Richmond Journal of Law and Technology

Volume 14 | Issue 4 Article 2

2008

Patenting Part-Human Chimeras, Transgenics And Stem Cells For Transplantation In The United States, Canada, And Europe

Gregory R. Hagen

Sébastien A. Gittens

PATENTING PART-HUMAN CHIMERAS, TRANSGENICS AND STEM CELLS FOR TRANSPLANTATION IN THE UNITED STATES, CANADA, AND EUROPE

By: Gregory R. Hagen* & Sébastien A. Gittens**

Cite as: Gregory R. Hagen & Sébastien A. Gittens, *Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe,* 14 Rich. J. L. & Tech. 11 (2008), http://law.richmond.edu/jolt/v14i4/article11.pdf.

INTRODUCTION

[1] The perceived need for part-human materials – considered to be biological materials containing human genetic material for the purposes of this paper – is at least twofold.[1] First, given the continued shortage of human organs and other human biological materials suitable for transplantation, thousands of persons will suffer illness and death each year.[2] While xenotransplantation – the transplantation, implantation, or infusion into a human recipient of cells, tissues, or organs from a non-

* Gregory R. Hagen is an Assistant Professor of Law at the University of Calgary.
** Sébastien A. Gittens is articling at Bennett Jones LLP in Calgary.

[1] The category of part-human therefore includes both animal-human combinations as well as stages of development of humans or animal-human combinations from embryo to maturity. The reason for defining "part- human" in terms of genetic make-up in the context of this paper is because close genetic matching decreases the rejection of transplanted material. Defined in this way, "part-human" encompasses human combinations that cross species boundaries, human beings at all stages of development, animal-human stem cells, and stem cells that contain both human and non-human DNA.

[2] For statistics, see *infra* at § I. The shortage of organs is so severe that the World Health Organization has recently expressed its concern over the development of "transplant tourism," the purchasing of organs from live donors in developing countries. *See* World Health Organization, *Who Proposes Global Agenda on Transplantation* (2007), *available at* http://www.who.int/mediacentre/news/releases/ 2007/pr12/en/index.html.

human animal source – has been occurring in some fashion for hundreds of years, it often results in rejection by the recipient's immune system.[3] In order to minimize the rejection of xenotransplants, the possibility of using part-human organs, tissues and cells, such as pig hearts containing human DNA, for transplantation is actively being explored.[4] Second, research using human embryonic stem cells could assist in developing treatments for diseases and in discovering new pharmaceuticals.[5] However, given the limited availability of human eggs used to create human embryonic stem cells and the ethical controversies associated with the harvesting of human eggs and the destruction of human embryos, it has been suggested that part-human stem cells be used for research purposes.[6]

[2] Because of the perceived need for part-human biotechnological material and the fact that patents on such subject matter would provide an incentive for its production, one would expect that it would be patentable. But, because of moral concerns associated with the creation of part-humans, such as the devaluation of humanity, the potential creation of new diseases that could afflict humans, and animal suffering, legislation has been enacted in some jurisdictions prohibiting the creation and/or use of

[3] For discussion of the history of xenotransplantation, see Jack-Yves Deschamps, et al., *History of Xenotransplantation*, 12 XENOTRANSPLANTATION 91 (2005). For current xenotransplantation practice and the problem of immune system rejection of xenografts, see Ashley Cox & Robert Zhong, *Current Advances in Xenotransplantation*, 4 HEPATOBILIARY PANCREAT DIS. INT. 490 (2005) and Brenda M. Ogle & Jeffrey L. Platt, *Xenografts*, *in* ENCYCLOPEDIA OF BIOMATERIALS AND BIOMEDICAL ENGINEERING 1780 (Gary E. Wnek & Gary L. Bowlin eds., 2004). Xenotransplantation also includes the transplantation, implantation, or infusion into a human recipient of human body fluids, cells, tissues or organs that have had *ex vivo* contact with live non-human animal cells, tissues, or organs. For the definition of "xenotransplantation," see U.S. Food and Drug Administration, *Xenotransplantation Action Plan* (2001), *available at* http://www.fda.gov/cber/xap/xap.htm#back.

[4] Jeffrey L. Platt, *Fusion of Approaches to the Treatment of Organ Failure*, 4 AM. J. TRANSPLANT 74 (2004).

[5] *See*, *e.g.*, STEM CELL AND GENE-BASED THERAPY: FRONTIERS IN REGENERATIVE MEDICINE (Alexander Battler & Jonathan Leor eds., 2006); Hannes Hentze et al., *Cell Therapy and the Safety of Embryonic Stem Cell-Derived Grafts*, 25 TRENDS BIOTECH. 24 (2007).

[6] United Kingdom Parliament, Select Committee on Science and Technology, *Fifth Report* (2007), *available at* http://www.publications.parliament.uk/pa/cm200607/cmselect/cmsctech/272/27206.htm#n113.

some part-human subject matter.[7] Where this has occurred, patents either cannot be granted on such subject matter or, if they can be granted, cannot be exploited without violating the law.[8] Furthermore, even in cases where the creation and/or use of part-human materials is not prohibited, residual uncertainty exists regarding whether, and in which cases, patents can be granted on part-human materials.

---

[7] For an informed ethical discussion that sets out some of the ethical objections to the creation of part-human materials, see Scottish Council on Human Bioethics, *Embryonic, Fetal and Post-Natal Animal-Human Mixtures: An Ethical Discussion* (2005), *available at* http://www.schb.org.uk/, and BioCentre: The Centre for Bioethics and Public Policy, *The New Inter-Species Future? An Ethical Discussion of Embryonic, Fetal and Post Natal Human-Nonhuman Combinations* (2007)*, available at* http://www.bioethics.ac.uk/index.php?do=topic&sid=13. As for legislation, in Canada, the Assisted Human Reproduction Act, 2004 S.C., ch. 2, § 5(1)(i) prohibits the knowing creation of a chimera, or the transplantation of a chimera into either a human being or a non-human life form. For further discussion and clarification, see Françoise Baylis, *Betwixt and Between Human Stem Cell Guidelines and Legislation*, 11 HEALTH L. REV. 44 (2002) and Sylvie Bordet et al., *Legal Aspects of Animal-Human Combinations in Canada*, 1MCGILL HEALTH L. PUB. (2007), *available at* http://mhlp.mcgill.ca/texts/volume1/pdf/bordet-feldman-knoppers.pdf. For an analysis of U.S. law as well as a moral framework for the regulation of animal-human combinations, see Stephen Munzer, *Human-Non Human Chimera in Embryonic Stem Cell Research*, 21 HARV. J.L. & TECH. 123 (2007) *available at* http://jolt.law.harvard.edu/articles/pdf/v21/MUNZER_Human-Nonhuman_Chimeras.pdf. For a comparison of Canadian and U.S. law on mixed species, see Nicole E. Kopinski, Comment, *Human-NonHuman Chimera: A Regulatory Proposal on the Blurring of Species Lines*, 45 B.C. L. REV. 667 (2004). Some European countries, such as Denmark, France, and Germany prohibit the mixing of human gametes with the live gametes of other animals, but in the U.K. such activity is licensed under the Human Fertilisation and Embryology Act, 1990 c. 37. For a review of European policy on stem cell research, see Rosario M. Isasi & Bartha Maria Knoppers, *Mind the Gap: Policy Approaches to Embryonic Stem Cell and Cloning Research in 50 Countries*, 13 EUR. J. HEALTH L. 9 (2006). For a general overview of stem cell policies, see The Hinxton Group, World Stem Cell Policies, http://www.hinxtongroup.org/wp_am_exc.html#us (last visited July 3, 2007).

[8] In Canada, § 42 of the Patent Act explicitly provides positive rights to the patentee: "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used . . . " subject, of course, to other laws that prohibited the exercise of such rights. Patent Act, R.S.C., ch. P-4 (2005). Hence, in Canada, where there are regulations prohibiting the making, constructing, use, or sale of a particular technology, it may not be lawful to grant a patent right to that technology. Where patent rights are negative rights, as in the United States, it is not necessarily inconsistent to grant a patent right to some technology where there is a regulation prohibiting its making, constructing, using, or selling.

[3] The use of inherently vague biological concepts – such as human and higher life forms – make it difficult to determine in a non-arbitrary, consistent, and predictable way when material containing human DNA is patentable. For example, despite intense opposition to the patenting of human genetic material,[9] in Canada, the United States, and Europe, isolated human elements, including nucleotide sequences, are generally eligible for patenting.[10] At the same time, however, one cannot patent a *human being* in any of these jurisdictions.[11] The difficulty occurs in intermediary cases, such as determining the amount of human DNA that is required to make a part-human organ grown in a sheep unpatentable. A second illustration concerns the Canadian rule that higher life forms are not patentable but lower life forms are patentable.[12] Unicellular organisms are traditionally classified as lower life forms in Canada while multicellular organisms are considered to be higher life forms.[13] Further, every stage of development of a higher life form from fertilized egg on is

[9] For example, see John Sulston, *Heritage of Humanity*, LE MONDE DIPLOMATIQUE (2002), *available at* http://mondediplo.com/2002/12/15genome. John Sulston was the 2002 recipient of the Nobel Prize for Physiology or Medicine and a major contributor to the mapping of the human genome. *See also*, Kevin E. Noonan, *The Continuing Threat to Human Gene Patenting*, PATENT DOCS, Oct. 16, 2007, *available at* http://www.patentdocs.net/patent_docs/2007/10/the-continuing-.html (discussing the recent attempt to amend U.S. patent legislation to prohibit patenting human genetic material).

[10] *See* United States Patent and Trademark Office Utility Examination Guidelines, 66 Fed. Reg. 1092 (Jan. 5, 2001); CANADIAN INTELLECTUAL PROPERTY OFFICE, MANUAL OF PATENT OFFICE PRACTICE (2007) *available at* http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/mopop-e.html; Council Directive 98/44, art. 5(2), 1998 O.J. (L 213) (Biotechnology Directive). For an analysis, see DAVID CAMPBELL & STÉPHANE BERGERON, STUDY ON THE BREADTH OF HUMAN GENE PATENTS GRANTED BY THE CIPO, THE EPO, AND THE USPTO: SCIENCE METRIX FINAL REPORT (2005), *available at* http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/h_ah00128e.html; E. Richard Gold, *Patents in Genes* (2000), *available at* http://cbac-cccb.ca/epic/site/cbac-cccb.nsf/en/ah00419e.html#genes. The Nuffield Council on Bioethics has produced a useful list of the kinds of DNA-related patents that exist. THE NUFFIELD COUNCIL ON BIOETHICS, THE ETHICS OF PATENTING DNA: A DISCUSSION PAPER (2002), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/theethicsofpatentingdna.pdf.

[11] Of the three jurisdictions discussed herein, only Europe prohibits the patenting of humans explicitly under legislation. *See infra*, §IV.

[12] Harvard C. v. Canada, [2002] 4 S.C.R. 45, 2002 SCC 76 ¶ 158 (Can.) ("*Harvard College*").

[13] CIPO, MANUAL, *supra* note 10, at § 12.04.

considered to be a higher life form in Canada.[14] Hence, a fertilized animal egg has been determined to be unpatentable in Canada notwithstanding that it is a single cell – thus contradicting the principle that lower life forms are patentable.[15]

[4] This paper is not intended to be a survey of the patentability of biotechnology generally,[16] of the ethics and law regarding the creation, use, and patenting of part-human biological materials,[17] or of the ethics and law of xenotransplantation as a medical procedure.[18] Nor does it take a position on the issue of whether ethical concerns are relevant to the patentability of subject matter in addition to whether the subject matter at issue is new, useful, and inventive. Rather, its more limited aim is to discuss the uncertain application of the biological criteria that are *currently used* in the United States, Canada, and Europe to distinguish

[14] CIPO, OFFICE PRACTICE REGARDING FERTILIZED EGGS, STEM CELLS, ORGANS AND TISSUES (2006), *available at* http://strategis.ic.gc.ca/sc_mrksv/cipo/patents/notice_jun20_06-e.html.

[15] *Id.*

[16] *See*, *e.g.*, GRAHAM DUTFIELD, INTELLECTUAL PROPERTY RIGHTS AND THE LIFE SCIENCE INDUSTRIES: A TWENTIETH CENTURY HISTORY (2003); and DANIEL J. KEVLES, A HISTORY OF PATENTING LIFE IN THE U.S. WITH COMPARATIVE ATTENTION TO EUROPE AND CANADA (European Commission 2002), *available at* http://ec.europa.eu/european_group_ethics/publications/docs/study_kevles_en.pdf; OLIVER MILLS, BIOTECHNOLOGICAL INVENTIONS: MORAL RESTRAINTS AND PATENT LAW (2005).

[17] Jerzy Koopman, *The Patentability of Transgenic Animals in the U.S. of America and the European Union: A Proposal for Harmonization*, 13 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 103 (2002) (comparing U.S. and European law on the patentability of transgenic animals). For the ethics of creating part-human materials, see Jason Scott Robert & Françoise Baylis, *Crossing Species Boundaries*, 3 AM. J. BIOETH. 1, 1-2 (2003), and accompanying commentaries.

[18] For a systematic account of the law and ethics of xenotransplantation, *see* SHEILA A.M. MCLEAN & LAURA WILLIAMSON, XENOTRANSPLANTATION (2005) *and* Melanie J. Mortensen, *In the Shadow of Doctor Moreau: A Contextual Reading of the Proposed Canadian Standard for Xenotransplantation*, 2 U. O. L. T. J. 37, 46 (2005) (expressing the, perhaps, overly-cautious view, that "[x]enotransplantation ought to remain a distant possibility until the risks are better appreciated and the technology is fully regulated on a truly international scale."). The Nuffield Council on Bioethics said in contrast that "once all the necessary safeguards have been set in place, xenotransplantation may be offered to suitable patients." THE NUFFIELD COUNCIL ON BIOETHICS, ANIMAL-TO-HUMAN TRANSPLANTS: THE ETHICS OF XENOTRANSPLANTATION (1996), *available at* http://www.nuffieldbioethics.org/fileLibrary/pdf/xenotransplantation.pdf.

between patentable and unpatentable subject matter, particularly, part-human materials that could be used for transplantation.

[5] Section I motivates the discussion by describing the shortage of human materials for transplantation and research and the potential use of part-human materials to satisfy that need. Section II offers a brief overview of the science and technology of part-human biological materials, focusing on chimeric and transgenic biological materials, as well as part-human stem cells. Section III introduces the problem of providing a principled distinction between patentable part-humans and unpatentable part-humans and, in Canada, the distinction between patentable lower life forms and unpatentable higher life forms. Section III then argues that the vagueness of the concepts of biological human and higher life form prevents a principled basis for distinguishing between those part-humans that are patentable from those that are not in a way that is consistent with current patent office practice. A replacement rule is presented that prohibits the patenting of reflective, rational agents – that is, persons – whether human or not.[19] Finally, Section IV compares the patentability of part-human biological material in the United States, Canada, and Europe. It also identifies some of the obstacles to implementing a rule against patenting persons in the United States, Canada and Europe.

I. BACKGROUND

A. HUMAN MATERIALS FOR TRANSPLANTATION & MEDICAL RESEARCH

[6] The primary need for human biological materials is for the transplantation of organs, tissues, and cells into humans. Human organ transplantation can be used to treat diseases of the heart, lungs, liver, kidneys, and pancreas, which are some of the most common causes of

[19] It is beyond the scope of this paper to fully describe the nature of persons in a way that is relevant for patentability issues. For an introduction to the issue, see ERIC T. OLSON, *Personal Identity*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed., Spring 2007), *available at* http://plato.stanford.edu/archives/spr2007/entries/identity-personal/. Rawls considers moral persons to be those who possess a capacity for a sense of justice and a capacity for a conception of the good. *See* JOHN RAWLS, POLITICAL LIBERALISM 19 (1993).

infirmity and death.[20] Already, the transplantation of skin tissue is used to treat burns, bone to facilitate spinal fusions, and tendons to reconstruct knee ligaments.[21] Advances in understanding the differentiation of stem cells into different cell types have fuelled the belief that stem cell transplantation can treat cardiovascular, neurological, pancreatic, hematological, dermatological, and musculoskeletal injuries and diseases.[22]

[7] Autotransplantation and allotransplantation are the types of transplantation extensively relied upon today. The former is a process through which material is harvested and subsequently transplanted from one part of an individual's body to another. The latter occurs where material is harvested from one individual and subsequently transplanted to another *intra-species.* The limitations associated with autografts (i.e. the material used in autotransplantation) include the availability of material as well as donor site morbidity.[23] The challenges associated with allogeneic grafts (i.e. the cells, tissues or organs involved in allotransplantation) include: (i) donor-recipient blood type compatibility; (ii) donor-recipient physical compatibility (e.g. organ size, capacity and lifespan); (iii) the transmission of pathogens (e.g. human immunodeficiency virus, as well as hepatitis B and C viruses); (iv) the use of immunosuppressive pharmaceuticals to circumvent transplant immunorejection; and (v) chronic donor organ shortage.[24]

---

[20] *See generally* Canadian Institute for Health Information, Table 1A, Transplants by Organ and Donor Type, Canada and Provinces, Summary Statistics, Jan. 1 to Dec. 31, 2003 (Number) (2), *available at* http://www.cihi.ca/cihiweb/en/downloads/reports_corrstats2003c_t1a_e.pdf (last visited Mar. 20, 2008).

[21] *See* SHARON STEVENSON & STEVEN P. ARNOCZKY, *Transplantation of Musculoskeletal Tissues*, *in* ORTHOPAEDIC BASIC SCIENCE 567 (Joseph A. Buckwater et al. eds., 2d ed. 2000).

[22] *See*, *e.g.*, STEM CELL AND GENE-BASED THERAPY, *supra* note 5; Hentze et al., *supra* note 5.

[23] STEVENSON & ARNOCZKY, *supra* note 21, at 571.

[24] *See id.* at 568-70; Robert I. Lechler et al., *Organ Transplantation – How Much of the Promise Has Been Realized?*, 11 NAT. MED. 605 (2005); Ming H. Zheng et al., *Challenges in the Evaluation of Safety and Efficacy of Human Tissue and Cell Based Products*, 76 ANZ J. SURG. 843 (2006).

[8] Some records are available concerning the shortage of organs. According to the Canadian Institute for Health Information's Canadian Organ Replacement Register, the number of individuals waiting for an (allogeneic) organ transplant in Canada has been relatively stable at approximately 4,000 patients between 2001and 2004.[25] While roughly 1,800 transplants had been performed annually during these years, approximately 225 patients, or an average of five individuals per week, died awaiting a transplant.[26] Clinical allotransplantation in Canada has been hampered by the lack of available organs for transplantation.[27] In the United States, the number of individuals on the waiting list for an organ transplant for each year between 2001 and 2004 was approximately 86,700.[28] The number of organ transplants that were performed annually between 2001 and 2004 averaged approximately 25,400 per year.[29] The number of individuals who died annually while waiting for a transplant during that time period averaged approximately 6,700 per year.[30] Eurotransplant, which gathers transplant statistics for Austria, Belgium, Germany, Luxembourg, the Netherlands, and Slovenia, a cumulative population of approximately 122 million, recorded 15,086 persons on its waiting list for 2007.[31] For this same population during 2007, the number of transplantations was 5,985.[32] In the U.K. with a population of approximately 60 million, there were 7,234 on the waiting list as of March

[25] Canadian Institute for Health Information, Table 1A, *supra* note 20.
[26] *Id*.
[27] Canadian Institute for Health Information, *Canada's Organ Donation Rate Still Too Low to Meet the Need, Reports CIHI*, *available at* http://secure.cihi.ca/cihiweb/dispPage.jsp?cw_page=media_14apr2004_e (last visited Mar. 20, 2008). *See also* Pascal Bucher et al., *Xenotransplantation: an Update on Recent Progress and Future Perspectives*, 18 TRANSPLANT INT'L 894 (2005).
[28] United Network for Organ Sharing: News, *available at* http://www.unos.org/./ (last visited Apr. 6, 2008). Note that there is duplication in this result since some patients are listed with more than one transplant center.
[29] *Id*.
[30] *Id.*
[31] Eurotransplant, *available at* http://www.eurotransplant.nl/./ (last visited Apr. 6, 2008). This table displays the waiting lists for kidney, heart, liver, lung, and pancreas transplants (double transplantations were not counted in this list).
[32] *Id*.

31, 2007.[33] The total number of transplants completed during the financial year of 2006-2007 was 3,087.[34]

[9] The need for stem cell transplantation is also great. Human stem cells, which have the ability to regenerate through cellular division and differentiate into the many different type of cells of the human body, were first isolated in 1998 by James Thomson from the inner cell mass of an early stage human embryo donated to research from excess embryos produced *in vitro*.[35] The sources of human stem cells now include embryonic stem cells (isolated from the inner mass of human embryos),[36] adult stem cells, [37] umbilical cord blood cells, [38] and stem cells from amniotic fluid.[39] The most established stem cell therapies use hematopoietic stem cells to treat patients with leukemia, sickle cell anemia, bone marrow damage, metabolic disorders, and various immunodeficiencies as well as skin grafts to treat severe burns (as skin contains stem cells immediately under its top layer).[40] Restricted to North America alone, it is estimated that 14,985 people had autologous or allogeneic stem cell transplantation for leukemia, lymphoma, myeloma, myleodysplastic syndrome, and other blood cancers in 2003.[41]

---

[33] Transplant Activity in the UK, *available at* http://www.uktransplant.org.uk/ukt/statistics/transplant_activity_report/current_activity_reports/ukt/transplant_activity_uk_2006-2007.pdf (last visited Apr. 6, 2008).

[34] *Id.* This number is for all transplant types.

[35] *See* James A. Thomson et al., *Embryonic Stem Cell Lines Derived from Human Blastocysts*, 6 SCI. 282, 1145-47 (1998). Plants also have stem cells but only animal stem cells are relevant in this context.

[36] Embryonic stem cells usually come from surplus blastocysts from IVF clinics but can also be created through somatic cell nuclear transfer. *See* I. Wilmut et al., *Somatic Cell Nuclear Transfer*, 419 NAT. 583 (Oct. 10, 2002).

[37] *See* DIRK STRUNK & CHRISTOF STAMM, *Adult Human Cells for Myocardial Tissue Repair*, *in* STEM CELL AND GENE-BASED THERAPY, *supra* note 5, at 17.

[38] *See* Gal Goldstein et al., *Human Umbilical Cord Blood Transplantation: A Viable Option for Stem Cell Graft*, *in* STEM CELL AND GENE-BASED THERAPY, *supra* note 5, at 333.

[39] *See* Paolo De Coppi et al., *Isolation of Amniotic Stem Cell Lines with Potential for Therapy*, 25 NAT. BIOTECH. 100 (2007).

[40] THE NATIONAL ACADEMIES, UNDERSTANDING STEM CELLS, *available at* http://dels.nas.edu/dels/rpt_briefs/stem-cell-high.pdf.

[41] Leukemia and Lymphoma Society, Blood and Marrow Stem Cell Transplantation, *available at* http://www.leukemia-lymphoma.org/all_page?item_id=5965 (citing Center for International Blood & Marrow Transplant Research). For further information, see

[10] A second need for human materials is for medical research. The production of stem cells, for instance, may contribute toward the development of treatments for diseases that are studied. [42] Researchers could grow stem cells with specific genetic abnormalities that, if allowed to fully develop, could manifest clinically as a given disease such as cystic fibrosis, multiple sclerosis, and Alzheimer's in order to: (i) explore the pathogenesis of such conditions; and (ii) elucidate novel biochemical targets for target-based drug discovery.[43]

B. THE POTENTIAL NEED FOR PART-HUMAN MATERIALS

[11] To address the shortfall of biological materials, other sources, such as non-heart beating donors (i.e. organs from patients whose death is confirmed by irreversible cardio-pulmonary arrest) as well as the application of biotechnological advances, are actively being pursued.[44] In fact, biosynthetic tissues and organs, including synthetic skin and bone substitutes, may eventually become a viable alternative to traditional transplantation materials. Numerous restrictions, however, such as the technical limitations associated with engineering complex tissues so as to duplicate their innate function *in vivo,* currently inhibit their production and use. [45] As a result, the leading potential solution to this shortage for the foreseeable future is xenotransplantation.

[12] A central limitation of xenotransplantation is the risk of xenozoonoses (i.e., the transmission of novel viral and microbial pathogens from xenograft to human recipient).[46] Further, even if the

---

CIBMTR, *Progress Report*, *available at* http://www.cibmtr.org/ABOUT/Annual_Report/DOCS/annual_report.pdf.

[42] STEM CELL AND GENE-BASED THERAPY, *supra* note 5, at vii.

[43] United Kingdom Parliament, *supra* note 6.

[44] *See* Bucher et al., *supra* note 27; Ogle et al., *supra* note 3.

[45] Mark A. Knight & Gregory R. Evans, *Tissue Engineering: Progress and Challenges*, 114 PLAS. & RECONSTR. SURG. 26e, 35e (2004).

[46] *Id*. at 32e-33e. In pigs, these viruses are known as porcine endogenous retroviruses ("PERV"). At present, PERVs cannot be eliminated from the pig's DNA, but it might be possible in the future. *See* Interview by Frontline: Organ Farm, Interview with Robin Weiss, M.D., Virologist, University College, London, *available at* http://www.pbs.org/wgbh/pages/frontline/shows/organfarm/interviews/weiss.html. Examples of existing viruses that have crossed the species barrier include "mad cow" disease, Ebola, Hantavirus, rabies, herpes, hepatitis B and C, influenza, and the human

problem of xenozoonoses could be solved, xenograft immunorejection would remain a critical barrier to xenotransplantation. The mechanism through which an immunological response deleteriously affects a xenograft depends upon the type of graft transplanted.[47] For example, cell and tissue xenografts are susceptible to primary non-function, which is characterized by macrophage and cellular-mediated rejection of the graft.[48] Organ xenografts are subject to various types of vascular rejection, among which include mechanisms that are induced by either anti-donor antibodies (to galactose-α1,3-galactose oligosaccharides present on the graft's cell surfaces, for example) or T-cells.[49] Regardless of the specific mechanism, the biochemical cascades involved in the immune system's destruction of a transplanted xenograft are abstruse and have yet to be completely understood.[50] Confronted with the challenges associated with the xenobiotic immunological response, some scientists have suggested that the use of animal-human combinations could decrease immune system rejection of transplanted materials.[51]

[13] The second potential need for part-human biological materials arises with the limitations associated with the production of stem cells for research and transplantation. Eventually the reprogramming of an

immunodeficiency virus ("HIV"), which probably originated in monkeys. *See*, *e.g.*, FDA, *Guidance for Industry: Public Health Issues Posed by the Use of Nonhuman Primate Xenografts in Humans* ("FDA Primate Guidelines"), *available at* http://www.fda.gov/CBER/gdlns/xenoprim.pdf.

[47] Jeffrey L. Platt, *Knocking Out Xenograft Rejection*, 20 NAT. BIOTECH. 231, 231 (2002).

[48] *Id.* at 231, fig. 1.

[49] *Id.* The binding of the recipient's endogenous antibodies to galactose-α1,3-galactose oligosaccharides present on the xenotransplant's cell surfaces results in the graft's parenchyma and vasculature being immediately destroyed upon reperfusion due to interstitial hemorrhage and thrombosis. This process, which is the first immunological insult that must be surmounted, is known as hyperacute rejection. *See* Henk-Jan Schuurman et al., *Pathology of Xenograft Rejection: A Commentary*, 10 XENOTRANSPLANTATION 293, 294 (2003).

[50] *See* L. Bühler et al., *Xenotransplantation – State of the Art – Update 1999*, 4 FRONTIERS IN BIOSCI. 416, 425 (1999). While powerful immunosuppressive drugs have decreased the rate of acute rejection significantly, long-term functional graft survival is poor due to chronic rejection. *See* Spiros Delis et al., *Bone Marrow-Induced Tolerance in the Era of Pancreas and Islets Transplantation*, 32 PANCREAS 1, 1 (2006).

[51] *See*, *e.g.*, Cristina Costa et al., *Transgenic Pigs Designed to Express Human CD59 and H-Transferase to Avoid Humoral Xenograft Rejection*, 9 XENOTRANSPLANTATION 45 (2002); Robin A. Weiss, *Transgenic Pigs and Virus Adaptation*, 391 NATURE 327 (1998).

individual's own cells may allow for the autotransplantation of stem cells, but the technology is, so far, still experimental.[52] In the meantime, a large number of human eggs is required for research, the availability of which is limited.[53] Surplus eggs that are from *in vitro* fertilization ("IVF") clinics are limited and in some jurisdictions not available at all.[54] Furthermore, "the use of human eggs for research has also raised concerns about whether it is appropriate to encourage women to undergo an invasive and potentially harmful procedure [to collect eggs], without providing any direct medical benefit to the donor."[55] Even if sufficient surplus human stem cells were available from IVF clinics for research and transplantation, there would be a risk of immune incompatibility with the recipient of the stem cells.[56] In addition, when human eggs are available, it is very difficult to create a human embryonic stem cell line that clones the genetic makeup of the recipient.[57] Finally, there are ethical issues concerning the creation of human embryonic stem cells where it involves the destruction of a human blastocyst.[58] Thus, some researchers are planning to use techniques that combine human DNA with a cow's egg to produce cow-human hybrid embryos for research purposes.[59] Other researchers are investigating alternative sources of stem cells for transplantation, such as fetal porcine cells.[60]

---

[52] Takahashi K. et al., *Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors*, 131 CELL 861, 869 (2007).

[53] Dr. Lyle Armstrong of Newcastle University notes that "we would need in excess of 30 oocytes [eggs] to have a reasonable chance of producing an ESC [embryonic stem cell] line for each patient." *See* United Kingdom Parliament, *supra* note 6, at ¶ 51. Dr. Stephen Minger at King's College London stated that "until the efficiency of successful SCNT [somatic cell nuclear transfer] in humans can be increased significantly (to perhaps 10-20%) ten to twenty percent) alternative sources of oocytes specifically for SCNT are needed." *Id.*

[54] For example, German Embryo Protection Law prohibits the fertilization of more eggs than are necessary for implantation within one cycle. *See* Christian Starck, *Embryonic Stem Cell Research According to German and European Law - Part 2/2*, 7 GERMAN L.J. (2006), *available at* http://www.germanlawjournal.com/article.php?id=740.

[55] *See* United Kingdom Parliament, *supra* note 6, at ¶ 50.

[56] THE NATIONAL ACADEMIES, *supra* note 40, at 14.

[57] "Hwang failed to generate a stem cell line after nuclear transfer – or cloning – of 2,000 fresh human eggs." *See* King's College London, *Stem Cell Research License Application* (2006), *available at* http://www.kcl.ac.uk/phpnews/wmview.php?ArtID=1476.

[58] United Kingdom Parliament, *supra* note 6, at ¶ 34-44.

[59] *Id.*

[60] STEM CELL AND GENE-BASED THERAPY, *supra* note 5, at 124.

II. PART-HUMAN MATERIALS FOR TRANSPLANTATION

[14] Three kinds of part-human materials are of primary interest for transplantation: embryonic chimeras, transgenic materials, and cytoplasmic hybrid stem cells or "cybrids."[61]

A. CHIMERAS

[15] A broad concept of the chimeric organism, broader than the one that is contained in the Canadian legislation, is ". . . a mixture of cells from two or more genetically distinct organisms of the same or different species."[62] For instance, human-animal embryonic chimeras can be

[61] For a useful categorization of part-humans see the United Kingdom Parliament, *supra* note 6, at ¶ 27-31.

[62] Francoise Baylis & Jason S. Robert, *Part-Human Chimeras: Worrying the Facts, Probing the Ethics*. , 7(5) AM. J. BIOETHICS 41, 41 (2007). Both Canadian law and proposed U.S. legislation concern human chimeras rather than chimeras generally. Human Chimera Prohibition Act of 2005, S. 659, 109th Cong. (2005); Human Chimera Prohibition Act of 2005, S. 1373, 109th Cong. (2005)); Assisted Human Reproduction Act, 2004 S.C., c.2 (Can.). Under Canadian legislation, for instance, "chimera" has been narrowly defined as "an embryo into which a cell of any non-human life form has been introduced" or "an embryo that consists of cells of more than one embryo, foetus or human being." In addition, "embryo" means a human organism during the first 56 days of its development following fertilization or creation, excluding any time during which its development has been suspended, and includes any cell derived from such an organism that is used for the purpose of creating a human being. Assisted Human Reproduction Act, 2004 S.C., c. 2, s. 3 (Can.). Therefore, it does not prohibit the incorporation of human genetic material into non-humans, although it prohibits the creation of other forms of part-humans. Section 301 of the U.S. Human Chimera Prohibition Act of 2005, which did not pass, defined "human chimera" to mean :

> (A) a human embryo into which a non-human cell, or any component part of a non-human cell, has been introduced; (B) a human embryo that consists of cells derived from more than 1 human embryo, fetus, or born individual; (C) a human egg that has been fertilized by a non-human sperm; (D) a non-human egg that has been fertilized by a human sperm; (E) a human egg into which a non-human nucleus has been introduced; (F) a non-human egg into which a human nucleus has been introduced; (G) a human egg or a non-human egg that otherwise contains haploid sets of chromosomes from both a human and a non-human life form; (H) a non-human life form engineered such that human gametes develop within the body of a non-human life form; or (I) a non-human life form engineered such that it contains a human

produced through the fusing of human cells (e.g. stem cells) with a non-human embryo yielding an organism whose individual cells are derived entirely from either the animal or the human.[63] Examples of chimeras include: (i) the incorporation of human stem cells into post-blastocyst stages of non-human embryos of mice, sheep, monkeys, pigs, and goats;[64] and (ii) the incorporation of human stem cells into a mouse blastocyst.[65]

[16] The rationale for using a chimera as a source of biological material for transplantation begins by considering the shortcomings of other sources of materials. Setting aside the reproductive cloning of an entire human for spare parts as immoral and impractical (because of the long period of organogenesis), another method of creating materials for transplantation would be to generate an organ through tissue engineering. This might be attempted by using somatic cell nuclear transfer to generate embryonic stem cells that are histocompatible with (i.e. will not be rejected by) the individual, and then those embryonic stem cells could be used to generate a functional organ, such as a lung.[66] However, at this time, little is known about whether, and to what extent, stem cells can be coaxed into developing into intact anatomically complex organs with functioning vasculature.[67]

[17] Consequently, it has been suggested that organogenesis might best occur in an animal host as a xenograft, allowing human cells to fuse with those of the host animal.[68] At the Mayo clinic, Platt carried out an experiment in which human hematopoietic stem cells (from which all red and white blood cells develop) were injected into fetal pigs at forty days

---

> brain or a brain derived wholly or predominantly from human neural tissues.

Human Chimera Prohibition Act of 2005, S. 1373, 109th Cong. § 301 (2005).

[63] Baylis & Robert, *Part-Human Chimeras*, *supra* note 62, at 44.

[64] BioCentre, *supra* note 7.

[65] *Id.* In 2003, it was reported that scientists from Maria Biotech in South Korea injected human embryonic stem cells labeled with a fluorescent protein into 11 eleven mouse blastocysts which later developed in foster mice. The five offspring contained fluorescent cells in the heart, kidney, liver, and bones. Nell Boyce, *Mixing Species – and Crossing a Line?*, 135(14) U.S. NEWS & WORLD REPORT, Oct. 27, 2003, at 58.

[66] BioCentre, *supra* note 7; Ogle, *supra* note 3, at 75.

[67] Ogle, *supra* note 3, at 75; *see also* Knight & Evans, *supra* note 45.

[68] Ogle, *supra* note 3, at 76.

gestation.[69] When the pigs were born, human cells were found in their internal organs and throughout the blood system. [70] However, the pigs were not pure chimeras as over 60% of the non-pig cells were pig-human hybrid cell fusions in which two cells were integrated into a new viable cell.[71] This methodology of growing organs in host animals has been furthered by Esmail Zanjani whose group transplanted embryonically derived human hematopoietic stem cells into a sheep's foetus.[72] These grown sheep-human chimeras were subsequently reported to have had organs, including a liver, heart, and pancreas that are 15% human.[73] Crucially, where development of an organ takes place in a foreign environment, it acquires the necessary blood vessels from the host.[74] Unfortunately, as a result, an organ developed in an animal host would contain xenogeneic blood vessels, which in turn would be targeted by the host immune system.[75] It is hoped, however, that after transplantation of the part-human organs developed using this method, the human part of the organs would be accepted even if the non-human part is rejected.[76]

B. TRANSGENICS

[18] While chimeric organisms possess two genetically distinct populations of cells, transgenic organisms consist of only one genetically distinct population of cells that have been altered by the introduction of

---

[69] Gaia Vince, *Pig-Human Chimeras Contain Cell Surprise*, NEW SCIENTIST, Jan. 13, 2004, *available at* http://www.newscientist.com/article/dn4558-pighuman-chimeras-contain-cell-surprise.html. *See also*, Platt, *supra* note 47.

[70] Vince, *supra* note 69.

[71] *Id.* These cell fusions were found to be synkaryons, hybrids in which not only the cell membrane and cytoplasm has fused but also the nuclear membrane and nucleaplasm have as well. For further information on synkaryons, see ARIE H. BARTAL & YASHAR HIRSHAUT, METHODS OF HYBRIDOMA FORMATION 2 (Humana Press 1987).

[72] Christopher Thomas Scott, *Chimeras in the Crosshairs*, 24 NAT. BIOTECH. 487, 488 (2006). *See also* Claudia Joseph, *Now Scientists Create a Sheep That's 15% Human*, DAILY MAIL, *available at* http://www.dailymail.co.uk/pages/live/articles/news/news.html?in_article_id=444436&in_page_id=1770&in_a_source=&ct=5 (last visited July 3, 2007).

[73] Scott, *supra* note 72, at 488.

[74] Ogle, *supra* note 3, at 76.

[75] *Id.*

[76] Scott, *supra* note 72, at 488.

DNA sequences from sources external to the organism.[77] Numerous attempts have been made to manipulate a given organism's genome by inserting a xenogenic gene in order to achieve the expression of a desired phenotype.[78] One of the goals of some recent genetic engineering is the "humanization" of xenograft organs to improve their immunocompatibility with humans.[79] To this end, much focus has been placed on the use of pigs. Despite the immunological disparity between humans and pigs, pigs are preferred over other species due to their superiority in terms of breeding, availability, and cost; moreover they are also morally less problematic compared to animals higher on the phylogenetic scale.[80] In addition, the fact that pigs do share a certain degree of physiological, anatomical and biochemical similarities with humans,[81] and that the porcine genome can be readily manipulated through genetic engineering, also weigh in favor of their use.[82]

[19] One of the first transgenic pigs specifically engineered for xenotransplantation was the human complement regulatory protein (hDAF) transgenic pig.[83] While hDAF does not prevent anti-galactose-α1,3-galactose antibody binding, the incorporation of this human gene into the porcine genome resulted in the expression of a protein capable of inhibiting the complement cascade involved in hyperacute rejection ("HAR") of xenografts.[84] While the results from a study in which hDAF chimeric organs were transplanted into primates demonstrated that the

[77] *See generally* BioCentre, *The New Inter-Species Future? An Ethical Discussion of Embryonic, Fetal and Post-Natal Human-Nonhuman Combinations*, June 2007, *available at* http://www.bioethics.ac.uk/index.php?do=topic&sid=13 (last visited Mar. 20, 2008).
[78] *Id.* at 48-49. Examples include the production of human insulin and the expression of human protein in the milk of goats and sheep and the "white" of chicken eggs. *Id. See generally* Pascal Bucher et al., Xenotransplantation: An Update on Recent Progress and Future Perspectives, 18 TRANSPLANT INT'L 894 (2005).
[79] Interview by Frontline with Robin Weiss, *supra* note 46.
[80] Bucher et al., *supra* note 27.
[81] *Id.*
[82] A. Ravelingien & J. Braeckman, *To the Core of Porcine Matter: Evaluating Arguments Against Producing Transgenic Pigs*, 11 XENOTRANSPLANTATION 371 (2004).
[83] Henk-Jan Schuurman et al., *Incidence of Hyperacute Rejection in Pig-to-Primate Transplantation Using Organs From hDAF-Transgenic Donors*, 15 TRANSPLANTATION 1146 (2002).
[84] *Id.*; *see also* Interview by Frontline with Robert Weiss, M.D., *supra* note 46.

genetic modification successfully circumvented HAR,[85] this approach does not seem to adequately circumvent the problem of chronic graft rejection.[86] Research is, therefore, presently taking place to try to eliminate or reduce these epitopes while genetically engineering the expression of human complement regulatory proteins, such as CD59, in animals.[87]

C. CYBRIDS

[20] The shortage of human embryonic stem cells, and the concerns associated with the destruction of human embryos to produce embryonic stem cells, has resulted in the call for the creation and use of embryos of, and stem cells derived from, animal-human combinations.[88] The idea is to use non-human eggs stripped of their chromosomes as a host for the production of part-human stem cells, analogous to the use of pigs or sheep as a host for the production of part-human organs.[89] In fact, in 1998, Advanced Cell Technology claimed that it had created an embryo, a so-called "cytoplasmic hybrid embryo,"[90] by fusing the nucleus of an adult human cell with an enucleated cow egg using nuclear transfer of skin

[85] Schuurman et al., *supra* note 83.

[86] Another study demonstrated that the median survival time of hDAF-expressing porcine kidneys in monkeys, albeit an improvement over controls, was merely thirteen days. *See* Afzal Zaidi et al., *Life-Supporting Pig-to-Primate Renal Xenotransplantation Using Genetically Modified Donors*, 65 TRANSPLANTATION 1584 (1998).

[87] *See* U.S. Patent No. 7,166,278 (filed Jan. 23, 2007), *available at* http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=7,166,278.PN.&OS=PN/7,166,278&RS=PN/7,166,278.

[88] United Kingdom Parliament, *supra* note 6.

[89] The U.K. Biosciences Federation is an example of an industry association that has called for the regulated use of chimeric stem cells for research purposes. However, it appears that such research purposes may include clinical uses in subjects. *See* Biosciences Federation, Government Proposals for the Regulation of Hybrid and Chimera Embryos, *available at* http://www.bsf.ac.uk/responses/HybridEmbryos.pdf (last visited Mar. 20, 2008).

[90] See the United Kingdom Parliament, *supra* note 6. Note that, according to BioCentre, "[t]he term hybrid may be misleading if one is normally used to restricting the term to the progeny resulting from sexual reproduction, whilst the term chimera may be misleading if one normally only associates this with an organism containing a distinct population of cells which differ in their genetic origin." BioCentre, *supra* note 7, at 55.

cells.[91] This egg, and the cells derived from the early age embryo which develops therefrom, could be used to provide an interim solution to the shortage of human stem cells for research and, perhaps, for transplantation purposes.

[21] Research teams from King's College, London and Newcastle University recently were granted separate licenses from the U.K. Human Fertilization and Embryo Authority ("HFEA") to produce embryonic stem cells by inserting the nucleus of a human cell, such as a skin cell, into the trophoblast or "shell" of a cow egg.[92] The research will involve the creation of embryos that would be approximately 1% animal and 99% human.[93] To be clear, these research teams have no plans to use any of the embryos for transplantation and must destroy them within fourteen days.[94] Rather, they are intended to be used as a means of experimenting on cow eggs to improve the ability to create human embryonic stem cells using human eggs,[95] and to develop disease-specific human embryonic stem cell

[91] It should be noted that the conclusion drawn by company officials was merely inferential; no assays were carried out to determine whether the cells created were in fact human stem cells. *See* Eliot Marshall, *Claim of Human-Cow Embryo Greeted With Skepticism*, 282 SCI. 1390 (1998).

[92] *See* Human Fertilisation & Embrylogy Authority, Research News, *available at* http://www.hfea.gov.uk/en/377.html (last visited Mar. 20, 2008).

[93] "Any being created in this way would have DNA 99% identical with that of the adult from whom the human nucleus was taken; the remaining 1% of DNA (i.e. mitochondrial DNA) would come from the unnucleated animal oocyte."). *See* Baylis & Roberts, *Crossing Species Boundaries*, *supra* note 17, at 8. Interestingly, one of the applicants, Stephen Minger from King's College, glossed over the fact that a small percentage of the embryo will be non-human. He said that, "[o]nce the nucleus of the animal egg is removed it essentially no longer has a species identity and when replaced with a human nucleus, the resulting embryo and cell line will have human genetic identity." Press Release, King's College London, Stem Cell Research License Application (Nov. 7, 2006), *available at* http://www.kcl.ac.uk/phpnews/wmview.php?ArtID=1476. As the HFEA notes, ". . . this is not strictly correct, as although the vast majority of genetic identity would be human, heritable extra-nuclear genetic material such as that present in the cellular structures mitochondria would be bovine in origin." PHG Foundation, *Human-Cow Chimeric Embryos for Stem Cell Research*, Nov. 2006, *available at* http://www.phgu.org.uk/ecard?link_ID=2798 (last visited Mar. 20, 2008).

[94] Science Daily, *Hybrid Human-Animal Embryo Research Approved in the UK*, Jan. 18, 2008, *available at* http://www.sciencedaily.com/releases/2008/01/080118102223.htm.

[95] Press Release, Newcastle University, Researchers Seek Permission for Stem Cell Work Using Animal Eggs, (Nov. 6, 2006), *available at* http://www.ncl.ac.uk/press.office/press.release/content.phtml?ref=1162836050 (last

lines from individuals suffering from genetic forms of neurodegenerative disorders in order to assist in developing new treatments for such diseases.[96]

III. PROHIBITED CATEGORIES: HUMAN BEINGS, HIGHER LIFE FORMS OR PERSONS?

A. PROHIBITING THE PATENTING OF HUMANS AND HIGHER LIFE FORMS

[22] Even if the creation and use of part-human materials could solve the problem of immune rejection, there would very likely be objections to the creation, use and patenting of such materials on the basis that such actions compromise the value of human beings. According to this criticism, while human biological materials are of value for their use in research and transplantation, human beings are of value because of the sanctity[97] of human life and the dignity[98] of human beings. On such a view, human beings are not patentable because it is incompatible with their special

visited Mar. 20, 2008). Minger notes, "[b]ut I will stress that the cell lines derived by SCNT will only be used for biological and pharmacological research, not for therapeutic purposes." Press Release, King's College London, Stem Cell Research Licence Application, *supra* note 93.

[96] Press Release, King's College London, Stem Cell Research Licence Application, *supra* note 93. The use of part-human embryos in such research has been supported by the U.K. United Kingdom Parliament, *supra* note 6. Notwithstanding, there is significant opposition to the mixing of human adult somatic cells with the live eggs of any non-human animal species. *See* BioCentre, *supra* note 7, at 59.

[97] For example, the Supreme Court of Canada said that "human life is seen to have a deep intrinsic [i.e. non-instrumental] value of its own" and legally is protected under s. 7 of the *Canadian Charter of Rights and Freedoms,* Part I of the *Constitution Act, 1982,* being Schedule B to the *Canada Act 1982* (U.K.), 1982, c. 11 [hereinafter *Charter*]; *Rodriguez v. British Columbia (Attorney General),* [1993] 3 S.C.R. 519, 1993 SCC 75 (citing RONALD DWORKIN, LIFE'S DOMINION: AN ARGUMENT ABOUT ABORTION, EUTHANASIA, AND INDIVIDUAL FREEDOM (1993)).

[98] *See* IMMANUEL KANT, GROUNDWORK FOR THE METAPHYSICS OF MORALS (1785), *available at* http://www.earlymoderntexts.com/kgw.html (treating dignity as a worth of humans that is incomparably more valuable than that of mere goods); Timothy Caulfield & Roger Brownsword, *Human Dignity: A Guide to Policy Making in the Biotechnology Era?*, 7 NAT. REV. GENETICS 72 (2006) (surveying the use of dignity in bioethics and patenting issues and criticizing its use as a theoretical concept). In this article, however, the authors appear to use "dignity" in the sense of "intrinsic worth," thereby appearing to run the two kinds of value together. *Id.* For a book-length exposition of the value of the sanctity of life, see DWORKIN, *supra* note 97.

standing. More generally, the prohibition against patenting humans might be considered to be a special case of a more general prohibition against the patenting of any higher life forms.[99]

[23] The problem with a rule against patenting humans is the assumption of a fixed, well-defined human species identity. As Jason Scott and Francoise Baylis have pointed out, "[m]orally, . . . we rely on the notion of fixed species identities and boundaries in the way we live our lives and treat other creatures, whether in decisions about what we eat or what we patent."[100] However, this reliance is misplaced, given that the concept of human is too vague to determine when any given part-human material counts as human. This point is not made to ground an overbroad, skeptical thesis that patent law is inherently indeterminate. Rather, the point is the narrower one that the concept of human cannot be determinately applied to part-human biological materials which are needed for medical purposes. Additional patentability criteria are needed, therefore, in order to determine whether part-human materials – whether they are animal-human combinations or early stages of human development – are patentable.

[24] Further, the vagueness is not merely linguistic, but reflects the fact that the common descent of animals has not resulted in any qualitative features – morphological, genetic, or behavioural – that can be considered essential for species membership.[101] Because of mutation, recombination, and random drift of genetic material, any given trait considered to be essential to a species could disappear in a future member of the species, making it a non-essential property.[102] Modern genomics shows, for example, that we are very close to chimpanzees: our genomes differ by a

[99] As will be discussed, *infra*, this is the view of the Canadian Supreme Court in *Harvard College*, [2002] 4 S.C.R. 45 (Can.). In that judgment, however, the Canadian Supreme Court purported to base its view solely on an interpretation of relevant legislation rather than concern itself with the moral implications of patenting humans or higher life forms.
[100] Robert & Baylis, *supra* note 17, at 6.
[101] Marc Ereshefsky, *Species*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed.) (Summer 2007), *available at* http://plato.stanford.edu/archives/sum2007/entries/species.
[102] *Id.*

mere 1.23%. [103] Even mice and humans are close genetically. While humans and mice diverged some 32 million years ago,[104] approximately 99% of the genes in humans have counterparts in the mouse, and 80% have identical, one-to-one counterparts.[105]

[25] Even if one started with a paradigm case of a human, say, any adult member of the species *Homo sapiens*, it is tempting to say that if there were very small differences between that paradigmatically human creature and another creature, the other creature would still be a human. For example, if a small amount of foreign DNA is added to a human, it is still a human (or similarly, if a small amount of human DNA is added to a non-human animal it is still non-human). Through iteration of this principle, however, one is led to the conclusion that very little, if any, human DNA is required for something to be human.[106] Further, any distinction to be drawn between human and non-human based upon relative amounts of human and non-non-human DNA would appear to be arbitrary.

[26] A second kind of vagueness concerns development: when does an individual animal or human life begin? Obviously there is a sense in which a sperm and egg from humans, for instance, are human forms of life rather than, say, a mouse form of life, but is that the relevant concept of a human life for the purposes of patenting? On the definition assumed in this paper, a human being at any stage of development is *part-human* –

[103] Chimpanzee Sequencing and Analysis Consortium, *Initial Sequence of the Chimpanzee Genome and Comparison with the Human Genome* 437 NATURE 69, 69 (2005) (regarding single-nucleotide substitutions); Wen-Hsiung Li & Matthew A. Saunders, *News and Views: The Chimpanzee and Us*, 437 NATURE 50 (2005).

[104] *See* Chen Su & Masatoshi Nei, *Evolutionary Dynamics of the T-Cell Receptor VB Gene Family as Inferred from the Human and Mouse Genomic Sequences*, 18 MOLECULAR BIOLOGY EVOLUTION 503 (2001*), cited in* Stuart A. Newman*, Averting the Clone Age: Prospects and Perils of Human Development Manipulation*, 19 J. CONTEMP. HEALTH L. & POL'Y, 431, 456 (2003).

[105] *See* Chris Gunter & Ritu Dhand, *Human Biology by Proxy*, 420 NATURE 509 (2002).); Mouse Genome Sequencing Consortium, *Initial Sequencing and Comparative Analysis of the Mouse Genome*, 420 NATURE 520 (2002).

[106] This classic sorites argument assumed that if you take away a grain of sand from a heap of sand, it would still be a heap. Hence, by iteration, one grain of sand is a heap of sand, which is false. "Sorites" comes from the Greek term "soros," which means heap. Dominic Hyde, *Sorites Paradox*, *in* THE STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed.) (Fall 2005), *available at* http://plato.stanford.edu/archives/fall2005/entries/sorites-paradox.

because it contains human DNA – but at what stage is a developing embryo considered to be an individual human being for the purposes of the principle against patenting human beings? If one considers only the material basis of a human, it is tempting to say that every stage of development of a human being from the fertilized egg onward is a human being. That is, if one starts with a paradigmatic fully developed human and accepts the principle that at the immediately prior stage of development of a human being the organism was a human being, then the conclusion must be that at every stage at which an organism is developing into a human being, it is a human being.

[27] It follows from this conclusion that even the zygote of a human being is itself a human being; just as the zygote of a sheep is itself a sheep. The idea that the zygote of a human *is* a human follows from the view that the development of an organism from a zygote is considered to be merely the growth of a "preformed" body or the deterministic result of material internal to the zygote, rather than the gradual epigenesis of a human embryo into a human being through the interaction of various internal and external developmental factors.[107] The historical figures associated with the preformationist doctrine include the biologists von Hartsoeker who, in 1694, used the image of a tiny man in the sperm, and Weissman who, in 1893, put forward a kind of genetic determinism in which cell division produces a mosaic of cells with different chromosomal materials so that "the fate of the cells is determined by forces situated within them, and not by external influences."[108] Similarly, the modern genetic version of preformation construes development as "a matter of the epigenetic activation of preformed genetic information." [109] It appears, on this genetic preformationist view, that development is nothing more than the activation of what is already present in the embryo and that the characteristics of adult humans are an expression of the genetic structure resulting from this activation. The implication of genetic preformationism

[107] *See* JANE MAIENSCHEIN, WHOSE VIEW OF LIFE?: EMBRYOS, CLONING, AND STEM CELLS (2003).
[108] AUGUST WEISMANWEISSMAN, THE GERM PLASM 32, 134 (W. Newton Parker & Harriet Rönnfeldt trans.) (1893), *quoted in* Jane Maienschein, *Epigenesis and Preformationism*, *in* STANFORD ENCYCLOPEDIA OF PHILOSOPHY (Edward N. Zalta ed.) (Fall 2006), *available at* http://plato.stanford.edu/archives/fall2006/entries/epigenesis.
[109] JASON SCOTT ROBERT, EMBRYOLOGY, EPIGENEIS AND EVOLUTION: TAKING DEVELOPMENT SERIOUSLY 56 (2004).

is that human fetuses, human embryos, human fertilized eggs, and human totipotent stem cells[110] are unpatentable because they *are* human beings merely in virtue of the presence of human DNA. It also follows that, if mature animal-human combinations had sufficient human DNA to be considered human, then every stage of development of that part-human would be unpatentable, even if it is never allowed to develop to maturity.

[28] The problem with the application of a preformationist analysis of development to patent law is that it is neither coherent with modern biological theory nor patent law. If human beings are unpatentable, then *every* human cell containing genetic material would be unpatentable on the preformationist view and this would significantly depart from existing patent law and policy.[111] Furthermore, the modern view of development is interactionist, which according to Mayr, is a "synthesis of epigenesis and preformation."[112] For Mayr, "[t]he process of development, the unfolding phenotype, is epigenetic. However, development is also preformationist because the zygote contains an inherited genetic program that largely determines the phenotype."[113] On this interactionist consensus, an individual life is not identified with its genetic blueprint and, therefore, the concept of an individual animal or human being need not encompass every stage of its development.[114]

[29] A third kind of vagueness concerns the biological concepts of higher and lower life form, which are distinguished by their degrees of cellular complexity. On this view, unicellular organisms are considered to be lower life forms while multicellular life forms are higher life forms .Using this distinction, one could attempt to avoid the problem of the vagueness of the concept of human by adopting the rule that no higher life forms are

[110] A totipotent stem cell can give rise to all the cell types that make up the body plus all of the cell types that make up the extraembryonic tissues such as the placenta. *See* U.S. National Institute of Health, http://stemcells.nih.gov/info/ (last visited Mar. 20, 2008).
[111] It departs from patent law because of the fact that isolated human genetic material is generally considered to be patentable. CAMPBELL et. al., supra note 10.
[112] ROBERT, *supra* note 109, at 39.
[113] ERNST MAYR, THIS IS BIOLOGY 158 (1887), *quoted in* ROBERT, *supra* note 109, at 38-39.
[114] This interactionist consensus has been itself criticized by Robert. ROBERT, *supra* note 109, at 56-57.

patentable, including humans.[115] Accordingly, no higher life form, whether it is a multicellular human or a multicellular animal-human combination, is patentable. There is no need, on this view, to determine the amount of human DNA that is needed to be unpatentable. So long as the subject matter is a higher life form, it is unpatentable.

[30] The main problem with cellular complexity as a criterion for patentability is the absence of a rationale for it. Even if there were a rationale, however, it would be difficult to provide a justification for the fact that that the zygote of a higher life form would be patentable but no further development of the zygote would be patentable. Further, why does the higher/lower distinction coincide with multicellular/unicellular? One could attempt to avoid the problem of justifying the distinction by deeming a higher life form to include all of its stages of development from fertilized eggs onward.[116] Hence, a fertilized animal egg would be considered to be a higher life form despite being a single cell, the least degree of cellular complexity.

[31] The claim that a zygote of a higher life form is itself a higher life form follows from the preformationist view described above since the zygote contains the genetic information that guides development. However, it is important to understand that the preformationist view is unable to limit the class of unpatentable cells to zygotes. In other words, since the nuclei of virtually all differentiated adult cells of an organism are genetically identical to each other and to the nucleus of the zygote from which they descended, in a broad sense, virtually all cells are totipotent.[117] Even a skin cell of a higher life form would be a higher life form in a broad sense because, given the appropriate technology, such as somatic cell nuclear transfer, it could – in the right environment and with the right technology – develop into an adult higher life form.[118] In the future, it

[115] *Harvard College*, [2002] 4 S.C.R. 45, 2002 SCC 76 (Can.).
[116] As does the Canadian Intellectual Property Office in its OFFICE PRACTICE REGARDING FERTILIZED EGGS, STEM CELLS, ORGANS AND TISSUES, *supra* note 14.
[117] This is the principle of nuclear equivalence. Clones and Clones, *available at* http://www.nytimes.com/books/first/n/nussbaum-clones.html?_r=1&oref=slogin (last visited Mar. 20, 2008).
[118] Curiously, at the same time, a pluripotent stem cell, which could develop into almost every type of cell in that body, but not into an entire human, is not a stage of development of a human. This distinction leads to the odd consequence that a human embryo whose

may even be possible to induce any human adult cell to become totipotent or pluripotent without the need of an unfertilized oocyte.[119] Hence, on such reasoning, every cell of a higher life form would be considered to be a higher life form and, thus unpatentable, despite being relatively simple in terms of cellular complexity.

[32] One might attempt to avoid the dubious conclusion that every cell of a higher life is unpatentable while saving the notion that only totipotent cells are unpatentable higher life forms by making a distinction between naturally totipotent cells (which would be unpatentable higher life forms) and artificial totipotent cells developed through the application of a given technology (which would be patentable lower life forms).[120] If the artificial/natural distinction is apt, however, it would render the cellular complexity distinction irrelevant to determining whether biological material is patentable. Patentability would depend merely upon whether technology has been used utilized to isolate the material. One would have to conclude, for example, that isolated totipotent stem cells that could be used for therapeutic purposes would fall within the artificially totipotent class because they have been isolated through the application of technology, rendering them patentable.

B. PROHIBITING THE PATENTING OF PERSONS

[33] Some writers have suggested that it is wrong to determine patentability based upon fine distinctions between types of subject matter.[121] However, given that in practice European, American, and Canadian patent-granting authorities *do* apply rules based upon the type of subject matter, a less radical solution is to replace the rule against patenting humans – and higher life forms in Canada - with a rule against patenting persons. This replacement is not meant to suggest that personhood is necessarily the only basis upon which to prohibit patents,

---

every cell is pluripotent is not patentable, while all of the cells of which it is composed are patentable.

[119] Takahashi K. et al., *supra* note 52.

[120] William J. Fitzpatrick, *Totipotency and the Moral Status of Embryos: New Problems for an Old Argument*, 35 J. SOC. PHIL. 108 (2004) (discussing a similar counterargument in the context of an argument against a human embryo having moral status).

[121] Dan L. Burk, *Reflections in a Darkling Glass: A Comparative Contemplation of the* Harvard College *Decision*, 39 CANADIAN BUS. L. J. 219, 219 (2003).

but merely that it replace the prohibition against patenting humans and, in Canada, higher life forms. Nor does it assume that the concept of a person is completely precise. However, by relying upon non-biological criteria to determine patentability, the new rule dispenses with the problem that biological criteria are too vague to distinguish between patentable and unpatentable biological material in a principled way.

[34] This rule is not entirely new, but is rarely described clearly in contrast to the existing rule against patenting humans. A number of years ago, for instance, Rachel Fishman proposed amending U.S. patent legislation to define "human" very broadly as, roughly, something born of a human or any animal possessing higher faculties.[122] Similarly, Thomas Magnani implicitly suggested the rule against patenting persons when he remarked that "[i]f a creature possessed the ability to reason in this fashion (commonly known as self-awareness), the U.S. Patent and Trademark office [USPTO] likely would find it to be human under the Thirteenth Amendment."[123] Finally, patent lawyer Sander Rabin recently proposed that there be a presumption against patents on genes or cells known to endow sentience or to affect human intellect, emotion, or behaviour, and a refusal to grant patents on genes functions until they are known not to endow an entity with human characteristics. [124]

[35] The acceptability of a rule prohibiting the patenting of human biological materials when they are persons will depend largely upon its ethical implications.[125] On the proposed view, while most persons are biologically human, they need not be, as persons are beings with additional properties or powers, such as rationality and autonomy.[126]

---

[122] Rachel E. Fishman, *Patenting Human Beings: Do Sub-Human Creatures Deserve Constitutional Protection?*, 15 AM. J. L. & MED. 461, 480-81 (1989).

[123] Thomas Magnani, *The Patentability of Human-Animal Chimeras*, 14 BERKELEY TECH. L.J. 443, 450 (1999).

[124] *Id.*

[125] *See* Sander Rabin, *The Human Use of Humanoid Beings: Chimeras and Patent Law*, 24 NATURE BIOTECH. 517, 519 (2006).

[126] As Kant noted,

> Beings whose existence depends not on our will but on nature, if they are not rational beings, have only relative value as means, and are therefore called 'things' [Sachen]; whereas rational beings are called 'persons,' because their nature already marks them out as ends in themselves (i.e. as not to be

Personhood is independent of membership in the species *Homo sapiens*.[127] Thus, the main problem associated with using biological concepts as criteria for patentability is that their use would depart from the ethical view that humans *per se* are the fundamental bearers of rights, the centre of the ethical universe.[128]

[36] It is beyond the scope of this paper to determine the criteria for moral standing. It is worthwhile noting, however, that, according to Singer, within the near future the value of humanity as an end in and of itself will be replaced with the value of persons:

> During the next 35 years, the traditional view of the sanctity of human life will collapse under pressure from scientific, technological, and demographic developments . . . [w]hen the traditional ethic of the sanctity of human life is proven indefensible at both the beginning and end of life, a new ethic will replace it. It will recognize that the concept of a person is distinct from that of a member of the species *Homo sapiens*, and that it is personhood, not species membership, that is most significant . . . .[129]

[37] Biotechnology is important from a philosophical perspective because the distinction between humanity and personhood would be practically

---

> used merely as means) - which makes such a being an object of respect, and something that sets limits to what anyone can choose to do.

Kant, *supra* note 98, at 28. The central importance of persons has been followed by non-consequentialists, see JOHN RAWLS, POLITICAL LIBERALISM 19 (Columbia Univ. Press 1993), as well as by consequentialists, see JAMES GRIFFIN, WELL-BEING: ITS MEANING, MEASUREMENT, AND MORAL IMPORTANCE (Oxford Univ. Press 1986). Caulfield and Brownsword are critical of the use of the concept of dignity, claiming that, since the concept of human dignity is a contested concept, it "is in danger of devolving into a hollow rhetorical slogan." *See* Caulfield & Brownsword, *supra* note 98, at 76.

[127] Peter Singer, *Sanctity of Life,* FOREIGN POL'Y, Sept.-Oct. 2005, at 41. If that criticism had any merit it would apply equally to the concept of equality, justice, fairness, and many other important concepts.

[128] *See generally* Peter Singer, *In Place of the Old Ethic*, *in* WRITINGS ON AN ETHICAL LIFE (2000) (discussing the ethical implications of the value of persons).

[129] *Singer, supra note 128* at 40-41.

manifested if a non-human person were created through genetic engineering. So, those who want to retain a close connection between personhood and humanity are opposed to creating animal-human combinations. For example, in response to the application by researchers at King's College, London and Newcastle University to the U.K. Human Fertilisation and Embryology Authority to create a mixed ninety-nine percent human and one-percent cow egg in order to conduct further research into the treatment of various illnesses, Calum MacKellar, the Director of Research of the Scottish Council of Bioethics, said: the following:

> [i]n the history of humankind, animals and human species have been separated. In this kind of procedure, you are mixing at a very intimate level animal eggs and human chromosomes, and you may begin to undermine the whole distinction between humans and animals . . . If that happens, it might also undermine human dignity and human rights. [130]

[38] Prohibiting the creation of part-humans would merely avoid the issue of standing, however, rather than solving it. The deeper problem is that species already do not have precise boundaries.[131] The lack of precise boundaries between humans and some non-humans casts doubt on the idea that moral standing is based upon the supposed uniqueness of humans rather than, say, the more forceful justification that the authority that persons have over themselves makes them capable of conferring normativity on moral claims.[132]

---

[130] Fergus Walsh, *Plan to Create Human-Cow Embryos*, BBC NEWS, Nov. 6, 2006, *available at* http://news.bbc.co.uk/2/hi/health/6121280.stm. Further, MacKeller appears to mix up the notion of human and person when he says: "Millions of people in the U.K. would see the creation of animal-human embryo combinations as the creation of very profound ethical problems. These are not just a pile of cells, but have a special moral status as a human person." Nic Fleming, *Go-Ahead Signalled for Animal-Human Embryos*, TELEGRAPH, Feb. 3, 2007, *available at* http://www.telegraph.co.uk/news/main.jhtml?xml=/news/2007/03/01/nembryo01.xml (last visited Apr. 6, 2008).

[131] *See* Mark A. Krause, *Biological Continuity and Great Ape Rights*, 2 ANIMAL L. 171, 174 (1996).

[132]

[39] The proposed rule would allow for the patenting of human materials, such as genes, proteins, isolated cells, totipotent stem cells, many non-human animals, tissues, organs and early stage embryos since they cannot be considered to be persons. In terms of mixed species, unlike the use of humanity as a criterion, it would be irrelevant for the purposes of patentability that the organism or other material contains human DNA except indirectly insofar as certain DNA expresses features that are tied to personhood. With the proposed rule, persons would not be patentable regardless of their genetic makeup and, more abstractly, regardless of the kind of material from which they are formed (e.g. whether they are carbon-based). Thus, if an animal that is used to grow a part-human organ is not a person, then that animal and its organs would be considered to be patentable. On the other hand, should some animals which could be used to grow part- human organs be considered persons, they would *not* be considered patentable. [133]

IV. THE PATENTABILITY OF PART-HUMAN BIOLOGICAL MATERIALS

[40] In the United States, the purpose of granting patents of invention is 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."[134] Similarly, in Canada, the purpose of patent law is to "advance research and development and to encourage broader economic activity" by granting exclusive rights to make, use and sell to be

> [T]he source of the normativity of moral claims must be found in the agent's own will, in particular in the fact that the laws of morality are the laws of the agent's own will and that its claims are ones she is prepared to make on herself. The capacity for self-conscious reflection about our actions confers on us a kind of authority over our-selves, and it is this authority which gives normativity to moral claims.

CHRISTINE M. KORSGAARD, THE SOURCES OF NORMATIVITY 19-20 (Onora O'Neill ed., Cambridge Univ. Press 1996).

[133] *See*, *e.g.*, FELIPE FERNANDEZ-ARMESTO, HUMANKIND: A BRIEF HISTORY 1-2 (Oxford Univ. Press 2004) (noting that it would be difficult to find any rational capacity that is not replicated in other apes, including language use, tool-making, symbolic imagination, and self awareness).

[134] U.S. CONST. art. I, § 8, cl. 8.

used, inventions.[135] In Europe, patent protection is "intended to encourage technical innovation . . . by recompensing the inventor for his creative work so as to stimulate inventive activity."[136]

[41] Internationally, the broad scope of patentable subject matter is recognized in the *Trade Related Aspects of Intellectual Property Rights* ("TRIPS"), which notes in Article 27(1) that, subject to certain exceptions "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[137] Although the scope of patentable subject matter is broad, internationally, there are exceptions permitted under TRIPS that could apply to part-humans.[138] The first exception provides that inventions may be excluded from patentability where the exclusion is necessary to protect *ordre public* (i.e. public policy) or morality, including the protection of human, animal or plant life or health or to avoid serious prejudice to the environment.[139] Thus, if part-humans were considered to be human beings or, more broadly, the patenting of part-humans was necessary to protect morality or public policy, then part-humans could be exempted if provided for under national law.[140] Second, TRIPS provides explicitly that animals other than micro-organisms may be excluded from patenting, so part-human animals could be exempted under Article 27(3).[141] In short, despite the broad scope of patentability of subject matter, WTO members have significant

[135] Free World Trust v. Électro Santé, Inc., [2000] S.C.R. 1024, 2000 SCC 66 (Can.), at ¶ 42.
[136] Jean-Luc Gal, *Community Law in Relation to Processes for the Cloning and Patentability of Inventions Relating to the Genome and Certain Human Cells*, 2000 REVUE DU DROIT DE L'UNION EUROPÉENNE 723, 835-54 (2000) (Fr.), *reprinted in* OPINION OF THE EUROPEAN GROUP ON ETHICS IN SCIENCE AND NEW TECHNOLOGIES TO THE EUROPEAN COMMISSION ON THE ETHICAL ASPECTS OF PATENTING INVENTIONS INVOLVING HUMAN STEM CELLS, at 25 (2002), *available at* http://ec.europa.eu/european_group_ethics/publications/docs/avis16_complet_en.pdf.
[137] Agreement on Trade Related Aspects of Intellectual Property Rights, WTO, Dec. 15, 1993, 33 I.L.M. 81, 93-94 (1994) [hereinafter *TRIPS*]. The *TRIPS* agreement is part of the Uruguay round of trade agreements establishing the World Trade Organization ("WTO") the successor to the General Agreement on Trade and Tariffs.
[138] *See id.* at 94.
[139] *Id.*
[140] *Id.*
[141] *Id.*

latitude to exempt human and part-human materials from patentability in domestic legislation.

[42] The following section examines the extent to which human and part-human materials are patentable in Canada, the United States, and Europe.

A. THE APPROACH OF THE UNITED STATES

[43] According to American patent law, "[w]hoever 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."[142] In *Diamond v. Chakrabarty*, the U.S. Supreme Court held by a five to four majority that 35 U.S.C. § 101 is to be interpreted broadly due to the deliberate use of "any" in conjunction with expansive terms such as "manufacture" and "composition of matter" found in the provision.[143] The decision has been widely interpreted to have held that "anything under the sun that is made by man" is patentable.[144] A broad and dynamic construction is supported according to the Supreme Court precisely because particular inventions were (by necessity) not contemplated by the drafter of patent legislation.[145]

[44] As a result, both living and non-living biological materials have been patented in the United States.[146] According to the USPTO, in the area of living matter, the "test set down by the Court (in *Chakrabarty*) for patentable subject matter in this area is whether the living matter is the result of human intervention."[147] Similarly, non-living biological materials, including human DNA sequences have been the subject of

[142] 35 U.S.C. §101.
[143] Diamond v. Chakrabarty, 447 U.S. 303, 308 (1980).
[144] There are some exceptions recognized, such as laws of nature, physical phenomena, and abstract ideas. *See id.* at 309.
[145] *Id.* at 315-16. The notion of a dynamic interpretation was introduced by the U.S. Supreme Court in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*., 534 U.S. 124, 135 (2001).
[146] U.S. PATENT AND TRADEMARK OFFICE [USPTO], MANUAL OF PATENT EXAMINING PROCEDURE § 2105 (2007), *available at* http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r3_2100.pdf.
[147] *Id.*

patents.[148] Although patents on human genes have been subject to criticism that they were not invented but merely discovered, the USPTO has responded that even if the genetic material had not been invented, its discovery can be the basis for obtaining a patent on the genetic composition that is isolated by human intervention from its natural state by purifying the gene, and separating it from other molecules naturally associated with it.[149] So long as the application "discloses a specific, substantial, and credible utility for the claimed isolated and purified gene, the isolated and purified gene composition may be patentable."[150]

[45] Furthermore, the patenting of human DNA is not considered by the USPTO to undermine the value of humanity nor to conflict with the legal prohibition against the ownership of human beings.[151] While some criticized the patenting of human DNA by saying that the sequence of the human genome lies at the core of humanity and, consequently, that no person should be able to own or control something of that nature; the USPTO responded that "[p]atents do not confer ownership of genes, genetic information, or sequences."[152] Rather, patents simply grant a right to some to exclude others from making, using, offering for sale, selling, or importing the patented subject matter for a limited time.[153]

[46] While isolated human biological material produced through human intervention has been held to be patentable, the USPTO has taken a different stance on human beings. In April 1987, in response to the Board of Patent Appeals' *Ex Parte Allen*[154] decision, the USPTO issued a notice stating explicitly that it considered "nonnaturally occurring, *nonhuman* multicellular living organisms, including animals, to be patentable subject

[148] *Philadelphia, Health and Education Corporation Obtains U.S. Patent (Nucleic Acid Sequences and Polypeptide Sequences)*, 21 BIOTECH PAT. NEWS, Jan. 2007.
[149] Utility Examination Guidelines, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001), *available at* http://www.uspto.gov/web/offices/com/sol/notices/utilexmguide.pdf.
[150] *Id.*
[151] *See id.*
[152] *Id.*
[153] *Id.* at 1093-94.
[154] *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (B.P.A.I. 1987), was a case based on a patent application for commercially useful polyploid oysters that were sterile but grew to be larger than conventional oysters.

matter within the scope of 35 U.S.C. 101."[155] However, "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."[156] Presumably, this constitutional reference was to the prohibition of slavery under the Thirteenth Amendment of the United States Constitution, which states that "[n]either slavery nor involuntary servitude, except as punishment for crime whereof the party shall have been duly convicted, shall exist within the United States, or any place subject to their jurisdiction."[157] As Magnani has noted, "the Thirteenth Amendment cannot effectively and consistently be applied . . . until the courts adopt a workable definition of 'human being,'"[158] but perhaps an even greater problem with the USPTO reasoning is that the slavery provision is likely better construed as pertaining to persons rather than humans *per se*.[159]

[47] While the USPTO's response to *Ex parte Allen* clarified its position regarding the patenting of nonhuman multicellular organisms, it did nothing to reconcile its treatment of isolated human biological material with that of human beings. This weakness was exploited when, in December 18, 1997, Jeremy Rifkin, a prominent opponent of biotechnology, and Dr. Stuart Newman, a cellular biologist at New York Medical College, filed a patent application covering the production of human-animal chimeras by inserting the genetic material from one species into an embryo of another to create, in effect, "human-animal" chimeras

---

[155] *See* Donald J. Quigg, *Patent and Trademark Office Notice: Animals- Patentability*, 1077 OFF. GAZETTE 24 (1987), *available at* http://www.justinhughes.net/patentingpeople/papers/Quigg.pdf. This is now reflected in the USPTO, MANUAL, *supra* note 146, at § 2105, *available at* http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2105.htm (last modified Dec. 28, 2007)
(emphasis added).

[156] *Id.*

[157] U.S. CONST. amend. XIII, § 1.

[158] Magnani, *supra* note 123, at 450.

[159] In fact, in a non-final rejection letter the USPTO examiner referred to the 1987 statement of Quigg as saying that ". . . a patent would be difficult at best to apply to humans in view of the constitutional rights of human persons." Office Action Summary from USPTO Examiner Deborah Crouch to Applicant Stuart A. Newman (Jan. 29, 2003) (on file with author).

that "could contain anything from a minuscule proportion to a majority of human cells."[160] While Rifkin and Newman never intended to actually create the chimeras which they claimed,[161] their objective in filing the application was to "raise these [ethical] issues before the public and the legal system in a particularly dramatic fashion."[162]

[48] In *Chakrabarty*, the U.S. Supreme Court explicitly rejected the relevance of ethical issues in determining the patentability of a genetically engineered bacterium capable of degrading multiple components of crude oil.[163] While the petitioners in *Chakrabarty* argued that such an expansive interpretation of § 101 to include genetically engineered organisms might result in a "gruesome parade of horribles," the Court justified its position by stating that, given the broad interpretation of what is patentable under § 101, such "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."[164] Moreover, the U.S. Supreme Court noted that:

> [w]hat is more important is that 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

---

[160] Stuart A. Newman, *The Legal Column: The Human Chimera Patent Initiative*, 9 LAHEY CLINIC MED. ETHICS 1, 4 (2002), *available at* www.nymc.edu/sanewman/PDFs/Lahey_Winter_2002.pdf. *See generally* Stuart A. Newman, *Chimeric Embryos and Animals Containing Human Cells*, U.S. Patent App. No. 08/993,564.

[161] Stuart A. Newman, *My Attempt to Patent a Human-Animal Chimera*, 27 L'OBSERVATOIRE DE LA GÉNÉTIQUE (2006), *available at* http://www.ircm.qc.ca/bioethique/obsgenetique/zoom/zoom_06/z_no27_06/za_no27_06_01.html.

[162] Newman, *supra* note 104, at 455.

[163] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[164] *Id.* at 316-17. *See also* Anna E. Lumelsky, Diamond v. Chakrabarty*: Gauging Congress's Response to Dynamic Statutory Interpretation by the Supreme Court*, 39 U.S.F. L. REV. 641, 658 (2005).

> interests, which in our democratic system is the business of elected representatives. [165]

[49] Notwithstanding that *Chakrabarty* countenanced the appropriateness of a legislative rather than a judicial balancing of values, the USPTO issued a non-final rejection of the Rifkin-Newman patent on March 18, 1999 for the reason that, amongst others, "the claimed invention is not considered to be patentable subject matter under 35 U.S.C. 101 because the broadest reasonable interpretation of the claimed invention as a whole embraces a human being."[166] Because Newman had failed to place limits on the percentage of human cells in the invention, it was found that the invention *could* embrace a human being.[167] In a media advisory released in response to public outcry associated with the application, the USPTO relied upon the beneficial-utility doctrine, also known as the moral-utility doctrine, to suggest that Rifkin-Newman chimeras would not be patentable: "[i]t is the position of the [US]PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, *they would fail to meet the public policy and morality aspects of the utility requirement."* [168]

[50] The USPTO's reference to the morality aspects of the utility requirement in its Media Advisory is to the moral utility doctrine which dates from the 1817 decision of Justice Story in *Lowell v. Lewis.*[169] In that decision, he explained that "[a]ll that the law requires is that the invention

---

[165] *Chakrabarty*, 447 U.S. at 317.

[166] Office Action Summary from USPTO Examiner Deborah Crouch to Applicant Stuart A. Newman, USPTO Non-Final Rejection Letter, at 2 (Mar. 1, 1999), *available at* http://portal.uspto.gov/external/portal/pair (search for Patent Application 08/993,564, then follow "Image File Wrapper" tab). For a further discussion of the other reasons for rejection, see Sean Coughlin, *The Newman Application and the USPTO's Unnecessary Response: Patentability of Humans and Human Embryos*, 5 CHI.-KENT J. INTELL. PROP. 90 (2006); Rabin, *supra* note 125.

[167] *See* Office Action Summary from USPTO Examiner D. Clark to Applicant Stuart A. Newman, USPTO Final Rejection Letter, at 7 (Oct. 29, 1999), *available at* http://portal.uspto.gov/external/portal/pair (search for Patent Application 08/993,564, then follow "Image File Wrapper" tab).

[168] U.S. Patent and Trademark Office, Media Advisory No. 98-6, *Facts on Patenting Life Forms Having a Relationship to Humans* (Apr. 1, 1998) (emphasis added), *available at* http://www.uspto.gov/web/offices/com/speeches/98-06.htm.

[169] Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817).

should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word 'useful,' therefore, is incorporated into the act in contradistinction to mischievous or immoral."[170] This reference is curious in a couple of respects. First of all, when the utility guidelines were released in April 1998, Bruce Lehman, the USPTO's Commissioner at the time, stated that "if an applicant presents a scientifically plausible use for the claimed invention, it will be sufficient to satisfy the utility requirement."[171] Second, the recent trend in American jurisprudence is to dismiss this doctrine. In *Juicy Whip, Inc. v. Orange Bang, Inc.*,[172] a case regarding the validity of a patent covering a beverage dispenser which has the capacity to deceive some members of the public, the court cast doubt on the broad applicability of the moral utility doctrine:

> The principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years. For example, years ago courts invalidated patents on gambling devices on the ground that they were immoral, but that is no longer the law . . . . As the Supreme Court put the point more generally, "[c]ongress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted."[173]

---

[170] *Id*. *See also* Benjamin D. Enerson, *Protecting Society from Patently Offensive Inventions: The Risk of Reviving the Moral Utility Doctrine*, 89 CORNELL L. REV. 685, 691 (2004).

[171] *See* Kevin J. Dunleavy & Milan M. Vinnola, *A Comparative Review of the Patenting of Biotechnological Inventions in the U.S. and Europe*, 3 J. WORLD INTELL. PROP. 65, 74 (2000).

[172] Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364 (Fed. Cir. 1999).

[173] *Id*. at 1366-68 (quoting Webber v. Virginia, 103 U.S. (13 Otto) 344, 347-48 (1880)). See also Brenner v. Manson, 383 U.S. 519, 533 (1966), in which the U.S. Supreme Court indicated that it did not accept Justice Story's interpretation of "utility." *Id.* The Court said,

> Justice Story's language sheds little light on our subject. Narrowly read it does no more than compel us to decide whether the invention in question is 'frivolous and insignificant' – a query no easier of application than the one built into the statute. Read more broadly, so as to allow the patenting of any invention not positively harmful to

[51] In the non-final rejection letter to Rifkin and Newman in January 2003, the examiner restated the moral utility doctrine but did not decide whether the claimed invention was immoral, noting merely that "[t]he question of whether humans should be the subject of exclusive patent rights raises grave issues going to the core of what a 'useful' invention is."[174] Instead, the USPTO examiner stated that "[d]espite the breadth of these terms recognized in *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980), the terms 'manufacture' or 'composition of matter' would not have been regarded in ordinary parlance when § 101 was passed as possibly reflecting a Congressional intent to encompass human beings."[175]

[52] It is odd that the Rifkin-Newman application would be rejected, in part, on grounds that appear to be out of step with the interpretive approach of *Chakrabarty*. In fact, the decision of the USPTO may have been motivated more by the personal reasons of Lehman rather than the merits of the patent application.[176] Commissioner Lehman was of the view that "every attempt to stop science has been characterized by darkness."[177] It is reported that Lehman acknowledged that he "was just deeply offended by anyone attempting to use the U.S. Patent Office to make a point, or to stop the advancement of science. [He] refused to make it easy" for Newman.[178] In using the USPTO to make *his* point, however, Lehman was doubly confused, for it not only buttressed Newman's point that part-humans should not be patentable, but also increased the lack of clarity regarding the patentability of part-humans.

> society, it places such a special meaning on the word 'useful' that we cannot accept it in the absence of evidence that Congress so intended.

Id.

[174] Office Action Summary from USPTO Examiner Deborah Crouch to Applicant Stuart A. Newman, USPTO Non-Final Rejection Letter, at 28 (Jan. 29, 2003), *available at* http://portal.uspto.gov/external/portal/pair (search for Patent Application 08/993,564, then follow "Image File Wrapper" tab). *See also*, Magnani, *supra* note 123, at 458. Magnani has maintained that even if a court subjected the Rifkin-Newman patent application to a moral utility test, it would be likely that the application would satisfy the test. *Id.*

[175] Office Action Summary (January Jan. 29, 2003), *supra* note 174, at 26.

[176] Coughlin, *supra* note 166, at § 2. The view appears naïve because it seems to imply that technology is value-neutral so that there can be no legitimate ethical or political issues concerning the development and use of new technology.

[177] *Id.* at § 3.

[178] *Id.*

[53] At the same time that the Rifkin-Newman patent was being prosecuted, some legislators who were opposed to the patenting of cloned and genetically modified human embryos were concerned that, under U.S. patent law, such subject matter may be patentable under U.S. patent law.[179] In order to prevent such patents from being granted, these legislators subverted the patent examination process by tying USPTO funding to a prohibition against patenting human organisms. That is, even if the Director is required by patent legislation to issue a patent for the invention,[180] the Director is prohibited from doing so by the Weldon amendment to the *Science, State, Justice, Commerce, and Related Agencies Appropriations Act*.[181] Since the enactment, the federal appropriations legislation has continued to prohibit the use of funds for the issue of patents on human organisms.[182] Thus, today, the USPTO's *Manual of Patent Examining Procedure* states: "If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human being, then a rejection under 35 U.S.C. § 101 must be made indicating that the claimed invention is directed to nonstatutory subject matter."[183]

[54] The prohibition against patenting humans is not easily applied to the issue of the patentability of part-human chimeras, transgenics or cybrids. Despite the prohibition, the USPTO has granted patents on some animals that contain human genetic material since such animals were *not* considered human beings. One patent, for example, is for a transgenic

[179] *See* National Right to Life Coalition, *Congress Bans Patents on Human Embryos; NRLC-backed Weldon Amendment Survives BIO attacks*, *available at* http://www.nrlc.org/killing_embryos/Human_Patenting/Weldonamendmentsurvives.html (last visited Mar. 20, 2008).

[180] 35 U.S.C. § 131 (2002). "The Director shall cause an examination to be made of the application and the alleged new invention; and if on such examination it appears that the applicant is entitled to a patent under the law, the Commissioner shall issue a patent therefor." *Id.*

[181] This act was introduced in 2004 by bioethically conservative Congressman David Weldon. National Right to Life Coalition, *supra* note 179, at ¶ 5.

[182] The current *Science, State, Justice, Commerce, and Related Agencies Appropriations Act, 2007* contains the following provision: "(Sec. 618) Prohibits the use of any of the funds appropriated or otherwise made available under this Act to issue patents on claims directed to or encompassing a human organism." Science, State, Justice, Commerce, and Related Agencies Appropriations Act of 2007, H.R. 5672, 109th Cong. § 618 (2006).

[183] USPTO, MANUAL, *supra* note 146.

swine having a transgene encoding a human HLA-DQ or HLA-DR protein.[184] Another claims a pig genetically engineered to express the hDAF, which may prevent HAR after xenotransplantation into humans.[185] Still another application claims a pig and its organs and cells, where a preferred embodiment of the transgene encodes a human protein.[186] Recently, a claim for organs, tissues or cells wherein the cells, tissues or organs are modified to express one or more human complement regulatory proteins was accepted.[187]

[55] At the same time it has granted patents on such part-human materials, the USPTO denies that it has any principled way of deciding which animal-human combinations are patentable. As Deputy Commissioner John Doll commented at the time of the denial of the Rifkin-Newman patent: "I don't think anyone knows in terms of crude percentages [of human genetic material] how to differentiate between humans and nonhumans."[188] On this matter, President George W. Bush and many members of Congress sought to definitively prevent the creation and patenting of certain chimeras through legislation, with the *Human Chimera Prohibition Act of 2005*.[189] The Act expressly stated its ethical concerns that some chimeras blur the lines between human and animal, male and female, parent and child, and one individual and another individual, threatening the respect for human dignity and the integrity of the human species.[190] The Act would have prohibited the creation of various types of chimeras (including a human embryo into which a non-

[184] U.S. Patent No. 6,639,122 (filed Sept. 19, 2000) (issued Oct. 28, 2003).
[185] *See* U.S. Patent No. 6,825,395 (filed Apr. 5, 2000) (issued Nov. 30, 2004).
[186] U.S. Patent No. 7,141,716 (filed Aug. 20, 2002) (issued Nov. 28, 2006).
[187] U.S. Patent No. 7,166,278 (filed Apr. 29, 2002) (issued Jan. 23, 2007).
[188] Rick Weiss, *U.S. Denies Patent for a Too-Human Hybrid*, WASH. POST, Feb. 13, 2005, at A03, *available at* http://www.washingtonpost.com/wp-dyn/articles/A19781-2005Feb12.html.
[189] Human Chimera Prohibition Act of 2006, S. 1373, 109th Cong. (2005); Human Chimera Prohibition Act of 2005, S. 659, 109th Cong. (2005). U.S. President Bush said in his 2006 State of the Union Address: "[t]onight I ask you to pass legislation to prohibit the most egregious abuses of medical research: human cloning in all its forms, creating or implanting embryos for experiments, creating human-animal hybrids, and buying, selling, or patenting human embryos." George W. Bush, U.S. President, 2006 State of the Union Address (Jan. 31, 2006), *available at* http://www.whitehouse.gov/stateoftheunion/2006/index.html.
[190] *Id.*

human cell, or any component part of a non-human cell, was inserted); but it was not passed by Congress.[191]

[56] The problem of applying the rule against patenting humans also arises in the case of the patentability of embryonic stem cells containing human DNA, whether containing only human, or containing non-human DNA, as do stem cells extracted from a part- human cybrid embryo. On this matter, in January 1999, Q. Todd Dickinson, the then Acting Commissioner of Patents and Trademarks, stated that it was the position of the USPTO that purified and isolated stem cell lines were patentable subject-matter under 35 U.S.C. § 101, just as is the case for other biologically pure compositions.[192] While Dickinson's blanket statement would seem to apply to human totipotent stem cells, which could in principle develop into a human being, more recent pronouncements interpreting the Weldon amendment have made it clear that there is a USPTO policy against granting a patent on human beings at any stage of development.[193] In 2003, then USPTO Director Rogan, who was a President G.W. Bush appointee, wrote: "[t]he USPTO understands the Weldon Amendment to provide unequivocal congressional backing for the longstanding USPTO policy of refusing to grant any patent containing a claim that encompasses any member of the species *Homo sapiens* at any stage of development . . . including a human embryo or human fetus."[194] In addition, the USPTO policy "applies regardless of the manner and mechanism used to bring a human organism into existence (e.g., somatic

[191] *See generally id.*

[192] Statement from Q. Todd Dickinson, Acting Assistant Secretary Sec'y of Commerce and Acting Commissioner Comm'r of Patents and Trademarks before the Subcommittee Subcomm. on Labor, Health and Human Services., Education Edu. and Related Agencies of the Senate Appropriations Committee Comm. (Jan. 12, 1999), *available at* http://www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/stemcell.pdf.

[193] It has long been USPTO practice to reject any claim in a patent application that encompasses a human life-form at any stage of development, including a human embryo or human fetus . . . [The policy applies] regardless of the manner and mechanism used to bring a human organism into existence (e.g. somatic cell nuclear transfer, *in vitro* fertilization, parthenogenesis).

Letter from James E. Rogan, Under Secretary Sec'y and DirectorDir., USPTO to U.S. Senate Committee Comm. on Appropriations (received Nov. 20, 2003), *available at* http://www.nrlc.org/killing_embryos/Human_Patenting/patentletter112003.html.

[194] *Id.*

cell nuclear transfer, in vitro fertilization, parthenogenesis)."[195] Although a human totipotent cell might be considered to be a stage of development of a human, it is reported that negotiators from the Senate and House agreed that the prohibition against patenting genetically engineered human embryos, fetuses and human beings would not extend to human stem cells, genes, cells, tissue, and "other biological products."[196]

[57] The patentability of human totipotent stem cells appeared to be confirmed when, on March 13, 2001, James Thomson was issued a patent that specifically claimed primate (including human) embryonic stem cells.[197] In Thomson's invention, "[p]rimate ES cells of the present invention are pluripotent. By 'pluripotent' we mean that the cell has the ability to develop into any cell derived from the three main germ cell layers *or an embryo itself*."[198] In other words, the human embryonic stem cells claimed were not merely pluripotent, but also totipotent. While the claims in this patent were recently rejected upon re-examination, they were not rejected on the basis of its subject matter but on the basis of that the invention was anticipated.[199] By 2004, approximately thirty-eight patents had been issued with claims to embryonic stem cells or processes encompassing human products or processes.[200] Within some of these

---

[195] *Id.*

[196] Kaisernetwork.org, National Politics & Policy, *Lawmakers Reach Agreement on Appropriations Bill Language Barring Patents on "Human Organisms*," *available at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=2&DR_ID=21029 (last visited Mar. 20, 2008).

[197] This is one of the Wisconsin Alumni Research Foundation ("WARF") patents. U.S. Patent No. 6,200,806 (filed June 26, 1998) (issued Mar. 13, 2001).

[198] *Id.* (emphasis added).

[199] *See* Kevin E. Noonan, *WARF Stem Cell Patent Claims Rejected in Re-Examination* (Apr. 3, 2007), *available at* http://patentdocs.typepad.com/patent_docs/2007/04/warf_stem_cell_.html (last visited Apr. 6, 2008).

[200] *See generally* Raymond R. Mandra & Alicia A. Russo, *Stem Cells and Patenting and Related Regulatory Issues: A U.S. Perspective*, 7 BIO-SCI. L. REV. 143, 144-45 (2004-2005), *available at* http://www.fitzpatrickcella.com/publications/pubItem.cfm?pubID=333; Enca Martin-Rendon and Derek J. Blake*, Patenting Human Genes and Stem Cells*, RECENT PATS. ON DNA & GENE SEQUENCES 2007, 1, 25-34, *available at* http://www.bentham.org/dnag/samples/dnag1-1/Martin-Rendon.pdf (last visited Mar. 20, 2008) (describing recent patents related to pluripotent stem cells and pluripotency genes, and technology developed to manipulate the genetic material of those stem cells).

patents are claims to totipotent stem cells. For instance, the patent issued to Geron Corporation for "[m]ethods and materials for the growth of primate-derived primordial stem cells in feeder-free culture" stands out.[201] It claims a cellular composition comprising undifferentiated primate primordial cells, which includes both pluripotent and totipotent primate stem cells, but does not exclude human primate stem cells.[202] It appears then that, in the United States, human and part-human totipotent stem cells are patentable despite the fact that human beings at any stage of development are not patentable. The fact that, as will be discussed, Europe and Canada have concluded that human totipotent stem cells are *unpatentable* on the basis that they are stages of human development demonstrated the difficulty of arriving at a principled rule against patenting human beings.

B. THE CANADIAN APPROACH

[58] The Canadian Patent Act defines "invention" as "any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."[203] As is the case in the United States, the Canadian Patent Office has granted patents on isolated non-living biological materials, including human biological materials.[204] In Canada, however, all higher life forms, including humans, are unpatentable.[205]

---

[201] U.S. Patent No. 6,800,480 (filed Aug. 29, 2000) (issued Oct. 5, 2004). It might be argued that the patentability of totipotent stem cells is purely academic since pluripotent cells might be all that is needed for therapeutic purposes. This remains to be seen. Meanwhile, the description maintains that ". . . it is desirable to maintain cultures of totipotent primordial stem cells for extended periods or indefinitely. The ability to maintain cultures of undifferentiated, totipotent, primate-derived primordial stem cells for long periods facilitates the use of such cells for therapeutic purposes." *Id.* at 53.

[202] *Id.*

[203] Patent Act, R.S.C., ch. P-4, § 2 (1985). Under the Canadian Patent Act, "[t]he Commissioner shall grant a patent for an invention to the inventor or the inventor's legal representative if an application for the patent in Canada is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met." *Id.* at § 27(1).

[204] *See* GOLD, *supra* note 10; E. Richard Gold, *Human Gene Patents: Recent Developments* (2002), *available at* http://strategis.ic.gc.ca/epic/site/cbac-cccb.nsf/vwapj/Research-2002_Gold-Developments-Final_e.pdf.

[205] *See Harvard College*, [2002] 4 S.C.R. 45, 2002 SCC 76 ¶155 (Can.).

While the Supreme Court of Canada found that the categories of subject matter provided in patent legislation were sufficiently broad to include unforeseen technologies, unlike the U.S. Supreme Court in *Chakrabarty*, it held that legislators intended that the listed categories were exhaustive so as to exclude subject matter not included in the categories provided. [206]

[59] In particular, the Supreme Court of Canada held in *Harvard College v. Canada* that higher life forms are not patentable because they are neither manufactures nor compositions of matter under the Patent Act.[207] The Supreme Court of Canada arrived at this conclusion while considering the patentability of non-human transgenic mammals, which were genetically engineered to give the host organism a heightened susceptibility to the development of cancer.[208] One of the claims, for which the case is popularly known, was for a genetically engineered mouse that promised to be particularly useful as a tool for cancer research.[209] After dismissing the idea that the claimed invention could be an "art, process, or machine," the Supreme Court of Canada applied its interpretive principles to determine whether the oncomouse (as well as other organisms in the claims) was a "manufacture or composition of matter" based upon: (i) the words of the Act; (ii) the scheme of the Act; (iii) the object of the Act; and (iv) the intention of Parliament and related legislation.[210]

[60] In examining the meaning of the terms in issue, the Supreme Court of Canada noted that English Courts had defined "manufacture" as "something made by the hands of man,"[211] but it found that "a complex life form such as a mouse or a chimpanzee cannot easily be characterized as 'something made by the hands of man.'"[212] It was also not a composition of matter, which the Court defined as "[a] substance or

[206] *See id.* at ¶ 158.
[207] *See* Patent Act, R.S.C., ch. P-4, § 2 (1985).
[208] *See Harvard College*, [2002] 4 S.C.R. 45 at ¶ 1.
[209] The genetic manipulation of the murine genome in this case was accomplished by Philip Leder (of Harvard University) and Timothy Stewart (of Genentech). *See* Emir Aly Crowne Mohammed, *Cat in the Hat, a Mouse in the House – Comparative Perspectives on Harvard Mouse*, 18 I.P.J. 169, 170 (2004).
[210] *Harvard College*, [2002] 4 S.C.R. 45 at ¶ 154.
[211] *Id.* at ¶ 159
[212] *Id.*

preparation formed by combination or mixture of various ingredients,"[213] since "the process by which a fertilized egg becomes an adult mouse is a complex process, elements of which require no human intervention."[214] Moreover, since "animal life forms have numerous unique qualities that transcend the particular matter of which they are composed [it is difficult]. . . to conceptualize higher life forms as mere 'composition[s] of matter.'"[215] Justice Bastarache, writing for the majority, noted further that "[a]lthough some in society may hold the view that higher life forms are mere 'composition[s] of matter,' the phrase does not fit well with common understandings of *human* and animal life."[216] Further, the object of the Act, the intent of the legislators, and the scheme of both the Patent Act and the Plant Breeders' Rights Act, S.C.., ch. P-14.6, support such a conclusion.[217] Higher life forms – including human beings, part-human chimeras, and transgenics – are therefore unpatentable in Canada.[218]

[61] In spite of the Supreme Court of Canada ruling against the patentability of higher life forms, such materials are protected *indirectly* under Canadian law. In *Monsanto v. Schmeiser*, the Supreme Court of Canada ruled that cultivation of a whole canola plant amounted to the use of its patented parts: its chimeric genes and cells.[219] Hence, the Court found that the use of a genetically modified canola plant by Schmeiser was an infringement of Monsanto's patent rights in the modified genes and cells contained in the plant. The canola plant had been modified to be resistant to Monsanto's Roundup herbicide.[220] The Court held that the possession of the patented genes contained in the canola plants by Schmeiser were presumed to be a use of the plant.[221] Schmeiser objected,

---

[213] *Id.* at ¶ 162
[214] *Id.*
[215] *Id.* at ¶ 163.
[216] *Id.* at ¶ 163 (emphasis added).
[217] *See id.* at ¶¶ 167-96.
[218] *See id* at ¶ 166.
[219] *See* Monsanto Canada, Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34 ¶ 1 (Can).
[220] *See id.* at ¶ 5.
[221] *See id.* at ¶¶ 83-87. The Court gave the following Lego blocks analogy:

> By analogy, then, the law holds 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. In the case at bar, the patented

asserting that by not spraying Roundup on the canola plants and having no intention to do so in his commercial operations, he had rebutted this presumption; the Court disagreed: "[t]he farmer benefits from that advantage from the outset: if there is reason to spray in the future, the farmer may proceed to do so."[222] In fact, the Court went as far as to say that the potential use of the gene is itself a benefit, analogous to the standby utility of a fire extinguisher hanging on a wall.[223] Hence, "[w]hether or not a farmer sprays with Roundup herbicide, cultivating canola containing the patented genes and cells provides stand-by utility."[224] Schmeiser could have rebutted the presumption by quickly removing the canola plants and by showing the concentration of such plants was consistent with unsolicited "blow-by" canola, but he did neither.[225] On the basis of the reasoning in *Monsanto*, it appears that higher animal life forms – presumably not including humans – can be protected given the existence of patented genes or cells comprising them.[226]

[62] The problem of distinguishing between higher life forms and lower life forms mirrors the problem of distinguishing between human and non-human. CIPO considers the distinction as one of degree of complexity, namely, the distinction between multicellular and unicellular organisms. [227] The Canadian MPOP considers animals (including humans), plants, seeds, and mushrooms "higher life forms."[228] Lower life forms, which are

> genes and cells are not merely a "part" of the plant; rather, the patented genes are present throughout the genetically modified plant and the patented cells compose its entire physical structure. In that sense, the cells are somewhat analogous to Lego blocks: if an infringing use were alleged in building a structure with patented Lego blocks, it would be no bar to a finding of infringement that only the blocks were patented and not the entire structure. If anything, the fact that the Lego structure could not exist independently of the patented blocks would strengthen the claim, underlining the significance of the patented invention to the whole product, object, or process.

Id. at ¶ 42.
[222] *Id.* at ¶ 84.
[223] *See id.* at ¶ 47.
[224] *Id.* at ¶ 84
[225] *See id*. at ¶ 86.
[226] This includes totipotent stem cells that contained patented DNA.
[227] *See* CIPO, MANUAL, *supra* note 10, at § 12.04.01.
[228] *Id*.

patentable, include microscopic algae, moulds and yeasts, bacteria, protozoa, viruses, cells in culture, transformed cell lines, and hybridomas.[229] At the same time, however, human genetic material and human cell lines are patentable subject matter.[230] Nevertheless, based upon this distinction, no part-human higher life forms, whether human-animal chimeras, transgenics, or hybrids are patentable in Canada. *Monsanto* may indirectly protect genetically modified part-humans, provided they are not considered human beings.

[63] As mentioned, human development illustrates the problem of distinguishing between higher and lower life forms. If higher life forms are to be identified with multicellular life forms and lower life forms with unicellular life forms, then despite the fact that an isolated fertilized egg of a higher life form will naturally develop into a higher life form, the isolated fertilized egg *is*, based upon the premises supplied by the MPOP, patentable by virtue of being a lower life form. The same conclusion follows if the fertilized egg is an animal-human combination, such as a cybrid. This conclusion is a generalization of the Supreme Court of Canada's finding concerning the oncomouse:

> [f]urther, all members of the Court in *Harvard Mouse* noted in obiter that a fertilized, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse (at para. 3, per Binnie J. for the minority; at para. 162, per Bastarache J. for the majority).[231]

Since fertilized eggs are totipotent in the sense that they can develop into a higher life form in the right environment, this suggests that totipotency is not a bar to patentability in Canada, including the patentability of totipotent stem cells.

[64] Nevertheless, the CIPO confirms that animals at any stage of development, from fertilized eggs on, as well as totipotent stem cells, are *unpatentable* in its view because they *could* develop into an entire animal:

---

[229] *Id.*
[230] *See* CAMPBELL & BERGERON, *supra* note 10.
[231] Monsanto Canada, Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34 ¶ 23 (Can.).

> [t]he Patent Office takes the position that animals at any stage of development, from fertilized eggs on, are higher life forms and are thus not patentable subject matter under section 2 of the *Patent Act*. Totipotent stem cells, which have the same potential as fertilized eggs to develop into an entire animal, are considered to be equivalents of fertilized eggs and are thus higher life forms and are not patentable subject matter . . . .[232]

Embryonic, multipotent and pluripotent stem cells, which do not have the potential to develop into an entire animal, are patentable subject matter.[233]

[65] CIPO's position clearly contradicts the view taken by the Supreme Court of Canada that a fertilized egg, which is totipotent, is patentable despite its potential for developing into a fully developed higher life form.[234] The contradiction between CIPO and the Supreme Court of Canada regarding whether a totipotent stem cell is patentable is symptomatic of the difficulty involved in making a principled distinction between the concepts of higher and lower life form.

[66] The CIPO *Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues* is strikingly similar to the 2003 U.K. Practice Notice on *Inventions Involving Human Embryonic Stem Cells*, except for the

[232] CIPO, OFFICE PRACTICE, *supra* note 14.
[233] *Id.*
[234] *See id.* In its recent draft update to the CIPO's *Manual*, the CIPO has responded to this argument, at least implicitly, by modifying the distinction between higher and lower life forms in the case of totipotent stem cells and fertilized animal eggs. It states at § 17.02.01a:

> For the purposes of section 2 of the Patent Act, life forms have in view of jurisprudence been divided into lower life forms (statutory) and higher life forms (non-statutory). With the exception of fertilized eggs and totipotent stem cells, the distinction between lower and higher life forms is whether the life form is unicellular (lower) or multicellular (higher)."

CIPO, MANUAL, *supra* note 10.

substitution in the Canadian policy of "higher life form" for "human."[235] The U.K. Practice Notice reads:

> [h]uman totipotent cells have the potential to develop into an entire human body. In view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability by Paragraph 3(a) of Schedule A2 to the Patents Act 1977. The Office will therefore not grant patents for human totipotent cells.[236]

CIPO would likely deny that it has adopted the U.K. approach and for good reason. Under European patent law, the prohibition against patenting totipotent cells is explicitly based upon a broad prohibition against patenting a human body at every stage of development.[237] In contrast to Canada, the European prohibition is further grounded in the broad legal prohibition against patenting when it is against public policy or morality.[238] Neither of these prohibitions explicitly exists in patent legislation in Canada. This leaves open the question as to the grounds for CIPO's conclusions. If ethical concerns did not ground its reasoning, then it may have implicitly based its rationale on a preformationist theory of development. As discussed above, however, the preformationist theory of development is not generally accepted in the biological community.[239]

[67] In its reasoning, the Supreme Court of Canada explicitly held that ethical and policy grounds could not be used to limit the type of subject matter eligible for patenting under the Patent Act.[240] Nevertheless, in the Court's reasoning, the principle that humans are not patentable was a premise in its conclusion that higher life forms are not patentable. To begin with, in *Harvard College*, while the majority held that an

---

[235] *See* United Kingdom Intellectual Property Office, *Inventions Involving Human Embryonic Stem Cells*, *available at* http://www.ipo.gov.uk/patent/p-decisionmaking/p-law/p-law-notice/p-law-notice-stemcells.htm.
[236] *Id.*
[237] *See* discussion *infra* Part IV.C.
[238] *See* discussion *infra* Part IV.C.
[239] *See* discussion *supra* Part III.A.
[240] *See* Monsanto Canada, Inc. v. Schmeiser, [2004] 1 S.C.R. 902, 2004 SCC 34 ¶ 93 (Can); *Harvard College*, [2002] 4 S.C.R. 45, 2002 SCC 76 ¶ 155 (Can).

oncomouse was not a composition of matter, it also stated that "[e]ven if a higher life form could, scientifically, be regarded as a 'composition of matter,' the scheme of the Act indicate[d] that the patentability of higher life forms was not contemplated by Parliament."[241] It gave the following reason:

> [o]wing to the fact that the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, *ethical* and environmental concerns that the Act does not contemplate, I conclude that the Commissioner was correct to reject the patent application.[242]

[68] Furthermore, in considering the concerns referred to in the preceding quotation, the Supreme Court of Canada noted that "the most significant issue . . . is the patentability of human life."[243] In particular, in defense of the distinction between higher and lower life forms, the Supreme Court of Canada invoked the principle that human life is not patentable:

> [t]he 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. Perhaps more importantly, there appears to be a consensus that human life is not patentable; yet this distinction is also not explicit in the Act. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms.[244]

[69] While the Supreme Court of Canada regarded CIPO's distinction between higher and lower life forms as defensible – namely, that between unicellular and multicellular organisms[245] – and did not seek to alter the distinction,[246] it was willing to grant that the line could be drawn

[241] *Harvard College*, [2002] 4 S.C.R. 45 at ¶ 155.
[242] *Id.* at ¶ 155 (emphasis added).
[243] *Id.* at ¶ 175.
[244] *Id.* at ¶ 199. Justice Bastarache, writing for the majority, noted that "[w]hatever justification is used to support the assumption, there seems to be little debate that human life is not patentable." *Id.* at ¶ 177.
[245] *See* CIPO, MANUAL, *supra* note 10, at § 12.04.01.
[246] *See Harvard College*, [2002] 4 S.C.R. 45 at ¶ 199.

elsewhere, such as between sentient and non-sentient creatures. In that respect, the majority remarked that "if sentience is the determining factor that renders a higher life form incapable of receiving patent protection, then the current line between higher and lower life forms is misplaced."[247] It is worth pointing out that, in the reasoning of the Supreme Court of Canada, the distinction between higher and lower life forms was not supported solely by the prohibition against patenting humans, but also based upon the presence or absence of features possessed by paradigmatic examples of higher life forms.[248] For animals, such features include "the capacity to display emotion and complexity of reaction and to direct behaviour in a manner that is not predictable as stimulus and response,"[249] as well as the persistence of identity through material and genetic change.[250]

[70] In fact, the Supreme Court of Canada raised doubts about the grounds for a biologically-based distinction in the context of human transplantation, alluding – albeit haphazardly – to the idea that the proper distinction between patentable and unpatentable is based upon personhood. For example, the Supreme Court of Canada suggested that a human organ may be patentable because human tissues and organs are not protected under section 7 of the Charter of Rights and Freedoms.[251] The Court noted that, "[a]pplicants may also seek to patent human tissues and organs rather than the *entire person*, in which case s. 7 may not apply . . . ."[252] While suggesting a rationale under section 7 of the Charter[253] for permitting the patenting of human organs and tissues, but not persons, it still maintained that "it is not an appropriate judicial function for the

[247] *Id.* at ¶ 204.
[248] The fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed makes it difficult to conceptualize higher life forms as mere "composition[s] of matter." *Id.* at ¶ 163.
[249] *Id.* at ¶ 204.
[250] *See id.* at ¶ 163.
[251] *See Charter*, *supra* note 97, at § 7.
[252] *Harvard College*, [2002] 4 S.C.R. 45 at ¶ 180 (emphasis added).
[253] *See Charter*, *supra* note 97, at § 7. Presumably, an entire person cannot be patented in Canada in virtue of § 40, which states that "[w]henever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, he shall refuse the application and, by registered letter addressed to the applicant or his registered agent, notify the applicant of the refusal and of the ground or reason therefore." Patent Act, R.S.C., ch. P-4, § 40 (1985).

courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded."[254]

[71] The Supreme Court of Canada even raised the issue as to how to distinguish between the patentability of humans and part-human materials where such materials could be used for transplantation. It noted in *Harvard College* that,

> [t]he patenting of body parts raises yet another issue: the increasingly blurred line between human beings and other higher life forms. In the new field of xenotransplantation, human genes are introduced into mammals such as pigs to make the animals' organs more acceptable to the human body for the purposes of organ transplantation. As noted by the intervener Animal Alliance of Canada, at para. 68 of its submissions, this scientific development calls into question the once clear distinction between human and animal life:
>
> The pig receives human genes. The human receives pig organs. Where does the pig end and the human begin? How much DNA does it take before one becomes the other? The answer to these questions, once ridiculous and offensive, may now just be a matter of degree.[255]

[254] *Id.* at ¶ 181. Like many other commentators, the Supreme Court of Canada equivocates between person and human. A good example is found in *R. v. Clay*, where the Court says ". . . the liberty right within s. 7 is thought to touch the core of what it means to be an autonomous *human being* blessed with dignity and independence in "matters that can properly be characterized as fundamentally or inherently *personal*." R. v. Clay, [2003] 3 S.C.R. 735, 2003 SCC 75 ¶ 31 (Can.) (emphasis added).

[255] *Harvard College*, [2002] 4 S.C.R. 45 at ¶ 180. On CIPO's account, no parts of higher life forms are patentable. It says: "[f]urther, the Office takes the position that organs and tissues are not compositions of matter for the purposes of the definition of invention under section 2 of the Patent Act, R.S.C. 1985, c. P-4 and are therefore not patentable subject matter. Organs and tissues are created by complex processes, elements of which require no human intervention, and do not consist of ingredients or substances that have been combined or mixed together by a person." *See* CIPO, OFFICE PRACTICE, *supra* note 14.

While the patenting of part-human higher life forms and their parts is prohibited in Canada, the Supreme Court of Canada did not attempt to draw its own distinction between patentable and non-patentable part-humans, concluding that "a judicially crafted exception from patentability for human beings does not adequately address issues such as what defines a human being and whether parts of the human body as opposed to the entire *person* would be patentable."[256] Justice Bastarache, writing for the Court, noted that "in my view, this Court does not possess the institutional competence to deal with issues of this complexity, which presumably will require Parliament to engage in public debate, a balancing of competing societal interests and intricate legislative drafting."[257] Unfortunately, it appears that the Parliament of Canada does not want to deal with these issues yet.

C. THE APPROACH OF THE EUROPEAN UNION

[72] There is no uniform answer to the question of which part-human biological materials are patentable in Europe due to the jurisdictional complexities of the European patent system. Patents on inventions in Europe may be granted by either national patent offices or by the European Patent Office ("EPO").[258] The EPO, which operates within the legal framework of the *European Patent Convention*,[259] grants a bundle of national patent rights since a European Community patent does not yet exist. National patent offices, on the other hand, operate under their respective national law, which implements the *Biotechnology Directive*, key European legislation concerning the patenting of biotechnology.[260] Although the EPO is not bound by the *Biotechnology Directive*, in June 1999 the Administrative Council of the EPO amended the *Implementing Regulations* to the *EPC* to include a new section on biotechnological inventions incorporating several key Articles of the *Biotechnology*

[256] *Harvard College*, [2002] 4 S.C.R. 45 at ¶ 206 (emphasis added).
[257] *Id*. at ¶ 183.
[258] *See generally* MILLS, *supra* note 16.
[259] *Convention on the Grant of European Patents*, EUR. PAT. CONVENTION, *available at* http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ma1.html [hereinafter *EPC*].
[260] AURORA PLOMER, STEM CELL PATENTS: EUROPEAN PATENT LAW AND ETHICS REPORT 30-31, 84 (2006), *available at* http://www.nottingham.ac.uk/law/StemCellProject/reports.htm.

Directive. [261] Nonetheless, different decisions may be made by the EPO and national patent authorities based upon the same criteria for patentability.

[73] As in the United States and Canada, in Europe the scope of patentable subject matter is broad. Article 52(1) *EPC* states that "European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step."[262] The *Biotechnology Directive* makes it clear that ". . . inventions which are new, which involve an inventive step and which are susceptible of industrial application shall be patentable even if they concern a product consisting of or containing biological material or a process by means of which biological material is produced, processed or used."[263] While exceptions to Article 52(1) of the *EPC* have been narrowly construed in several cases[264] the scope of patentability of biological materials containing human DNA remains unclear in some respects.

[74] In respect of the patenting of isolated parts of the human body, the *Biotechnology Directive* and *EPC* each provide that: "[a]n element

[261] Rules 23b-23e of the *Implementing Regulations to the Convention on the Grant of European Patents* of October 5, 1973, as last amended by Decision of the Administrative Council of the European Patent Organisation of December 9, 2004 [hereinafter *Implementing Regulations*]. Please note that a revised version of the *European Patent Convention* [hereinafter *EPC*] entered into force on December 13, 2007. The Rules cited in this paper are to the earlier version to avoid confusion. A list that cross-references the old and new numbering is available at http://www.epo.org/patents/law/legal-texts/html/epc/2000/e/ma2.html.

[262] Subsection 52(2) provides that: "[t]he following in particular shall not be regarded as inventions within the meaning of paragraph 1: (a) discoveries, scientific theories and mathematical methods; (b) aesthetic creations; (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; (d) presentations of information." *Id.*

[263] Article 3(1) *Biotechnology Directive*, *supra* note 10 and 52(1) *EPC*, *supra* note 261. Article 2(1), *Biotechnology Directive*, defines "biological materials" as any material containing genetic information and capable of reproducing itself or being reproduced in a biological system.

[264] In *Harvard/Oncomouse*, 1990 O.J. EPO 476 (T 0019/90 - 3.3.2), *available at* http://legal.european-patent-office.org/dg3/biblio/t900019ep1.htm, the EPO Board of Appeals held at 4:5 that "[a]ny such exception [to Article 52(1) *EPC*] must, as repeatedly pointed out by the Boards of Appeal, be narrowly construed." *Id.*

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."[265] The *Biotechnology Directive* further provides that,

> [such an element] is not excluded from patentability since it is, for example, the result of technical processes used to identify, purify and classify it and to reproduce it outside the human body, techniques which human beings alone are capable of putting into practice and which nature is incapable of accomplishing by itself.[266]

Furthermore, the *Biotechnology Directive* notes that isolating human elements and utilizing them for medical treatment – including, presumably, transplantation – is to be encouraged by the patent system.[267] If these were the only criteria for patentability, then a wide variety of part-human biological material would be patentable, including isolated human fertilized eggs, isolated totipotent stem cells, as well as isolated transgenic or chimeric materials, such as a cow-human cybrid.

[75] Despite its *prima facie* broad approach to the patentability of part-human biological materials, European patent legislation contains an explicit morality provision that prohibits the granting of patents on inventions whose commercial exploitation is immoral or against *ordre public*.[268] Moreover, while both Canadian and U.S. patent authorities prohibit the granting of patents on human beings at any stage of development inferring the principle from patent law, in Europe, there is an explicit prohibition on granting patents on human bodies at any stage of development. "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

[265] Article 5(2), *Biotechnology Directive, supra* note 10, and 23(e)(2) *EPC, supra* note 261.
[266] Recital 21, *Biotechnology Directive*, *supra* note 10.
[267] Recital 17, *Biotechnology Directive, supra* note 10.
[268] Article 6(1), *Biotechnology Directive, supra* note 10; Article 53(a) *EPC, supra* note 261

inventions." [269] This version of the rule against patenting humans suffers from many of the same problems as the U.S. rule against patenting humans. Each appears to presume a form of genetic preformationism that is out of step with biological theory. Furthermore, each leaves open the amount of DNA necessary for a part-human chimera or transgenic animal to be human and whether human or part-human embryonic stem cells are patentable.

[76] Consider the question as to whether isolated human embryonic stem cells are patentable. It has been thought that Rule 23(e)(1) *EPC*, prohibiting the patenting of human bodies, need not be considered in order to answer this question, since the *EPC* specifically prohibits the patenting of the "uses of human embryos for industrial or commercial purposes."[270] The scope of this prohibition was considered in light of opposition to European patent No. EP 0695351, titled "Isolation, selection and propagation of animal transgenic stem cells[,]" which describes a method of using genetic engineering to isolate stem cells - including embryonic stem cells - from more differentiated cells in a cell culture (the "Edinburgh patent").[271] The European Group on Ethics in Science and New Technologies ("EGE") had opined that *modified* human embryonic stem cell lines for specific industrial application fulfil the legal requirements for patentability.[272] However, the Opposition Division of the European Patent

[269] Article 5(1), *Biotechnology Directive, supra* note 10; Rule 23(e)(1) *EPC*, *supra* note 261.

[270] Rule 23(d)(c) *EPC, supra* note 258; Article 6(2)(c) *Biotechnology Directive*, *supra* note 10.

[271] *See* Press Release, European Patent Office, ""Edinburgh"" Patent Limited After European Patent Office Opposition Hearing (July 24, 2002), *available at* http://www.epo.org/aboutus/press/releases/archive/2002/24072002.html (last visited Apr. 6, 2008).

[272] EGE said at p. 15: "[t]herefore only stem cell lines which have been modified by in vitro treatments or genetically modified so that they have acquired characteristics for specific industrial application, fulfil the legal requirements for patentability." At the same time, with respect to isolated unmodified stem cells, it said at p. 15 that ". . . such isolated cells are so close to the human body, to the foetus or to the embryo they have been isolated from, that their patenting may be considered as a form of commercialisation of the human body." Opinion of the European Group on Ethics in Science and New Technologies, *Ethical Aspects of Patenting Inventions Involving Human Stem Cells* (May 7, 2002), *available at* http://europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf. However, it has been argued that since isolation of stem cells results in modification, patents on isolated

Office, which is responsible for determining whether grounds exist for revoking a patent, read Rule 23d(c) broadly, dismissing the opinion of EGE, to preclude patents on "not only the industrial or commercial use of human embryos but also the human ES cells retrieved therefrom by destruction of human embryos."[273] It reasoned that without such a broad interpretation, Rule 23(d)(c) would be redundant given that Rule 23(e)(1) *EPC* prohibits patenting the human body at any stage of development.[274] The result was that the Edinburgh patent was upheld by the Opposition Division in an amended form that included modified human and animal stem cells *other* than embryonic stem cells.[275]

[77] Similarly, in the Wisconsin Alumni Research Foundation ("WARF") case, the EPO Examination Division excluded from patentability not only James Thomson's process of isolating human embryos stem cells for industrial or commercial application but a *human* embryonic stem cell line when it necessarily involves the destruction of the human embryo from which the embryonic stem cells were derived.[276] By contrast, adult stem cells, such as hematopoietic stem cells and stem cells derived from nonhuman animal embryos are not caught under Rule 23d(c) *EPC*. Technology can change, however, and it is now possible, in principle, to produce totipotent stem cells without the destruction of an embryo.[277] Since the WARF decision has been appealed to the Enlarged Patent Board of Appeals of the EPO, it remains to be seen whether Rule 23(d)(c) EPC forbids the patenting of human embryonic stem cell cultures when, at the filing date, such materials could be prepared solely by a method which

---

stem cells should not be excluded solely as a result of their isolated quality. *See* Mats G. Hansson et al., *Commentary: Isolated Stem Cells – Patentable as Cultural Artifacts?* 25 STEM CELLS 1507-510 (June 2007).

[273] Decision of the Opposition Division of 21 July 2003 on European Patent No. EP0695351 (Univ. of Edinburgh), *cited in* Porter et al., s*upra* note 260, at 653.

[274] *Id.* at 653-54.

[275] *Id.*

[276] *Id.*; *see also* The Chartered Institute of Patent Attorneys [("CIPA], "), *Patentability of Stem Cells in Europe, available at* http://www.cipa.org.uk/pages/SCEurope.

[277] For example, Advanced Cell Technology has discovered a method of producing stem cells that does not interfere with the developmental process of the embryo in mice. In addition, it is now possible to produce biological material which will not develop into a fully developed organism but from which "embryonic" stem cells can be derived. *See* Porter et al., *supra* note 260.

necessarily involved the destruction of the human embryos from which the stem cells were derived, if the method was not part of the claims.[278]

[78] Whatever the result of the WARF appeal may be, Article 5(1) of the *Biotechnology Directive*, prohibiting the patenting of human bodies at any stage of development, was itself interpreted by the Commission of the European Communities in 2005 to exclude human totipotent stem cells from patentability:

> The provisions of the Directive are clear in relation to [human] totipotent stem cells, since each cell could develop into a human being on its own and under Article 5(1) the human body at the various stages of its formation and development cannot constitute a patentable invention.[279]

But, as Webber has pointed out, this interpretation raises the issue of how to reconcile the fact that isolated elements of the human body may constitute a patentable invention under Article 5(2) of the *Biotechnology Directive* with the fact that isolated totipotent stem cells are not patentable under Article 5(1) of the *Biotechnology Directive*.[280] In fact, Webber maintains that elements which have been isolated from the human body or produced in a technical manner are *not* excluded from patentability.[281] In his view, since human totipotent stem cells produced through human

[278] This is the question that the Enlarged Board of Appeal of the EPO faces with respect to the WARF patent application. *See* Wisconsin Alumni Research Foundation (T 1374/04 - 3.3.08) (referral by the Technical Board of Appeal to the Enlarged Board of Appeal), *available at* http://legal.european-patent-office.org/dg3/biblio/t041374ex1.htm.
[279] *Report from the Commission to the Council and the European Parliament – Development and Implications of Patent Law in the Field of Biotechnology and Genetic Engineering* (SEC(2005) 943), *available at* http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2005&nu_doc=312. For discussion, see Porter et al., *supra* note 260.
[280] Phillip M. Webber, *Patentability of Human Embryonic Cells under the EPC*, BIO-SCI. L. REV., *available at* http://pharmalicensing.com/features/disp/1119630334_42bc33fe14906.
[281] *Id.*

intervention are covered under Article 5(2) of the *Biotechnology Directive*, such cells are not excluded from patentability.[282]

[79] The *prima facie* difficulty facing Webber's argument is that Article 5(2) of the *Biotechnology Directive* is written in permissive form: it says that isolated elements of the human body *may* constitute patentable inventions, even if the structure of that element is identical to that of a natural element; whereas Article 5(1) of the *Biotechnology Directive* is mandatory in form.[283] The mandatory nature of Article 5(1) forbids patenting the human body at any stage of development. The problem with this answer to Webber is that – even if it were correct – it does not satisfactorily settle the deeper question of whether 5(1) precludes the patentability of human stem cells that are not a natural stage of development of a human body, such as a fertilized egg produced through in vitro fertilization, parthenogenesis,[284] or from non-embryonic totipotent stem cells isolated from post-natal connective tissue.[285] It is arguable; furthermore, that no stem cell that has been extracted from an embryo is a natural stage of human development in any case, since it would not have developed into a mature human body on its own. More generally, if Article 5(1) does prohibit the patenting of any isolated totipotent cells, then there is the further problem that it appears to imply that no human cells can be patented since almost all cells of a human body could, in the right environment, develop into a mature human whether after transfer of the cell nucleus into a human egg or, through technology that allows for the reprogramming of an adult human cell without nuclear transfer.[286]

[80] A further difficulty concerns the patentability of part-human organs suitable for transplantation. There are no provisions in either the

[282] *Id.*
[283] "May" is ambiguous. It could also be intended to mean that isolated elements of the human body shall not be regarded as unpatentable just because they are identical to natural elements.
[284] *See*, *e.g.*, Chris Williams, S*tem Cell Fraudster Made 'Virgin Birth' Breakthrough*, THE REGISTER, Aug. 3, 2007, *available at* http://www.theregister.co.uk/2007/08/03/hwang_parthenogenesis/print.html.
[285] *See*, *e.g.*, World Intellectual Property Organization ("WIPO"), *Non-Embyonic Blastomere Like Totipotent Stem Cells*, *available at* http://www.wipo.int/pctdb/en/wo.jsp?wo=2006028723&IA=WO2006028723&DISPLAY=DESC (last visited Apr. 6, 2008).
[286] Takahashi K. et. al., *supra* note 52.

Biotechnology Directive or in Chapter VI of *Implementing Regulations* of the EPC that assist in determining the amount of human DNA that is necessary for part-human biological material, including stem cells, chimeras, cybrids, and stem cells extracted from cybrids to be considered to be human for the purposes of the *EPC* or the *Biotechnology Directive*. But in contrast to Canada and the United States, where there are no legislative prohibitions on the types of subject matter that are patentable based upon moral or public policy grounds, in Europe, the criteria for patentability expressly include exceptions based upon whether the publication or exploitation of the patent would be contrary to morality of public policy. Thus, there is the possibility that general principles of morality or public policy could prevent the patenting of some kinds of part-human biological materials notwithstanding the absence of an explicit provision prohibiting those kinds of materials. Article 53(a) of the *EPC* states:

> European patents shall not be granted in respect of:
>
> (a) inventions the publication or exploitation of which would be contrary to "ordre public" or morality, provided that the exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States; [287]

[81] Despite the intended effect of this provisions – to prohibit patents on inventions where their publication or exploitation is immoral or against public policy – the EPO cases have interpreted Article 53(3)(a) in a manner that limits its effect. The *Harvard/Onco-mouse* case held that

[287] European Patent Convention [EPC] art. 53(a), 1973, *available at* http://epo.org/patents/law/legal-texts/html/epc/1973/e/ar53.html; *see also EPC*, *supra* note 261. The European approach is permitted under § 27(2) 2 of *TRIPS*, which allows members to exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality. *See TRIPS*, *supra* note 137. Neither Canada nor the United States have *legislated* exceptions based upon those grounds. In fact, in 1993, Canada repealed a prohibition against patenting "an invention that has an illicit object in view" and did not incorporate a blanket "ordre public or morality" even though the purpose of the statutory revision was to bring Canadian law into compliance with international agreements. *Id.* For discussion, see generally *Harvard College*, [2002] 4 S.C.R. 45, 2002 SCC 76 ¶ 10 (Can.).

whether 53(a) was a bar to patentability of a transgenic mouse depended mainly on whether the suffering of animals and possible risks to the environment outweighed the invention's usefulness to mankind.[288] *Howard Florey/Relaxin* softened 53(3)(a) further, echoing *The Guidelines for Examination* of the EPO, by precluding patentability only when it is clear that ". . . it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable."[289]

[82] The subjective manner in which the Technical Board of Appeals of the EPO has interpreted the *EPC* morality provision has further blunted its impact. That is to say, the test is not whether *in fact* the publication or exploitation is contrary to morality but whether such actions are contrary to the morality and public policy that is *recognized* by European society as a whole.[290] Given the contentious nature of patenting biological materials

[288] *Harvard/Oncomouse*, *supra* note 264 at s. 5. Nevertheless, in the later WARF appeal, the Appeal Board said that it doubted that the weighing of interests test could apply to the "interests of human beings who could potentially benefit" against the interest of a human embryo to "get a life and of not being destroyed to benefit others." *See* Case T-1374/04, App. No. 96903521.1, Wisconsin Alumni Research Foundation, Interlocutory Decision of the Technical Board of Appeal at ¶ 55, *available* at http://legal.european-patent-office.org/dg3/biblio/t041374ex1.htm.

[289] *Howard Florey/Relaxin* [1995] EPO 388, at ¶ 6.2.1, *available at* http://legal.european-patent-office.org/dg3/biblio/v940008ep1.htm. This finding echoes the *Guidelines for Examination in the European Patent Office*, Part C, Chapter IV, 4.1, which provides that "[a] fair test to apply is to consider whether it is probable that the public in general would regard the invention as so abhorrent that the grant of patent rights would be inconceivable." *See Generally* Graeme Laurie, *Intellectual Property Protection of Biotechnological Inventions and Related Materials*, (Innogen Working Paper No. 4, 2003) *available at* http://www.innogen.ac.uk/assets_innogen/dynamic/1118847317818/working-paper-4.pdf.

[290] According to the EPO Technical Board of Appeals:

> [t]he concept of morality is related to the belief that some behaviour is right and acceptable whereas other behaviour is wrong, this belief being founded on the totality of the accepted norms which are deeply rooted in a particular culture. For the purposes of the *EPC*, the culture in question is the culture inherent in European society and civilization. Accordingly, under Art. 53(a) *EPC*, inventions the exploitation of which is not in conformity with the conventionally-accepted standards

containing human DNA and the difference in moral understanding and *ordre public* across diverse European cultures, it is unlikely that there will be a large measure of agreement on the issue of when biological material containing human DNA should be patented. As the patentability of an invention in even one European country would establish the absence of a pan-European norm against patentability, it can be argued that if the commercial exploitation of an invention is not contrary to morality or public policy in at least one European country, it should be patentable by the EPO.[291] Nevertheless, even if biotechnology patents are generously granted by the EPO, in this way they would be subject to revocation proceedings under national law.[292] European countries have implemented into their national law Article 6(1) of the *Biotechnology Directive,* a virtually identical provision to Article 53(a) *EPC*, which provides that "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."[293]

[83] Within European Union legislation, such as the *Biotechnology Directive*, there is a conscious use of open and vague concepts in order to provide a margin of appreciation for the Member States to achieve the transposition of Community Law into National Law at the expense of uniformity.[294] Thus, it is possible for different national patent offices to interpret the *Biotechnology Directive* differently, reflecting national

---

> of conduct pertaining to this culture are to be excluded from patentability as being contrary to morality.

Further, ". . . the concept of 'ordre public' [public policy] covers the protection of public security and the physical integrity of individuals as part of society." *Plant Genetics Systems*, [1995] EPO 545, (T 356/93), *available at* http://legal.european-pagen-office.org/dg3/biblio/t930356ex1.htm (approved by the Technical Board of Appeals at §10.2 of *Harvard/Oncomouse* (T 315/03), *available at* http://legal.european-patent-office.org/dg3/biblio/t030315ex1.htm).

[291] PLOMER, *supra* note 260, at 112-113.

[292] PLOMER, *supra* note 260, at 113.

[293] *Biotechnology Directive*, *supra* note 10, at Art. 6.1.

[294] PLOMER, *supra* note 260, at 39 (citing M. DOUGAN, NATIONAL REMEDIES BEFORE THE COURT OF JUSTICE 143 (Hart Publishing 2004)).

difference in views of morality and public policy.[295] For example, despite the EGE view that human pluripotent stem cells are not patentable, both Germany and Sweden, which have implemented the *Biotechnology Directive*, have granted patents on pluripotent stem cells.[296] Similarly, the U.K. Intellectual Property Office in its Practice Notice on *Inventions Involving Human Embryonic Stem Cells*,[297] takes the position that totipotent human stem cells *are not* patentable because they have the potential to develop into an entire human body.[298] At the same time, it is not contrary to morality or public policy to patent pluripotent human stem cells because, while they do not have the potential of totipotent stem cells, stem cell research does promise to provide new treatments for a wide range of serious diseases.[299] In fact, the U.K. has filed an *Amicus Curiae* submission to the Enlarged Board of Appeals of the EPO in relation to WARF arguing that, among other things, Rule 23d(c) does not prevent the patenting of claims directed to embryonic stem cell cultures.[300]

[84] Given the difficulty of arriving at a uniform and principled answer to whether part-human bodies can be patented in Europe as a whole, how difficult would it be to replace the prohibition against patenting human bodies with one prohibiting the patenting of persons? Legislation in Europe is decidedly ambiguous about whether humans or persons have a better claim to legal standing. As has been discussed, the value of the biological human is reflected in the *Biotechnology Directive* which

[295] Indeed, national variations in patent decision-making are likely to be upheld since, notwithstanding that the European Court of Justice can be seized of jurisdiction to interpret European Treaties in a uniform way, recital 39 of the *Biotechnology Directive* provides that *ordre public* and morality correspond to ethical principles recognised in individual Member States. *Biotechnology Directive*, *supra* note 10, at recital 39; *see also* PLOMER, *supra* note 260, at 113.

[296] See PLOMER, *supra* note 260, at 30.

[297] U.K. Intellectual Property Office, *Inventions Involving Human Embryonic Stem Cells*, *available at* http://www.patent.gov.uk/patent/p-decisionmaking/p-law/p-law-notice/p-law-notice-stemcells.htm ("Human totipotent cells have the potential to develop into an entire human body. In view of this potential, such cells are not patentable because the human body at the various stages of its formation and development is excluded from patentability by Paragraph 3(a) of Schedule A2 to the *Patents Act* 1977. The Office will therefore not grant patents for human totipotent cells.").

[298] *Id*.

[299] *Id.*

[300] United Kingdom, Case G2/06 – WARF Amicus Curiae submission of the United Kingdom, *available at* http://www.ipo.gov.uk/warf.pdf.

prohibits patenting the human body at the various stages of its formation and development – regardless of whether the human body is the body of a person.[301] The *Biomedicine Convention* also reflects "the need to respect the human being both as an individual and as a member of the human species and recognising the importance of ensuring the dignity of the human being."[302] The Explanatory Report to the *Biomedicine Convention* provides that it was a generally accepted principle that "human dignity and the identity of the human being had to be respected as soon as life began."[303] At the same time, most of the provisions embodied in the *European Convention on Human Rights*[304] and some provisions of the *Biotechnology Directive* support the idea that persons are of greater concern morally than are *humans per* se. The European Convention on Human Rights states, for instance, that "[e]veryone has the right to liberty and security of person."[305] The *Biotechnology Directive* provides that ". . . patent law must be applied so as to respect the fundamental principles safeguarding the dignity and integrity of the person."[306] While a uniform change in law would be very difficult at the European level, at the national level there may be more latitude for changes in patentability criteria as European countries are afforded a margin of interpretation to ". . . take

[301] *Biotechnology Directive*, *supra* note 10 at Art. 5.

[302] *Convention for the Protection of Human Rights and Dignity of the Human Being with Regard the Application of Biology and Medicine: Convention on Human Rights and Biomedicine*, Oviedo, 4.IV. (1997) [hereinafter *Biomedicine Convention*]. Susan Millns, professor of law at the University of Sussex and author on European Bio-Rights, appears to interpret the passage as requiring respect for persons in two aspects, as individuals and as members of the human species. In the latter case, according to Millns, since the preamble requires that medicine be used for the benefit of present and future generations, it suggests that the human species is of value apart from an individual member of the species. *See Consolidating Biorights in Europe*, *in* FRANCESCO FRANCIONI, BIOTECHNOLOGIES AND INTERNATIONAL RIGHTS 80 (2007). There are only twenty-one ratifications out of forty-seven Council of Europe members, which is not sufficient to indicate a consensus of values. *Id.*

[303] *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 BIOMED. EXPLANATORY REPORT, *available at* http://conventions.coe.int/Treaty/en/Reports/Html/164.htm.

[304] *Convention for the Protection of Human Rights and Fundamental Freedoms*, Nov. 4, 1950, 213 U.N.T.S 222, C.E.T.S. 5 [hereinafter *European Convention on Human Rights*].

[305] *Id.* at Art. 5. Most other provisions concern the rights of persons rather then humans, despite the title of the Convention.

[306] *Biotechnology Directive*, *supra* note 10, at recital 16.

account of the particular difficulties to which the use of certain patents may give rise in the social and cultural context of each Member State."[307]

CONCLUSION

[85] The use of part-human materials for research and transplantation has the potential to significantly alleviate human suffering. In Canada, the United States, and Europe, a rule exists forbidding the patenting of human beings. Because of the vagueness of this rule, its application is highly indeterminate and, therefore, has led to differing results in distinct jurisdictions. The USPTO has said that it cannot determine how much human DNA is necessary for something to be considered human. Although humans at any stage of development are not patentable in the United States, human totipotent stem cells – which could develop into mature humans – appear to be patentable. In Europe, the lack of moral consensus makes it unlikely that there would be a prohibition by the EPO of patents on animal-human combinations *per se*. Nevertheless, as in the United States, there is an indeterminacy regarding the amount of human DNA required to make animal-human combinations unpatentable. Despite the fact that totipotent stem cells appear to be patentable in the United States, human totipotent stem cells have been deemed to be unpatentable in Europe by the EPO and by some countries, such as the U.K. In Canada, based upon patentability criteria virtually identical to that of the U.S., the Supreme Court of Canada has ruled that higher life forms, including humans, are unpatentable. This implies that no animal-human combinations or their parts – such as tissues and organs – are patentable. Finally, although the Supreme Court of Canada has indicated in *obiter*

[307] Netherlands v. European Parliament and Council [2001] ECR I-07079 (C-377/98), at ¶ 38. In Evans v. U.K., Case 6339/05, March 2006, the European Court of Justice held that,

> [i]n the absence of any European consensus on the scientific and legal definition of the beginning of life, the issue of when the right to life begins comes within the margin of appreciation which the Court generally considers that States should enjoy in this sphere. Under English law . . . an embryo does not have independent rights or interests and cannot claim – or have claimed on its behalf – a right to life under Article 2 [of the *European Convention of Human Rights*].

Evans v. U.K. (Application No. 6339/05), FAMILY L. WEEK, Mar. 7, 2006, *available at* http://familylawweek.co.uk/print.asp?p=1776. For instance, the Preparatory Works to the *Additional Protocol on Human Cloning* notes that the definition of "human being" was to be left to domestic law to define. *See* PLOMER, *supra* note 260, at 62.

dicta that fertilized eggs of a mouse *are* patentable, CIPO has adopted a rule that neither fertilized eggs nor totipotent stem cells of animals are patentable.

[86] Short of eliminating patentability rules that depend upon fine distinctions between various kinds of subject matter, one solution to the problems raised by the use of biological criteria for patentability is to replace the rule against patenting humans and higher life forms with a rule that forbids the patenting of persons whether human or not. This is consistent with the ethical view that persons are the proper subject of rights rather than humans *per* se. A rule against patenting persons rather than one against patenting humans would replace biological criteria with non-biological criteria and result in a broader scope of patentable part-human materials that are useful for transplantation. However, significant obstacles exist to modifying the rule that prohibits the patenting of humans to one that prohibits the patenting of human persons in the patent law of the United States, Canada and Europe.

[87] In the United States, there is no sign that Congress would be prepared to adopt a rule prohibiting the patenting of persons. In Canada, the Supreme Court of Canada could strike down CIPO's interpretation of the Supreme Court of Canada that fertilized eggs and totipotent stem cells are higher life forms if only because it contradicts *obiter dicta* of the Supreme Court. However, in terms of animal-human combinations, while the Supreme Court of Canada, in *obiter dicta*, expressed openness to allowing patents on part-human organs and tissues used for transplantation, it has been unprepared to interfere with the CIPO's distinction between higher and lower life forms, preferring that the Canadian Parliament intervene. There is no indication, moreover, that Canadian Parliament is willing to intervene in matters of biotechnology patentability. In Europe, the difficulty of enacting the *Biotechnology Directive* would likely preclude re-opening it to substitute a rule against patenting persons for the present rule concerning human bodies. At a national level, however, there is latitude for implementing the *Biotechnology Directive* in accordance with national norms which might allow for greater scope in patenting animal-human combinations than at the EPO level. However, it would be difficult to interpret the explicit provision prohibiting the patenting of human bodies at any stage of

development in the *Biotechnology Directive* as prohibiting the patenting of persons instead.