person.[360]

Justice Wilson, writing one of the majority opinions and speaking for herself, agreed with the Chief Justice and with Justice Beetz, noting that "… the right to security of the person under s. 7 of the *Charter* protects both the physical and psychological integrity of the individual."[361] Beetz, J., writing for himself and Justice Estey, was of the view that "… the constitutional right to 'security of the person' must include some protection from state interference when a person's life or health is in danger… [but] section 7 cannot be invoked simply because a person's life or health is in danger… [t]here must be state intervention for 'security of the person' in s. 7 to be violated."[362]

In *Rodriguez v. British Columbia (Attorney General)*,[363] Justice Sopinka, writing for the majority, noted that the right to security of the person "… can be seen to encompass a

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[358] Hogg, supra note 356 at 34.2(f). Peter Hogg distinguished the Supreme Court's decision in *Dolphin Delivery* (a dispute between private parties relying on the common law) from its decisions in both *R. v. Rahey* and *British Columbia Government Employees' Union v. British Columbia* (a purely private dispute governed by statute law).

[359] *R. v. Morgentaler*, [1988] 1 S.C.R. 30 [hereinafter referred to as *Morgentaler*].

[360] *Ibid.* at 56.

[361] *Ibid.* at 173.

[362] *Ibid.* at 90.

[363] *Rodriguez v. British Columbia (Attorney General)*, [1993] 3 S.C.R. 519 [hereinafter referred to as *Rodriguez*].

notion of personal autonomy involving, at the very least, control over one's bodily integrity free from state interference and freedom from state-imposed psychological and emotional stress."[364] Note, however, that both *Rodriguez* and *Morgentaler, supra* considered the right to security of the person in the criminal law context.

In *R. v. Parker,*[365] the Ontario Court of Appeal was asked whether prohibitions under two federal statutes regarding the cultivation and possession of marihuana violated section 7 *Charter* rights to security of the person and to liberty.[366] The respondent, Parker, alleged that the prohibitions interfered with his health and therefore his security of the person and liberty interests.

The Court of Appeal noted that *Morgentaler, supra,* is the leading case where medical treatment and the criminal law intersect. In that case, state interference with bodily integrity and state-imposed psychological stress, at least in the criminal law context, constituted a breach of security of the person. This view of the right to security of the person is consistent with the view espoused in *Rodriguez, supra* and *G(J), supra*.[367]

The Court of Appeal relying on the Supreme Court's comments in *Morgentaler, supra* and *Rodriguez, supra* held that:

> … deprivation by means of a criminal sanction of access to medication reasonably required for the treatment of a medical condition that threatens the life or health constitutes a deprivation of security of the person… Depriving a patient of medication in such circumstances, through a criminal sanction, also constitutes a serious interference with both physical and psychological integrity.[368]

And later in the decision:

> … the constitutional right to security of the person must include some protection from state interference when a person's life or health is in danger… There must be state intervention for "security of the person" in s. 7 to be violated. If a rule of criminal law precludes a person from obtaining appropriate medical treatment when his or her life or health is in danger, then the state has intervened and this intervention constitutes a violation of that man's or woman's security of the person. *Security of the person must include a right of access to medical treatment for a condition representing a danger to life or health without fear of criminal sanction. If an Act of Parliament forces a person whose life or health is in danger to choose between, on the one hand, the commission of a crime to obtain effective and timely medical treatment and, on the other hand, inadequate treatment or no treatment at all, the right to security of the person has been violated*.[369] [emphasis added]

If Jane and her physician ignore the court-ordered injunction and choose to create the medical therapy, they risk being held in contempt of court, with the possibility of imprisonment and/or a fine. Jane's choice is between, on the one hand, potential loss of liberty in order to receive medical treatment and on the other hand, inadequate or no treatment at all. An argument could be made that Jane's right to security of the person would have been engaged.

In *G(J), supra*, Chief Justice Lamer, writing for the Supreme Court, stated:

> … the restrictions on liberty and security of the person that s. 7 is concerned with are those that occur as a result of an individual's interaction with the justice system and its administration. In other words, the subject matter of section 7 is the state's conduct in the course of enforcing and securing compliance with the law, where the state's conduct deprives an individual of his or her right to life, liberty, or security of the person ... however, s. 7 is not limited solely to purely criminal or penal matters. There are other ways in which the government, in the course of the

364 *Ibid.* at 587-88.
365 *R. v. Parker* (July 31, 2000) [hereinafter referred to as *Parker*] Online: http://www.canlii.org/on/cas/onca/2000/2000onca359.html.
366 At trial, the judge held that the prohibitions violated the respondent's *Charter* rights under s. 7 to life, liberty and security of the person and were contrary to the principles of fundamental justice. Instead of striking down the prohibition, the trial judge read in an exemption for persons cultivating or possessing marihuana for their personal medically-approved use.
367 *Parker, supra* note 365, at 18.
368 *Ibid.* at 20.
369 *Ibid.* at 22.

> administration of justice, can deprive a person of their s. 7 rights to liberty and security of the person, i.e., civil committal to a mental institution.[370]

It could be argued that although the hypothetical does not engage the criminal justice system, the injunction would be issued as a result of Jane's interaction with the justice system and its administration. Section 7 of the *Charter* would thus be engaged.

The courts might agree that Jane's section 7 *Charter* rights to liberty and to security of the person would be violated by a court-ordered injunction. The courts would then proceed to the next stage of inquiry under section 7 and determine whether the state deprivation would be in accordance with the principles of fundamental justice. This step requires the identification and definition of the relevant principles of fundamental justice by the complainant. At this point in time, it would be highly speculative to consider what such principles, if any, may be relevant.

If the courts determine that the deprivation was in accordance with the principles of fundamental justice, then it would be considered constitutional. If, on the other hand, the courts conclude that the deprivation was not in accordance with the principles of fundamental justice, a *Charter* deprivation would have been made out by the complainant. The courts may conclude that the state would be unable to justify the deprivation under section 1 of the *Charter,* or it might look to see whether the state has justified the deprivation as a reasonable limit prescribed by law in a free and democratic society.

The courts faced with such a compelling situation might create a common law exemption or defence to patent infringement similar to what has been proposed by legislators in the U.S. (an extension of the medical treatment defence). The courts might design the defence to allow licensed physicians and heath care facilities to use the unlicensed process when undertaking a medically necessary activity.

Although the hypothetical dealt with the patenting of a process, the same analysis would apply if the patented subject matter was an isolated human gene. It is important to note that this analysis is based on hypothetical facts. It is possible that with different facts before it, the courts would undertake a different analysis. In the case where the patentee was a government department, the dispute would no longer be between two private parties, but would directly implicate an action, the refusal to license, by government and would be subject to *Charter* scrutiny.

6.4.5.3 Could the grant of a patent over a genetic therapy that self-replicates within the human body engage any rights under the Charter?

The following hypothetical is provided to assist with the analysis and discussion:

> Jane Doe discovers, after genetic testing, that she carries the gene for a late-onset disease, Huntington's chorea. Researchers have recently developed a process for delivering an engineered gene to replace the Huntington's gene, via a retrovirus (a type of vector), in all of the body's cells, including her germ or sex cells. The researchers patent the healthy DNA sequence, but not the delivery process since it is a form of medical treatment and as such is not patentable. Once inside Jane Doe's body, the engineered gene knocks out and replaces the Huntington's gene in all her cells.
>
> Jane decides to have a child. She wonders however, whether the process of reproducing whereby she would pass the genetically engineered healthy gene to her offspring would violate the patent. The patentee claims that it would and that Jane would first require a licence from the patentee before she could reproduce. Would such a patent engage Jane's human rights?

As noted earlier, a patent grants to the patentee the right to exclude others from using, making or selling the invention. The nucleus in Jane's cells, including her ova or eggs contains the patented gene. It could be argued that, by reproducing, Jane has "used" or "made" the patented gene without first obtaining a licence from the patentee and thus she would have infringed the patent.

[370] *G.(J.) supra* note 349, at para. 65.

The same arguments and analysis would apply to this situation that applied with respect to the first hypothetical. Assuming the patentee is a private entity and not a government entity, it is unlikely that the *Charter* would be available to assist Jane.

If Jane proceeded to reproduce and her offspring inherited the genetically-altered gene, what would be the patentee's options? The patentee could seek a court ordered injunction prohibiting Jane and her offspring from reproducing without a licence. Jane would argue that the *Charter* is engaged because the court-ordered injunction would be a resolution to a private dispute that is governed by legislation (the *Patent Act*), and thus qualifies as a government action.[371]

It is highly unlikely that a court would issue such an injunction. First, it could be argued that under international human rights instruments, persons have a right to reproductive autonomy (see the arguments in Chapters 2 and 3). These human rights instruments would be introduced to assist the Canadian courts in their interpretation of the *Charter* and of the *Patent Act*.

In addition, as noted earlier, the jurisprudence under s. 7 of the *Charter* suggests that the right to liberty and security of the person include the right to reproductive autonomy. It is unlikely that the courts would issue an injunction preventing a person from reproducing. This would most likely be a case where fundamental human rights (Jane's right to reproduce) would trump intellectual property rights (the rights of the patentee).

6.5 Does the Patenting of a Human In Vitro Embryo Raise any Human Rights Issues?

*(Note: in this section the term "*in vitro *embryo" is used to describe the fertilized human egg from the moment of fertilization to the fœtal stage, which begins eight weeks post fertilization)*

6.5.1 International and Regional Instruments

International Human Rights Instruments

The ICCPR provides the following in article 8, paragraphs 1 and 2:

> *Article 8*
>
> 1. No one shall be held in slavery; slavery and the slave-trade in all their forms shall be prohibited.
>
> 2. No one shall be held in servitude.

Article 8, paragraphs (1) and (2), are considered to guarantee some of the most fundamental human rights: freedom from slavery and servitude.[372] Slavery occurs when one person owns another such that the former can totally exploit the latter with impunity.[373] Article 8, paragraph (1), prohibits slavery. Article 8, paragraph (2), prohibits servitude which is a broader concept than slavery. It includes other forms of egregious economic exploitation or dominance by one person over another, as well as slavery-like practices.[374]

The Human Rights Committee (the "HRC") has expressed concerns with the practice of "bonded labour" in India as a possible violation of article 8. Bonded labour is a practice where a debtor pledges either his or her personal services, or the services of someone they control (often a child), as security for the debt.[375] The HRC has expressed deep concerns with other activities, including the trafficking in women for the purposes of prostitution and child labour and prostitution, which violate article 8. State Parties are responsible for protecting all persons within their jurisdiction from article 8 abuses by private bodies, as well as by the State itself.[376] Canada, as a party to the ICCPR, is obliged to comply with its provisions. Although the provisions of the ICCPR could not form the basis of an action in a Canadian court, they could be cited to

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371 Hogg, *supra* note 356, at 34.2(f).
372 Sarah Joseph, Jenny Schultz, and Melissa Castan, *the International Covenant on Civil and Political Rights: Cases, Materials, and Commentary* (Oxford: Oxford University Press, 2000) at 198.
373 *Ibid.* at 199.
374 *Ibid.*
375 *Ibid.*
376 *Ibid.* at 199-200.

support a particular interpretation of the *Charter* or of domestic legislation, such as the *Patent Act*.

Trade Agreements

Canada is a member of the WTO and thus must comply with the provisions of the TRIPS Agreement. In the event of a dispute and non-compliance, Canada could face possible retaliation in the form of trade sanctions. Article 27, paragraph (2), allows members to exclude from patentability certain subject matters in order to protect *ordre public* or morality within their territory, as long as the exclusion is not made merely because the exploitation is prohibited by law. It states:

> Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by law.

According to European law, the term "*ordre public*" encompasses the protection of public security and the physical integrity of individuals as part of society, as well as the environment.[377] The EPO Guidelines for Examination notes that *ordre public* is linked to "security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behaviour."[378] The EPO also must examine the morality of the commercial exploitation of a particular invention. It must establish whether an invention would be so morally abhorrent that its patenting would be inconceivable to the public. The term "morality" encompasses all of the accepted norms which are deeply rooted in a particular culture.[379] It should be noted, however, that a marketing prohibition by a Member State cannot be used to justify its exclusion from patentability on the grounds of *ordre public* or morality. There must be a connection between the State law prohibiting marketability and *ordre public* or morality.[380]

There is of course no requirement for WTO Members to follow the European approach as set out above. Members have the flexibility to determine which situations are covered by the phrase *public ordre* and what constitutes morality in their particular community.[381]

Regional Instruments

Although Canada is not a member of the Council of Europe, it has observer status. The human rights instruments adopted by the Council are thus not binding on Canada. The instruments and how they have been interpreted may, however, be used by the courts to inform their interpretation of the *Charter*, as well as domestic legislation.

Article 18, paragraph (1), of the *Convention on Human Rights and Biomedicine*[382] provides that where research is permitted by law on an *in vitro* embryo, that law must ensure its protection. Article 18, paragraph (2), prohibits the creation of a human embryo solely for research purposes.

The European Parliament and the Council's *Directive*[383] provides in article 6, paragraph (2)(c), that the use of *in vitro* embryos for industrial or commercial purposes cannot be patented because their commercial exploitation would be contrary to *ordre public* or morality. In also provides in article 5, paragraph (1) that the human body at any stage of development and formation, including the sequence or partial sequence of a gene, does not constitute a patentable invention.

The Organization of American States (the"OAS") is a regional organization with membership from South and Central American, the Caribbean, the U.S. and Canada. It is a regional agency within the meaning of Article 52 of the U.N. *Charter*. In 1969 the OAS adopted the *American Convention on Human Rights* (the "*Convention*").[384] Canada is neither a signatory to nor has it ratified the *Convention*.

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377 United Nations Conference on Trade and Development (UNCTD) secretariat and the International Centre for Trade and Sustainable Development, Draft *TRIPS and Development: Resource Book* (Geneva, 2002) at 2.5.3 (page 40). Online: http://www.iprsonline.org/unctadictsd/ResourceBookIndex.htm (accessed April 20, 2005).

378 *Ibid.* at 2.5.3 (pages 40-41).

379 *Ibid.* at 2.5.3 (page 41).

380 *Ibid.* at 2.5.3. (page 39).

381 *Ibid.* at 2.5.3 (page 40).

382 *Convention*, *supra* note 131.

383 *Directive*, *supra* note 138.

384 *American Convention on Human Rights*, O.A.S. Treaty Series No. 36, 1144 U.N.T.S. 123, entered into force 18 July 1978.

Article 4, paragraph (1), of the *Convention* states:

> Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of life.

This article qualifies the protection of the unborn with the phrase "in general." The *Travaux Préparatoires* to the *Convention* notes that there was strong opposition by some members to a proposal to delete the phrase "in general." There was concern that the right to lawful abortion, which exists in some States, might be compromised. A majority of the Members States, however, were of the view that article 4 should protect the life of the unborn since they consider abortion a crime.[385]

6.5.2 The Law in Other Jurisdictions

The U.S.

The U.S. *Patent Act* does not provide an exhaustive list of subject matters that are not patentable. As long as the invention is a new or useful process, machine, manufacture or composition of matter, it may be patented. The U.S. Congress considers this list of subject matter to be quite broad and to include "anything under the sun that is made by man."[386] The courts have, however, excluded certain things from patentability, including the laws of nature and natural phenomena, including a mineral in the earth and a plant in the wild.[387]

In the report entitled *Reproduction and Responsibility: The Regulation of New Biotechnologies*,[388] the President's Council on Bioethics notes that there is no provision in the *Patent Act* that expressly provides for the consideration of morals in determining patentability. The Report notes that to date patents have been granted over modified human tissues and cell lines, as well as human DNA. It points out that the prospect of future patents over human gametes and embryos raises ethical concerns.[389] The Council notes that, for one thing, since the patent would create a quasi-property right in another, or in a part of another, a patent over a human embryo would be deeply troubling.[390] The Report recommends that Congress amend the patent laws to prohibit the patenting of human embryos and restrict the patenting of human sperm and ova.[391]

State law

There is at least one state, Louisiana, that assigns legal rights to the human *in vitro* embryo from the moment of conception. The Louisiana *Civil Code* protects the *in vitro* embryo and deems it to be a juridical person who can sue and be sued, until such time as it is transferred into a woman's womb.[392]

Case law

On February 6, 2005, a Cook County judge in the state of Illinois ruled, in a case involving a mistakenly discarded *in vitro* embryo, that the embryo was legally a "human being."[393] The couple were experiencing infertility and sought the assistance of a fertility clinic. After successful treatment, the couple believed that their *in vitro* embryo had been cryopresserved by the Center for future reproductive use. However, when the couple returned two years later to undergo further fertility treatments, with the *in vitro* embryo, they discovered that the Center had mistakenly discarded their embryo.[394]

The couple sued for damages claiming that the Center's disposal amounted to a case of wrongful death. The claim was rejected by two judges prior to the ruling by Judge Lawrence which found in favour of the couple. Judge Lawrence wrote:

> Philosophers and theologians may debate, but there is not doubt in the mind of the Illinois legislature when life begins. It begins at conception.[395]

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385 See chapter 2 footnote 246.
386 Sheldon w. Halpern, et al., *supra* note 10, at 227.
387 *Ibid.* at 227 (relying on *Chakrabarty, supra* and *Diehr, supra*).
388 The President's Council on Bioethics, *Reproduction and Responsibility: The Regulation of New Biotechnologies* (Washington, D.C., March 2004) at 160. Online: http://www.bioethics.gov.
389 *Ibid.*
390 *Ibid.*
391 *Ibid.* at 181 and 202.
392 Louisiana *Civil Code* § 26 (1988).
393 Patrick Rucker, "Judge says lost embryo a human, ruling clears way for couple's suit" *Chicago Tribune* (6 February 2005).
394 *Ibid.*
395 *Ibid.*

At the time of writing, the lawyer for the Center was still considering a response to the decision. A number of commentators were of the view that the judge had misrepresented state law and had relied on language from an invalidated state abortion law.[396]

The UK

The UK *Patent Act*[397] provides in section 1(3) the ability to exclude from patentability "… an invention, the commercial exploitation of which would be contrary to public policy or morality." The UK *Human Fertilisation and Embryology Act*[398] was recently amended to allow the creation of human *in vitro* embryos solely for research purposes.

The UK is obliged to follow the *Directive*. The UK PO recently issued a practice note confirming that it will not grant patents over processes for obtaining stem cells from human embryos since it believes that these processes are excluded from patentability by the *Directive's* prohibition of the uses of human embryos for industrial or commercial purposes.[399] Furthermore, the PO will not grant patents over human pluripotent cells because of their potential to develop into an entire human body.[400]

6.5.3 Canada

It is unclear whether the Commissioner of Patents would grant a patent over a human *in vitro* embryo at the single-cell stage of development. PO practice provides that higher life forms, i.e., seeds, plants and animals (multicellular organisms), are not patentable subject matter.

Both the dissent and majority opinion in *Harvard College, supra,* considered in *obiter* that a genetically modified fertilized mouse egg (a unicellular mouse embryo) would likely constitute patentable subject matter.[401] If faced with a patent application for a unicellular or pronuclear human *in vitro* embryo,[402] the Commissioner may consider the central issue to be whether a unicellular organism can be considered a "higher life form" for the purposes of the *Patent Act*.

The dissent in *Harvard College, supra*, and, to some extent, the majority in *Monsanto, supra*,[403] noted that that questions of patentability, patent infringement and, to some extent, scope are to be resolved by the application of established principles of patent law, not principles of morality or ethics, which are matters more properly left to Parliament. Although section 40 of the *Patent Act* requires the Commissioner to reject a patent application if he or she believes that it would contravene the law, there is no law in Canada prohibiting the patenting of a human *in vitro* embryo.

The majority in *Harvard College, supra*, also commented in *obiter* that it saw no reason for altering the line drawn by the PO between higher and lower life forms for the purposes of patentability.[404] Justice Bastarache stated:

> … I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the Act, is nonetheless defensible on the basis of common sense differences between the two.[405]

In Canada today, the common law has thus drawn the patentability line between higher and lower life forms. The question as to whether certain human biological materials will be patentable depends in part on the Patent Commissioner's determination as to whether they are a higher or a lower life form. For example, a pronuclear human *in vitro* embryo might be considered a lower life form and thus patentable because it is a single-celled

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396 *Ibid.*

397 *Patents Act 1997*, c. 37, as amended by *Patents Act 2004*, Ch. 16.

398 *Human Fertilisation and Embryology Act 1990*, U.K., c.37.

399 Boult Wade Tennant, European Patent and Trade Mark Attorneys, *Patenting Stem Cells in Europe* — bulletin (August 2004) at 1. Online: http://www.boult.com/information/BulletinPrint.cfm. Accessed March 2005.

400 *Ibid.* at 1.

401 *Harvard Mouse*, *supra* note 265.

402 The term pronuclear embryo is used to describe the unicellular human in vitro embryo. See Damario M.A. and Hammitt D.G. et al. "Embryo cryopreservation at the pronuclear stage and efficient embryo use optimizes the chance for a liveborn infant from a single oocyte retrieval" Fertil. Steril. 2000 Apr; 73(4): 767-74.

403 The majority members of the Supreme Court in *Monsanto* were largely those members (Chief Justice McLachlin, Justices Major and Binnie) who wrote the dissent in *Harvard Mouse*. In *Harvard Mouse* the dissent rejected the approach of deciding patentability on the basis of whether the biological materials were a higher or lower life form. Although the issue in *Monsanto* was patent infringement and not patentability, the majority in *Monsanto* based it decision on patent principles.

404 *Harvard Mouse*, *supra* note 265, at para. 199.

405 *Ibid.*

entity. On the other hand, the Patent Commissioner might find that it falls within the category of a higher life form and thus is not patentable. There may, however, be unanticipated consequences to a finding that a pronuclear human *in vitro* embryo is a higher life form, such as implications for the use of human *in vitro* embryos in projects of research or implications on the reproductive right of a woman to terminate her pregnancy.

The *Assisted Human Reproduction Act* (the "AHR Act") applies to sperm, eggs and to fertilized human eggs (including unicellular or pronuclear embryos) that are created for reproduction. The AHR Act also applies to supernumerary multicellular or pronuclear *in vitro* embryos donated and used for research purposes. Questions of patentability, however, are not addressed in the legislation since those would be beyond or outside its legislative scope. Its primary objective is the health and safety of both women using reproductive technologies to create a child and of any children born as a result of those technologies.

Case law

There is no case law directly on point. However, in *Daigle v. Tremblay*,[406] the Supreme Court held that a fœtus is not a person with legal rights under the Quebec *Charter*, but did not address the issue under the Canadian *Charter*. In *Morgentaler, supra*, Justice Wilson, writing one of the majority opinions and speaking for herself, noted that the state's interest in protecting the developing fœtus would only become "compelling" at some point in the second trimester of pregnancy. Until that point in the development of the fœtus, the woman's right to liberty under *Charter* gave her absolute authority to decide whether to abort.[407]

6.5.4 Discussion

The analysis and discussion relates to the following hypothetical situation:

> Researchers at a prominent university in Canada have invented a process to insert the gene for a type of bowel cancer into a pronuclear human *in vitro* embryo and to chemically suspend its further division and development. The embryo can be used in research to test pharmaceuticals in order to find a cure for bowel cancer. The research was approved and licensed by the Assisted Human Reproduction Agency of Canada under the *Assisted Human Reproduction Act*.
>
> The researchers have applied to the Patent Commissioner for a patent over the process and the genetically altered pronuclear *in vitro* embryo. Would the grant of such a patent raise any human rights issues?

In the hypothetical situation, the human embryo is being used solely for research purposes and, under the AHR Act, would be prohibited from further use in reproduction. The text of the *Charter* generally refers to rights-holders as either "everyone" or "person." The courts have held that these terms include both human beings and corporations (fictional persons), depending on the right in question. Under the common law, an *in vitro* embryo is not considered to be a person (human being) with legal rights, until it is born alive.

"Fœtus" is the term given to the implanted embryo when it reaches the eight week stage of development within a woman's uterus. If a fœtus is not a person with rights under the law and the state has no compelling interest in it, it is unlikely that the courts would find that a pronuclear *in vitro* embryo is a juridical person with rights.

On the other hand, one could argue that when the embryo exists outside a woman's body, there is no need to balance the rights of the woman with the rights of the developing embryo. For example, the Louisiana *Civil Code* grants the *in vitro* embryo legal rights, until such time as the embryo is transferred into a woman's womb. It is at the point of transfer that the two sets of rights could come into conflict and thus the embryo ceases to have any legal rights.

In the future, if Parliament or the common law assigned the pronuclear human *in vitro* embryo legal status and rights, the grant of a patent over a pronuclear *in vitro* embryo may engage human rights, such as liberty and security of the person. In addition, it might raise human

[406] *Daigle v. Tremblay*, [1989] 2 S.C.R. 530.
[407] *Morgentaler, supra* note 359, at 183.

rights issues related to ownership and slavery that are specifically set out in provisions under the ICCPR.

The dissent in *Harvard College, supra* opined that, under section 40 of the *Patent Act*, the Commissioner of Patents could refuse to grant a patent over a human being on the basis of the *Charter*. The current legal position, however, is that a human embryo is not a human being capable of possessing legal rights and thus would not qualify for protection under the *Charter*. If the genetically altered pronuclear *in vitro* embryo met the *Patent Act*'s definition of an invention, i.e., a manufacture or a composition of matter, and the criterion for patentability, i.e., non-obvious, new and useful, the Commissioner could likely not rely on the *Charter* or any existing Canadian law to refuse a patent application under section 40 of the Act.

The Commissioner might characterize the pronuclear embryo as a higher life form and thus not patentable. Such a ruling, however, might have far reaching unanticipated consequences. It might have implications for women's reproductive autonomy rights and for research on supernumerary human *in vitro* embryos.

6.6 Conclusion

One could argue that the dissent in *Harvard Mouse, supra*, was correct in its interpretation of how questions of patentability were to be addressed under the *Patent Act*'s legislative scheme. Nowhere in the Act is there a reference to or a provision providing a distinction between higher and lower life forms for the purposes of patentability. The Act, when read as a whole, lends strong support to the argument that the patentability of subject matter should be determined on the basis of the definitions and criteria set out in the legislation. This means that there is no room under the *Patent Act* for moral and ethical questions relating to the patentability of certain animal and human materials. If Parliament is concerned with what the Commissioner patents under the Act, it has the authority to make the necessary amendments to the Act.

The courts have made it clear that judges are not well placed to address these issues. These are matters best addressed by officials who represent and are accountable to the public. In recent years, there have been calls for Parliament to amend the Act to clarify the patentability of certain biological materials in Canada, such as human *in vitro* embryos. The CBAC has issued two reports to Parliament suggesting a number of amendments to the Act, but Parliament has remained silent.

The apparent absence of political will to address these difficult questions, coupled with a possible expansion of the scope of patentability, arguably may result in the granting of property rights over excised human materials that differ little from the same materials in the human body. The rationale for denying property rights to individuals over their excised bodily materials may no longer be defensible when biotechnology companies can attain such rights with minimal inventive effort.

The impact on human dignity is difficult to predict. Some would argue that the ability to sell and profit from excised bodily materials will enhance their subjective feelings of self-respect and self-worth. Others would be concerned that the commercialization and commodification of the human body, as the site of the soul and personhood, will de-value and cheapen life and ultimately, diminish human dignity. Although human dignity is not a free-standing human or constitutional right, it is the underlying value of most of the fundamental human rights at the international level and domestically in the *Charter*.

Intellectual property rights in the form of patents were designed to grant to the inventor a monopoly to capitalize on his or her invention. Patent rights allow the patentee to exclude others from using, selling or making the patented invention in return for disclosing information about the invention to further knowledge within society. This social bargain works well when the invention is inanimate materials, e.g. metal or plastic. One can argue, however, that when these same patent rights apply to processes involving or to human biological materials and genetic therapies, the unrestricted ability to exclude all others from using, making or selling may be too broad and may no longer serve the best interests of society.

The chapter illustrates that, in order to engage human rights under the *Charter*, government action must be implicated. It is unlikely that the grant of a patent by the

state would engage any human rights since it only provides the patentee with a right to exclude others from using, making or selling the patented invention. In the case of patented human biological materials, it would require the presence of a number of facts before one could argue that human rights are engaged.

The hypothetical scenarios were designed with the objective of raising human rights issues. The likelihood of such scenarios occurring is impossible to predict. While it is possible to conclude that the patenting of human biological materials raises serious ethical and moral concerns, because the *Charter* only applies to government action it requires the patentee's assertion of his or her rights under the *Patent Act* to engage the *Charter*. It is clear that reliance on the *Charter* to deal with the ethical and moral issues that will continue to arise from the patenting of human biological materials is problematic. The time has come for Parliament to amend the *Patent Act* to exempt certain human biological materials that society considers unpatentable.