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Potency, Patenting and Preformation: The Patentability of Totipotent Cells in Canada

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Abstract

The Canadian Intellectual Property Office's (CIPO) publication entitled, Office Practice Regarding the Patentability of Fertilized Eggs, Stem Cells and Tissues, is examined with respect to the patentability of totipotent cells. It is conjectured that its position against the patentability of totipotent cells is based upon a mistaken view of animal development and stem cell differentiation called "genetic preformationism." This view holds that the DNA in a totipotent cell is the sole determinant of development and differentiation so that a totipotent cell containing the DNA of a higher life form is a higher life form. It ignores the fact that modern biologists have recognised an increasingly important role for non-genetic, environmental factors in both animal development and stem cell differentiation. Given that the CIPO's views on development and differentiation are incorrect and the process of developing the Notice lacked transparency, justification and intelligibility, it cannot justifiably reject an application for a patent on a fertilised egg or totipotent stem cell on the basis of the reasons given in the Office Practice Regarding the Patentability of Fertilized Eggs, Stem Cells and Tissues. This paper suggests that there are legal, practical and scientific limits of the ability of the CIPO, like other patent offices, to apply patent legislation wisely to fundamentally new technologies.

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1. Introduction

In 2006, the Canadian Intellectual Property Office ("CIPO")[1] released its *Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues ("Stem Cell Notice")*.[2] Without engaging in any formal consultation, the CIPO took the position that fertilised eggs and totipotent stem cells, which have the potential to develop into a higher life form, *are* higher life forms.[3] It reasoned further that, since higher life forms[4] are not patentable under Canadian law,[5] fertilised eggs and totipotent stem cells are not patentable subject matter.[6] Pluripotent stem cells, which can develop into every kind of cell except for extra-embryonic cells, are not higher life forms and, therefore, are patentable subject matter in its view.[7] By 2008, the CIPO's position had been included in the draft biotechnology chapter[8] of its *Manual of Patent Office Practice* (MPOP),[9] which underwent formal consultation that ended on January 25, 2008. However, the CIPO did not provide any justification for its identification of potential higher life forms – i.e. totipotent cells – with actual higher life forms either in the *Stem Cell Notice*, its draft biotechnology chapter of the *MPOP* or in internal documentation.[10]

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[1] The CIPO is a Special Operating Agency associated with Industry Canada that is responsible for the administration of the intellectual property system in Canada. The head of the CIPO, its Chief Executive Officer, is the Commissioner of Patents and Registrar of Trade-marks. The CIPO's mandate stems from statutory and other authorities, including the *Patent Act*, the *Trade-marks Act*, the *Copyright Act*, the *Industrial Design Act,* the *Integrated Circuit Topography Act* and the *Public Servants Inventions Act*. The Commissioner of Patents is appointed by an order-in-council.

[2] CIPO, "Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues" (2006) available at http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/wr00295e.html (accessed 17 October 2008).

[3] *Ibid.*

[4] Humans are the paradigmatic higher life form, but this category is typically thought to include plants, animals and, more generally, any multicellular organism. See the discussion below at s 4.3.

[5] *Harvard College v Canada (Commissioner of Patents),* 2002 SCC 76 (*Harvard*).

[6] See note 2.

[7] *Ibid.*

[8] CIPO, "Biotechnology" (2008) available at http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/wr00758e.html (accessed 17 October 2008).

[9] CIPO, "Manual of Patent Office Practice" (2007) (*MPOP*) available at http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/h_wr00720e.html (accessed 17 October 2008).

[10] Internal documents concerning the development of *Stem Cell Notice* were provided to the author under the *Access to Information Act* R.S., 1985, c. A-1. The CIPO initially refused to release the requested documents voluntarily or, at least, the information officer was unable to understand the nature of the author's request. The materials were requested as of September 24, 2007 and 41 pages of material were supplied. There is no record of any public submissions in the documents nor is there a record of submissions in the CIPO Consultation Archive, available at http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/wr00450e.html (accessed 17 October 2008).

The *Stem Cell Notice* embodies a conservative regulatory style as it rejects the extension of patents into a key area of biotechnology: totipotent stem cells. While this regulatory style is out of step with the international trend of continual expansion of patent law into new areas of technology, it is in keeping with the Canadian reluctance to expand patentable subject matter.[11] In the case of the patentability of totipotent cells, however, this style is not only surprising but, arguably unjustifiable, given that the Supreme Court of Canada held in *Harvard*[12] and *Monsanto v Schmeiser*[13] that a fertilised egg of a mouse is patentable subject matter notwithstanding that it could develop into a higher life form, the latter being a type of entity that the Court had previously found to be unpatentable.[14] Surely, the Supreme Court would apply similar reasoning to find that a totipotent stem cell is also patentable subject matter. The CIPO's response to this problem (at least internally) has been to point out that the statements of the Supreme Court in *Harvard* and *Monsanto* are merely *obiter dicta*,[15] but, as will be discussed, this is not at all a satisfactory resolution of the issue since *obiter dicta* can be authoritative. Additional substantive difficulties with the CIPO's position include the fact that both unicellular organisms (including fertilised eggs and stem cells) and totipotent plant cells have previously been considered to be patentable according to the CIPO's own policies and that it contradicts its own stated view by regarding some unicellular organisms – i.e. totipotent cells – to be higher life forms.

Given the unfortunate absence of a rationale for the CIPO's identification of potential higher life forms with actual higher life forms in the *Stem Cell Notice* and in its internal documentation, one can only speculate on the reasons for its policy. Two possible rationales for the CIPO's position are considered in this paper. First, the CIPO may have been overly influenced by European legislation[16] and the European Patent Office's (EPO) *Guidelines for Examination in the European Patent Office*[17] according to which humans at any stage of development may not be patented. More specifically, if one generalises the UK Notice on *Inventions Involving Human*

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[11] Canadian courts and the patent office have been more reluctant than their US counterparts to allow patenting of contentious new technologies. See David Vaver, "Invention in Patent Law: A Review and a Modest Proposal" (2003) 11 *International Journal of Law and Information Technology,* 286-307.

[12] *Harvard,* see note 5 at para 162.

[13] *Monsanto Canada Inc. v Schmeiser*, 2004 SCC 34 (*Schmeiser*), at para 23.

[14] This surprise is reflected in some observations of the practicing community. See D Schwartz, "New Canadian Patent Office Policy Concerning Patentability of Fertilized Eggs, Stem Cells, Organs and Tissues" (2006) available at http://www.smart-biggar.ca/SB/index.cfm?RedirectPage=/Publications/publications.cfm?ThisID=400 (accessed 17 October 2008). See also I Clark, "Canada Biotechnology Patent Prosecution Under Review" (2008) available at http://www.managingip.com/Article/1968938/Biotechnology-patent-prosecution-under-review.html (accessed 17 October 2008).

[15] CIPO, "Stem Cell Patenting." (On file with the author)

[16] Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions OJ L 213, 30.7.1998,13–21, (*Biotechnology Directive*) and *Implementing Regulations to the Convention on the Grant of European Patents of October 5, 1973 (EPC)*, as amended (*Regulations*). Please note that a revised version of the *EPC* entered into force on December 13, 2007. The Rules cited in this paper are to the earlier version to avoid confusion.

[17] European Patent Office, "Guidelines for Examination in the European Patent Office" (2007), ch 4.5, interpreting Biotechnology Directive *Article* 53(a).available at http://www.epo.org/patents/law/legal-texts/guidelines.html (accessed 17 October 2008).

Embryonic Stem Cells[18] so that it applies to all animals as well as humans, then one arrives at the CIPO position. Second, the CIPO may have assumed a theory of animal development and stem cell differentiation according to which an animal is identified by its genetic blueprint – a modern version of the old idea that the animal was already formed in its earlier embryonic stages.[19] If this were a correct theory of development, then one could argue that, since the same DNA is present at all stages of development of a higher life form, it is the *same higher life form* at every stage of development. So, if one cannot patent the animal, one cannot patent it at any stage of its development. A similar argument can be made for totipotent stem cells. While the CIPO may not hold either view, this paper conjectures that the CIPO has implicitly, and perhaps without realising it, adopted genetic preformationism as a theory of animal development and stem cell differentiation.

Since the CIPO must justify any decision to reject a patent, the adoption of a policy- that appears to be based upon either a mistaken theory of development and stem cell differentiation or, in fact, has no articulated rationale at all- raises the issue of whether the CIPO can justifiably reject a patent claiming a totipotent cell on the basis of the *Stem Cell Notice*. In the present case, the *Stem Cell Notice* contradicted the view of the Supreme Court of Canada regarding the patentability of totipotent stem cells and fertilised eggs; was developed without formal consultation and, ultimately; did not provide any rationale for its view that potential and actual higher life forms are equivalent. The process of developing the *Stem Cell Notice* lacked transparency, intelligibility and justification, and its position was not factually supported, while it is well understood that stem cell research holds great promise for advances in health biotechnology. In the circumstances, the rejection of patents based upon the *Stem Cell Notice* cannot be regarded as justified.[20]

More generally, this case study suggests that, despite the presence of highly qualified individuals within the CIPO, there are legal, practical and scientific limits to the ability of it (like other patent offices) to apply patent legislation wisely to fundamentally new technology.[21]

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[18] UK Intellectual Property Office, "Inventions involving human embryonic stem cells" (2007) Annex E to the *Examination Guidelines for Patent Applications relating to Biotechnological Inventions in the UK Intellectual Property Office.*

[19] The historical and philosophical context is discussed in J Maienschein, *Whose View of Life?* (Cambridge: Harvard University Press, 2003).

[20] To be clear, the issue in this paper is confined to whether totipotent cells are the kind of subject matter than can be patented – not whether they are useful, inventive and new. In particular, this paper does not address the criticism that one should not patent stem cells because doing so would produce innovation gridlock. See K Bergman & GD Graff, "The global stem cell patent landscape: implications for efficient technology transfer and commercial development" (2007) 25 *Nature Biotechnology*, 419 – 424 and more generally, M Heller, *The Gridlock Economy* (New York: Perseus Books, 2008).

[21] This is called "the problem of regulatory connection" in R Brownsword, *Rights, Regulation, and the Technological Revolution* (Oxford: OUP, 2008).

2. Fertilised eggs, stem cells & development

Stem cells are important because of both their therapeutic and research potential.[22] Stem cells are those cells that serve as a normal reservoir for new cells that are needed to replace dying or damaged cells.[23] Scientists are exploring the possibility of using cell-based therapies to treat diseases such as diabetes, Parkinson's, spinal cord injury, liver malfunction, heart failure, burns, osteoarthritis, and rheumatoid arthritis.[24] Such therapies require specialists to be able to manipulate stem cells easily and reproducibly with the necessary characteristics for successful differentiation, transplantation and engraftment.[25] Many serious medical conditions, such as cancer and birth defects, are caused by abnormal cell division and differentiation, scientists seek to better understand these processes in order to create more effective therapeutic methods.[26] Finally, standardised differentiated stem cells could be used to test new drugs on a range of distinct kinds of cell types once scientists are able to produce consistently identical differentiated cells.[27]

Stem cells have three unique properties amongst cells. First, stem cells are undifferentiated cells of the body rather than the more specialised muscle cells, brain cells or other kinds of cells.[28] Second, under certain physiologic conditions, they can be induced to become cells with special functions such as beating heart cells or insulin-producing cells of the pancreas.[29] Finally, they are able to renew themselves (in an undifferentiated state) for long periods through cell division.[30]

The healing potential of stem cells is rooted in their potency – their ability to differentiate into cells of different types. But there are varying degrees of potency. A multipotent stem cell has the ability to develop into more than one cell type of the body. [31] A pluripotent stem cell has the ability to give rise to all of the various cell types that make up the body.[32] Pluripotent cells cannot make so-called "extra-embryonic" tissues such as the amnion, chorion, and other components of the placenta.[33] Finally, a totipotent stem cell can give rise to all the cell types that make

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[22] National Institute of Health, "Stem Cell Basics" (2008) available at http://stemcells.nih.gov/info/basics/ (accessed 17 October 2008).

[23] A Kiessling and S Anderson, *Human Embryonic Stem Cells* (Sudbury, Mass.: Jones & Bartlett, 2003), at 4.

[24] See note 22.

[25] *Ibid*.

[26] *Ibid*.

[27] *Ibid*.

[28] *Ibid*.

[29] *Ibid*.

[30] *Ibid*.

[31] *Ibid*.

[32] *Ibid*.

[33] *Ibid*.

up the body plus all of the cell types that make up the extra embryonic tissues such as the placenta.[34]

Stem cells can be found in adult animal organs, fetal tissues and embryos.[35] They can also be produced as a result of technology, such as nuclear transplant technology[36] and by reprogramming adult stem cells by activating four genes in the adult cells.[37] Because of their potency, stem cells found at early stages of animal development are of particular interest. Their degree of potency varies during development, requiring some explanation. After the egg is activated, the zygote forms.[38] The zygote cleaves, resulting in cells – blastomeres – which continue to cleave.[39] These cells are totipotent up until about the sixteen-cell stage. This is because by the sixteen-cell stage (in humans) a blastocyst takes form: comprising an outer layer of cells; the trophoblast; a fluid-filled cavity; the blastocel; and a cluster of about thirty cells in the interior – the inner cell mass.[40] The outside of the blastocyst will become the placenta and the inside will develop into the animal body.[41] At that point, the cells contained in the inner cell mass of a blastocyst are pluripotent because they have "committed" to being part of the embryo rather than the placenta.[42] These are considered to be embryonic stem cells since, by legal fiat, "embryo" has been defined to extend back to the activated egg from 56 days of development.[43]

The importance of potency for therapeutic purposes is a commonplace. For instance, Ouyang and others have maintained that totipotent cells "are the ideal cell sources for tissue engineering and cell therapy."[44] Bodnar and others observe that "[t]he ability to maintain cultures of undifferentiated, totipotent, primate-derived primordial stem cells for long periods facilitates the use of such cells for therapeutic purposes."[45]

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[34] *Ibid*.

[35] See note 23, at 5.

[36] See note 23, at 123-140.

[37] K Takahashi et al., "Induction of Pluripotent Stem Cells from Adult Human Fibroblasts by Defined Factors" (2007) 131 *Cell*, 861-872. J. Yu, et al., "Induced Pluripotent Stem Cell Lines Derived from Human Somatic Cells" (2007) 318 *Science*, 1917-1920.

[38] See note 23, at 53-64.

[39] *Ibid.*

[40] See note 22.

[41] See note 23, at 95.

[42] *Ibid*.

[43] Under the *Canadian Assisted Human Reproduction Act*, 2004, c. 2, "embryo" means a human organism during the first 56 days of its development following fertilisation 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. The US National Institute of Health, see note, 22, above, from which the CIPO takes its terminology defined "human embryo" as "…the developing organism from the time of fertilization until the end of the eighth week of gestation, when it is called a fetus."

[44] A Ouyang, R Ng, S Yang, "Long-Term Culturing of Undifferentiated Embryonic Stem Cells in Conditioned Media and Three-Dimensional Fibrous Matrices Without Extracellular Matrix Coating" (2007) 25 *Stem Cells*, at 447 –454.

[45] A Bodnar et al, "Methods and materials for the growth of primate-derived primordial stem cells in feeder-free culture" U.S. Patent No. 6,800,480 (filed 29 Aug 2000) (issued 5 October 2004).

Consequently, inventors have applied for patents on totipotent stem cells. The need to provide incentives for therapeutic and research advances relating to totipotent cells makes the issue of their patentability particularly important.

A search of claims to *totipotent* cells in the CIPO database returned 73 responses including claims that have not issued.[46] The CIPO reports in internal documents that there are eight issued patents that include claims to totipotent stem cells.[47] For example, WR Grace was granted a patent which includes a claim to a mammalian cell, such as a fertilised egg or an undifferentiated preimplantation embryo cell, the DNA of which was stained fluorescent for visualisation.[48]

3. The CIPO's Office Practice Regarding Fertilised Eggs, Stem Cells & Tissues

The *Stem Cell Notice* sets out the CIPO's position on the patenting of fertilised eggs, stem cells, organs and tissues.[49] With regard to fertilised eggs and later stages of development, it said:[50]

> *The 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.*

This passage characterises animals at any stage of their development as higher rather than lower life forms. It appears to single out each stage of development as an individual and ascribes to it a property of being a higher life form. The classification holds regardless of the level of cellular complexity of the organism. So, even a (unicellular) mouse zygote is a higher life form despite being the least complex stage of mouse development. The CIPO does not give any reason in this passage for characterising things that are *becoming* higher life forms *as* higher life forms. It simply states its position without a rationale.

After its statement regarding animals at any stage of development, the *Stem Cell Notice* goes on to consider the patentability of stem cells by analogy to the patentability of fertilised eggs. Regarding totipotent stem cells, it says:[51]

> *Totipotent stem cells, which have the same potential as fertilized eggs to develop into an entire animal, are considered to be*

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[46] As of September 30, 2008.

[47] CIPO, "Canadian Patents Claiming Stem Cells" lists 21 stem cell patents with one being a totipotent stem cell (patent number 2274092). (On file with the author.) Another untitled document lists 31 patents claiming stem cells with seven of them including claims to totipotent stem cells. These are patent numbers are 2274092, 2183546, 2295861, 2319703, 2384170, 2250682, and 1271716.

[48] N First, "Technique for Visualization of Genetic Material" Canadian Patent No. 1271716, issued July 17, 1990.

[49] The patentability of organs and tissues of animals will not be addressed in this paper.

[50] See note 2.

[51] *Ibid*.

> *equivalents of fertilized eggs and are thus higher life forms and are not patentable subject matter.*

Here the *Stem Cell Notice* refers to the *potential* for development that totipotent stem cells possess. While the concept of totipotency that the CIPO cites from the US National Institute of Health concerns the ability to give rise to all the cell types that make up the body as well as extra embryonic tissues, the *Stem Cell Notice* speaks of the potential to develop into an *entire animal*.[52] It states that, because of the potential to develop into an entire animal, totipotent stem cells *are* higher life forms. It is worth emphasising that the CIPO does not say merely that totipotent cells have the *potential* to develop into a higher life form but simply declares that, like animals at any stage of development, they *are* higher life forms. The fundamental problem with the *Stem Cell Notice* is that the CIPO gives no reason either publicly or internally as to *why* it identifies potential higher life forms – e.g. fertilised animal eggs and totipotent animal stem cells – with actual higher life forms (fully developed animals). Taken literally, it seems that this view cannot be right. After all, that an acorn is not an oak tree and a block of bronze is not a sculpture are merely platitudes. Nor does the CIPO provide any reason why, for the purposes of patentability, potential higher life forms should, as a legal fiction, be regarded as higher life forms.

In internal documents, the CIPO states why it views fertilised eggs to be higher life forms. It says that "[t]he Office considers a fertilized egg, which has the inherent ability to develop into a human being or a whole animal, to be a complex or higher life form and outside the definition of invention in section 2 of the Patent Act."[53] It appears, then, that the reason why the CIPO considers that both fertilised eggs of a higher life form (as well as further stages) and totipotent stem cells of a higher life form *are* higher life forms, is that such materials have the *potential* to develop into an "entire" or "whole" animal – a paradigmatic higher life form. Again, the fundamental problem is that the CIPO does not say, either in public or internal documents, why a *potential* higher life form is an *actual* higher life form.

Before examining possible rationales for the CIPO position, the next section examines the difficulties with the position itself in relation to existing law and patent policy.

4. Difficulties with the CIPO Stem Cell Notice

4.1 Fertilised eggs and stem cells are compositions of matter

The most obvious problem with the position taken in the *Stem Cell Notice* is that it conflicts with statements made by the Supreme Court of Canada. In *Harvard*, Harvard College applied for a patent on non-human mammals (including an oncomouse) that are genetically modified to make them more cancer prone than they otherwise would be.[54] This well-known case focused on whether a genetically modified mammal is a

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[52] *Ibid*.

[53] See note 15.

[54] *Harvard,* see note 5.

composition of matter, a kind of subject matter that is eligible for patenting.[55] The Court defined "composition of matter" to mean "a substance or preparation formed by combination or mixture of various ingredients."[56] It noted, further, that "it does not seem unreasonable to assume that it must be the inventor who has combined or mixed the various ingredients."[57] It found that the body of the genetically-modified mouse does not consist of ingredients or substances that have been combined or mixed together by a person – it is not a composition of matter.[58] Moreover, it noted that the fact that animal life forms have numerous unique qualities that transcend the particular matter of which they are composed, makes it difficult to conceptualise them as mere compositions of matter.[59] Hence, it reasoned, such life forms are more than mere compositions of matter.[60] On these grounds, the Supreme Court of Canada rejected the patentability of genetically-modified mammals.

In the draft biotechnology chapter of the *MPOP*, the CIPO interpreted *Harvard* as implying that any stage of development of a higher life form is unpatentable:[61]

> *This decision has been interpreted by the Patent Office to mean that animals at any stage of development are not statutory matter for letters patent, and consequently that fertilized eggs and totipotent stem cells (which have the inherent ability to develop into animals) are included in the higher life form proscription.*

However, the CIPO's interpretation contradicts what the Supreme Court explicitly *says* in *Harvard*. Notwithstanding the fact that the genetically modified mouse was found to be unpatentable, the majority of the Supreme Court said that the genetically modified mouse egg from which it developed *is* a composition of matter:[62]

> *Owing to the fact that the technology by which a mouse predisposed to cancer is produced involves injecting the oncogene into a fertilized egg, the genetically altered egg would appear to be cognizable as "[a] substance or preparation formed by combination or mixture of various ingredients" or as [TRANSLATION] "[a]ction or manner of forming a whole . . . by assembling several parts".*

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[55] *Patent Act*, RS, 1985, ch P-4, s 2. Section 2 of the *Patent Act* provides that "invention" means 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.

[56] *Harvard*, see note 5, above, at para 162.

[57] *Ibid*.

[58] *Ibid*.

[59] *Harvard*, see note 5, *at* para 163. At paragraph 163 the Court gives the following example: "[a] person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilised egg cell; it simply would not be predisposed to cancer."

[60] *Ibid*.

[61] See note 8.

[62] *Harvard*, see note 5, at para 162.

The implication of this finding by the Supreme Court is that – providing that the other necessary requirements for an invention are met – the fertilised oncomouse egg is an invention. The minority endorsed this implication, saying the following:[63]

> *My colleague, Bastarache J., acknowledges that the fertilized, genetically altered oncomouse egg is an invention under our Patent Act, R.S.C. 1985, c. P-4 (para. 162). Thereafter, we part company, because my colleague goes on to conclude that the resulting oncomouse, that grows from the patented egg, is not itself patentable because it is not an invention.*

The position of the Supreme Court of Canada was rephrased in *Schmeiser*.[64] The issue in *Schmeiser* was whether Schmeiser was infringing by planting and harvesting genetically modified canola containing the patented gene and cell.[65] Schmeiser contended, amongst other things, that the patent on the genetically modified cell was invalid as it was unpatentable subject matter, since a patent in the cells would automatically restrict the use of the plant and seed, both of which the Supreme Court of Canada had judged unpatentable in *Harvard*.[66] The Court referred to its statements regarding the oncomouse egg in *Harvard* and said:[67]

> *... 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 ...*

There is nothing in either *Harvard* or *Schmeiser* to suggest that either fertilised non-human animal eggs or totipotent non-human animal stem cells extracted from early stage embryos would not also be considered compositions of matter and, therefore, patentable subject matter. On the patentability of fertilised *human* eggs and *human* totipotent stem cells, however, the Supreme Court remained uncommitted.[68]

4.2 Obiter Dicta can be authoritative.

The CIPO took its position with full knowledge of the Supreme Court of Canada's position regarding the patentability of fertilised eggs and, by implication, totipotent stem cells.[69] Its response to the statements of the Supreme Court on this matter has

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[63] *Harvard*, see note 5, *at* para 3.

[64] *Schmeiser,* see note 13.

[65] *Ibid.*

[66] *Schmeiser*, see note 13, at para 21.

[67] *Schmeiser*, see note 13, at para 23.

[68] At paragraph 179 of *Harvard,* see note 5, above the Supreme Court raises the issue of whether the prohibition of patenting humans extends to "…all precursors to the human body from zygotes to foetuses." In declining to answer, it says at paragraph 183 that "… 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."

[69] CIPO, "Canadian Practice with Respect to Life Forms." (On file with the author.)

been simply that "[a]ny comments on fertilized eggs were made in *obiter*."[70] In its internal correspondence there is no record of any analysis of the status of the Supreme Court's statement as *obiter dicta* or its implications. There is merely an assumption that such statements are not binding on the CIPO. The CIPO has admitted, in fact, that it gave no consideration to the possibility of *obiter* statements having any binding quality.[71]

Whether the Supreme Court's *obiter dicta* are legally binding or not, it is practically relevant that by adopting a policy that is contrary to the *obiter dicta* of the Supreme Court of Canada the CIPO is risking that the decisions of its examiners will be overturned on appeal. Both patent examiners and inventors need to be confident that the decisions that they make based upon the CIPO's policies will not be overturned on appeal. Yet, obviously, if the CIPO ignores the Supreme Court of Canada's decisions in formulating a policy, then no examiner or inventor can be confident that the decision will not be overturned. In short, the CIPO should have given extensive consideration to the Supreme Court's views rather than to merely curtly dismiss them as non-binding.

The CIPO's response to the Supreme Court is substantively inadequate inasmuch as it presupposes a strict separation between the *ratio decidendi* and *obiter dicta*, which does not exist. This was made clear in *R v Henry*, in which the Supreme Court observed that *obiter dicta* can be treated as binding in some cases.[72] In contrasting the Court's view with the erroneous "Sellar's principle" – according to which all statements made by the majority should be considered binding – it noted:[73]

> *All obiter do not have, and are not intended to have, the same weight. The weight decreases as one moves from the dispositive ratio decidendi to a wider circle of analysis which is obviously intended for guidance and which should be accepted as authoritative. Beyond that, there will be commentary, examples or exposition that are intended to be helpful and may be found to be persuasive, but are certainly not "binding" ....*

Arguably, the statement by the Supreme Court of Canada – that a genetically-engineered, fertilised mouse egg is a composition of matter – has a high degree of authoritative weight, since the very concept of *composition of matter* that is used to draw this conclusion is the concept that was applied to find that the oncomouse was not patentable.

So the CIPO requires a better response to the Supreme Court's pronouncements on the nature and patentability of fertilised oncomouse eggs than merely that they are

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[70] See note 15.

[71] CIPO Joint Liaison Committee. "Meeting Minutes # 110, 25 October, 2006" (2006) available at http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/wr00696e.html (accessed 17 October 2008). Responding to criticisms of D Schwartz, M Gillen replied: "Mr. Schwartz's submission has been fully reviewed by the Office and all the issues raised therein were considered previously when developing the policy, *with the exception of the alleged binding nature of reasoned obiter decisions*." (Emphasis added.)

[72] *R v Henry*, 2005 SCC 76.

[73] *Ibid,* at para 57.

obiter dicta. For example, instead of dismissing the statement, the CIPO could have accepted the authoritative significance of the Supreme Court's statement but attempted to limit its applicability. As the Supreme Court made clear in *Harvard*, its role was to determine whether higher life forms (and in particular, the oncomouse) are compositions of matter or manufactures of matter.[74] In reaching its conclusion, it relied upon the line drawn by the CIPO between higher and lower life forms.[75] It used the CIPO's distinction between higher and lower forms of life to find that the oncomouse is a higher life form and, impliedly, that the fertilised egg is not. While it found the line to be defensible, the Court observed that, ultimately, "… it is up to Parliament and not the courts to assess the validity of the distinction drawn by the Patent Office between higher life forms and lower life forms."[76] The CIPO could have argued, therefore, that it has the authority (absent contrary direction from Parliament) to *alter* the distinction between higher and lower life form, resulting in the policy contained in the *Stem Cell Notice* and a different conclusion regarding the patentability of totipotent cells than that provided by the Supreme Court. This conclusion is erroneous, it will be argued, but at least the CIPO would have provided a reason for its decision rather relying on an unsupportable legal view that *obiter dicta* cannot be binding.

4.3 Stem cells are unicellular compositions of matter

A greater difficulty than the contradiction with the statements of the Supreme Court, perhaps, is that the *Stem Cell Notice* appears to contradict the CIPO's own policies. First of all, according to the *MPOP*, lower life forms are patentable. The relevant passage reads: [77]

> *Uni-cellular life forms which are new, useful and inventive are patentable. In general, a process to produce, or which utilizes, these organisms is patentable. Uni-cellular life forms include:*
>
> - *microscopic algae;*
> - *moulds and yeasts;*
> - *bacteria;*
> - *protozoa;*
> - *viruses;*
> - *cells in culture;*
> - *transformed cell lines; and*

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[74] *Harvard*, see note 5, at para 153.

[75] *Harvard*, see note 5, at para 199.

[76] *Harvard*, see note 5, at paras 204 & 206.

[77] See note 9, at s 12.04.01.

- *hybridomas.*

Higher life forms are not patentable subject matter.

It is clear from the context that the lower life forms are understood to be unicellular life forms whereas higher life forms are multicellular.[78] For the proposition that unicellular life forms are patentable, the *MPOP* cites *Re Application of Abitibi Co*.[79] In fact, *Abitbi* went further in some respects, holding that micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines,[80] viruses and protozoa are patentable.[81] The Patent Appeal Board added that patentability would extend:

> *...to all new life forms ["all" seemingly including higher life forms[82]] which are produced en masse as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.*[83]

The distinction between higher and lower life forms was upheld or, at least, not altered by the Supreme Court of Canada in *Harvard*.[84] When animal fertilised eggs and stem cells are micro-organisms, they are patentable according to this reasoning.[85]

The *Stem Cell Notice* contradicts this conclusion, as it considers both totipotent stem cells and fertilised eggs to be higher life forms and, therefore, unpatentable. What justifies this change of view? In its internal document, "Stem Cell Patenting," the CIPO raised the following question:[86]

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[78] *Ibid*.

[79] *Re Application of Abitibi Co* [1982] 62 C.P.R. (2d) 8 (*Abitibi*).

[80] *Abitibi*, *ibid*, was followed by the Patent Appeal Board in *Application for Patent of Connaught Laboratories, Re* (1982), 82 C.P.R. (2d) 32 (P.A.B.).

[81] *Abitibi,* see note 79, above at 89-90. Arguably, since fungi generally grow multicellular filaments, the decision was not meant to exclude from patentability multicellular (i.e. higher) life forms that could be produced *en masse*. The Board said further that "[w]e can see no justifiable reason for distinguishing between these life forms [and other patentable life forms] when deciding the question of patentable subject-matter." However, it is not clear that it intended that higher life forms be patentable since it also said about its new category of patentable subject matter that "[w]hether it reaches up to higher life forms -- Plants (in the popular sense) or animals -- is more debatable."

[82] The minority in *Harvard,* see note 5, above, at para 127, say that *Abitibi* stands for the proposition "… only that lower life forms were patentable." The majority, in *Harvard*, while discussing *Abitibi* at para 198, remarked that "[t]he patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada."

[83] *Abitibi*, see note 79. Emphasis added.

[84] *Harvard*, see note 5, at para 199.

[85] At least when the fertilised egg or stem cell is too small to be seen by the naked eye. Some protest unicellular organisms (that are not animals) are visible to the naked eye.

[86] See note 15.

> *Cells, including human cells, have been patentable in Canada since 1982. Why is the Patent Office now changing its practice and refusing patent applications [which] claim totipotent stem cells?*

It answers as follows:[87]

> *Patent Office practice has not changed. Office practice since 1982 has been to grant patents on lower or less complex life forms but not on higher or more complex life forms. The Supreme Court of Canada in the Harvard decision [Harvard College v. Canada Commissioner of Patents, [2002] 4. S.C.R. 45] states at paragraph 199 that it saw "no reason to alter the line drawn by Patent Office". The Office considers totipotent stem cells which have the inherent ability to develop into human beings or whole animals, to be complex or higher life forms and not to be the type of life forms to which the Abitibi decision (Commissioner's Decision no. 933, March 18, 1982) applies….*

This is a misleading response in a number of ways. First of all, it blurs the distinction between unicellular and multicellular by replacing it with the less complex/more complex distinction. This blurring appears to be an attempt to suggest that the distinction between higher and lower life forms in the *MPOP* was not rigidly between unicellular and multicellular organisms but more open-textured, allowing for principled exceptions such as totipotent animal cells. But, the line in the *MPOP* is at least relatively bright: apart from the exception dealing with life forms produced *en masse,* lower life forms are unicellular organisms while higher life forms are multicellular organisms. Even if the distinction was intended to be subject to principled exceptions, the CIPO does not explain in its internal documents why a unicellular animal is more *complex* in the required sense than, say, a unicellular bacterium. That is, how can a totipotent animal cell be unicellular but still be complex? This blurring of the CIPO's distinction allows it to make a second misleading point, namely, that office practice has not changed because totipotent stem cells are higher life forms. But it is clear from comparing existing *MPOP* with the draft biotechnology chapter of the *MPOP* that the practice has changed. In the draft biotechnology chapter, the CIPO incorporates an exception to the old distinction that is not provided in the existing *MPOP*.[88]

> *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).*

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[87] *Ibid*.

[88] See note 8, at s 17.02.01a.

According to the draft biotechnology chapter of the *MPOP*, lower life forms include: microscopic algae; unicellular fungi, moulds and yeasts; bacteria; protozoa; viruses; transformed cell lines; hybridomas; and embryonic pluripotent and multipotent stem cells.[89]

In short, the CIPO *is* changing its office practice by concluding that unicellular totipotent cells are higher life forms. Furthermore, given the fact that the distinction between higher and lower life forms provided in the *MPOP* was defined rigidly – rather than flexibly by using principles or value factors – it is best described as a change of distinction rather than a new application of a flexible distinction. The problem with making this change is that sound definitional change is not simply a matter of fiat. The process of definitional change in the empirical sciences has been the subject of extensive study.[90] Such *ad hoc* changes to theories have typically been criticised in the philosophy of science as unsound when there is an acceptable alternative theory that does not require an *ad hoc* modification of definitions.[91] Alternative theories in the present instance could include: (i) higher life forms exist once there is substantial cell differentiation and coordination, which occur around day-16 after fertilisation;[92] (ii) higher life forms are those that are sentient;[93] (iii) a higher life form possesses particular qualities that transcend its material composition;[94] and (iv) a higher life form possesses higher level faculties, such as rationality and consciousness.[95]

A second contradiction relates to the treatment of totipotent cells in *Schmeiser*.[96] In that case, the Supreme Court of Canada upheld a patent on genetically modified genes and cells that made canola plants resistant to the Monsanto herbicide roundup.[97] It noted, moreover, that the protection is not limited to genes and cells in an isolated laboratory form, but applies equally to the patented cells and genes existing in canola seeds and plants.[98] The Court pointed out that "[o]nce the [genetically modified] cell is stimulated to grow into a plant, all of the differentiated cells in the plant will

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[89] *Ibid.*

[90] L Soler, H Sankey, Howard, P Hoyningen-Huene (Eds.), *Rethinking Scientific Change and Theory Comparison: Stabilities, Ruptures, Incommensurabilities?* (Dordrecht: Springer, 2008).

[91] Discussed in L Synder, "William Whewell" in E Zalta (ed.), *The Stanford Encyclopedia of Philosophy* (2008), available at http://plato.stanford.edu/archives/sum2008/entries/whewell (accessed 17 October 2008).

[92] B Smith & B Brogaard, "Sixteen Days" (2003) 28 *Journal of Medicine & Philosophy*, 45-78.

[93] This is raised as an option by the Supreme Court of Canada in *Harvard,* see note 5, above, at para 204. See also the list compiled by the minority at paragraph 52 of *Harvard.*

[94] The Supreme Court gives the following example at paragraph 163 of *Harvard,* note 5, above: "A person whose genetic make-up is modified by radiation does not cease to be him or herself. Likewise, the same mouse would exist absent the injection of the oncogene into the fertilised egg cell; it simply would not be predisposed to cancer."

[95] Peter Singer, "Sanctity of Life" Foreign Policy (September 2005) available at http://www.foreignpolicy.com/story/cms.php?story_id=3159 (accessed 17 October 2008).

[96] *Schmeiser*, see note 13, at para 21.

[97] *Schmeiser*, see note 13, at para 20.

[98] *Schmeiser*, see note 13, at para 17.

contain the chimeric gene, which will be passed on to offspring of the plant."[99] However, it has been known for more than forty years that, remarkably, a somatic plant cell has the ability to *dedifferentiate*, giving rise to a totipotent embryogenic cell that has the ability to proliferate and/or regenerate an embryo.[100] In this sense, the Monsanto patent covered genetically modified *totipotent* plant cells.

While the CIPO did not make the point that *Schmeiser* validates the patentability of totipotent plant cells in its internal documents, it did pose the fundamental question about why totipotent animal cells and totipotent plant cells are treated differently in *Stem Cell Patenting*.[101]

> *Many plant cells have the inherent ability to develop into whole plants. These cells are patentable whereas totipotent human or animal stem cells are not. With respect to patentability, what is the Patent Office's rationale for distinguishing between plant cells and human or animal totipotent stem cells?*

It answers:[102]

> *Since 1982, as a result of a Commissioner's Decision in re Abitibi (Commissioner's Decision no. 933, March 18, 1982), "life forms which are produced en masse as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess properties and characteristics" have been patentable. The practice of the Patent Office has been to include plant cells within this definition of a "lower life form." This practice was affirmed by the Supreme Court of Canada in the Schmeiser case where a patent with claims to plant cells was declared to be valid. Human and animal totipotent stem cells are not produced en masse and in large numbers. Instead, these cells quickly give rise to other cell types.*

In essence, the CIPO's response is that totipotent plant cells are lower life forms because they can be produced *en masse* as opposed to human totipotent cells which, supposedly, cannot be produced *en masse.* The CIPO does not give any criteria for the amount that constitutes "*en masse*" nor does it provide any evidence that totipotent animal and plant cells are not produced *en masse*. It would appear that totipotent cells that are produced *en masse* naturally in the body to act as a reservoir for differentiation should be considered lower life forms. Moreover, researchers recently have created a bioreactor and method for the mass production of human embryonic stem cells outside of the body that increases the number of existing stem cells in a

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[99] *Schmeiser*, see note 13, at para 20.

[100] J Verdeil, L Alemanno, N Niemenak and T John Tranbarger, "Pluripotent versus totipotent plant stem cells: dependence versus autonomy?" (2007) 12 *Trends in Plant Science*, 245-252, at 246.

[101] See note 15.

[102] *Ibid*.

culture by about two hundred-fold in fifteen days while maintaining the cells in their most potent undifferentiated state.[103]

A second problem with the CIPO's response to this question concerns the application of *Abitibi.* First of all, it interprets the *Abitibi* ruling that "*all* new life forms which are produced *en masse*…" are patentable as meaning only that *lower* life forms are patentable. It repeats this interpretation in the draft biotechnology chapter of the *MPOP*.[104]

> *In Commissioner's Decision 933 [Re Application of Abitibi Co. (1982), 62 C.P.R. (2nd), 81 P.A.B.)] it was determined that lower life forms which are produced en masse as chemical compounds are prepared, and which are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics are generally deemed to fall within the scope of section 2 as being either "manufactures" or "compositions of matter".*

As suggested, *Abitibi* may stand for the proposition that higher and lower life forms produced *en masse* are patentable. In that case, if totipotent animal cells can be, or presently are, produced *en masse*, then they are patentable. Even if this interpretation is incorrect, however, the scope of "lower life form" may include totipotent animal cells in certain circumstances. When discussing its rationale for the patentability of totipotent plant cells, the CIPO noted that it considered totipotent plant cells that are produced *en masse*, to be *lower* life forms. It takes this view notwithstanding that totipotent plant cells have the potential to develop into a higher life form. Presumably, the same reasoning applies to animals, so that totipotent animal cells produced *en masse* would be patentable. If and when totipotent animal cells can be produced *en masse,* according to this reasoning, the prohibition against patenting totipotent cells in the *Stem Cell Notice* would be inapplicable.

5. Possible rationales for the stem cell notice

In *Harvard*, the Supreme Court of Canada held that higher life forms are unpatentable.[105] For the CIPO, fertilised eggs and totipotent stem cells, which have the potential to become higher life forms, *are* higher life forms.[106] Hence, they are unpatentable.[107] From the documentary record, the core part of the development of the *Stem Cell Notice* appears to be a review of the jurisprudence from the U.S., Europe, the United Kingdom, Australia and Japan.[108] Although the relevance of the review of

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[103] See note 44.

[104] *Ibid.* Emphasis added.

[105] *Harvard,* see note 5.

[106] See note 2.

[107] *Ibid*.

[108] Japanese patent law will not be reviewed here except to note that, according to the CIPO, "…s. 32 [of Japanese Patent Law] is used to reject claims to human beings as well as claims to human foetuses, embryos and fertilized ova if these are being used to create a human being. If these 'products' have another purpose, they are not excluded from patentability under section 32. Thus human fertilized eggs,

the jurisprudence for the development of the *Stem Cell Notice* was not discussed in its two-and-a-half page review, the review was (presumably) intended to address whether the legal reasoning used in foreign settings might be applicable to the Canadian position. Unfortunately, its overly brief review of this jurisprudence contained no discussion of the relevance of foreign reasoning to the Canadian context.

This following section draws upon the CIPO's review of foreign policies with respect to totipotent cells and fertilised eggs in order to attempt to discern possible rationales for the position given in the *Stem Cell Notice.*

5.1 Possible rationale: Embryonic animals and totipotent animal stem cells have the same or similar moral status as more developed animals

One possible explanation of the CIPO's equation of totipotent cells with higher life forms is that totipotent cells are viewed as having the same, or similar, moral status as the higher life forms that they will become. This point of view is a generalisation of the familiar, though dubious, view that *embryonic humans* have the same or similar moral status as *human beings*.[109] It might be thought to justify treating totipotent stem cells as higher life forms for the purposes of patentability. Resnick's statement is typical of this point of view:[110]

> *Totipotent human embryonic stem cells, which, like the embryo, have the potential to develop into adult human beings, are also human life and have moral value. Totipotent embryonic stem cells have rights similar to those possessed by un-implanted embryos: they should not be killed for a frivolous reason or treated as property. A patent on a totipotent stem cell would violate its dignity. Pluripotent human stem cells, which can develop into any tissue type in the body but cannot become an adult human being, are not human beings at all and do not have any moral rights. Pluripotent stem cells can be bought, sold, and patented. Likewise, multipotent stem cells, which can develop into several different tissues types, are not human beings and have no rights. These cells can also be bought, sold, and patented.*

The suspicion that the CIPO could be assuming that totipotent cells have a moral status arises because a number of the CIPO's internal discussions and documents focused on the patentability of *human* biological materials, which tends to import all

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sperm, unfertilized human ova, zygotes, totipotent and pluripotent stem cells are patentable subject matter if they are to be used for some purpose other than the creation of a human being." No cases were cited. See CIPO, "Foreign Practice with Respect to Practice Involving Stem Cells." (On file with the author.) What CIPO did not mention is that s. 32 is the Japanese "morality provision." It reads: "The inventions liable to contravene public order, morality or public health shall not be patented, notwithstanding Section 29." The WIPO translation of Japanese Patent Law is available at http://www.wipo.int/clea/docs_new/pdf/en/jp/jp006en.pdf (accessed 17 October 2008).

[109] For a brief overview of the ethical issues of human stem cell research, see A Siegel, "Ethics of Stem Cell Research", in E Zalta (Ed) *The Stanford Encyclopedia of Philosophy* (2008) available at http://plato.stanford.edu/archives/fall2008/entries/stem-cells/ (accessed 17 October 2008).

[110] DB Resnick, "Embryonic Stem Cell Patents and Human Dignity" (2007) 15 *Health Care Analysis*, 211–222 at 220.

the ethical issues related to the patentability of humans. A key internal document that was used in developing the policy was entitled "Human Development."[111] Indeed, the very first line of the section entitled "Stem Cells – a primer" beings with the sentence "Human development begins when a sperm fertilises an egg."[112] The short review of foreign practice- including Europe, the U.K., Australia, Japan and the United States- deals with the patenting of *human* stem cells in each case.[113] In an e-mail from the CIPO to the UK's patent office, the main questions that were asked concerned the patentability of *human* biological materials: i.e. genetically modified human organs, human tissues, human germ cells and human embryonic stem cells.[114] Furthermore, two out of three charts were produced – entitled "Is it Patentable Subject Matter?" that were developed to "form the basis for what is expected to be a decision point on this issue"[115] – concerned the patentability of *human* products and process such as germ cells, somatic cells, stem cells, tissues, cloning and IVF in different jurisdictions.[116]

Suspicion is further heightened by the similarity of some language contained in the *Stem Cell Notice* with that contained in European law and policy containing ethical principles. European legislation embodies the following moral incorporation principle: "[i]nventions 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."[117] Article 5(1) of the *Biotechnology Directive* specifically prohibits the patenting of human bodies at any stage of development.[118]

> *The human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions.*

The Canadian *Stem Cell Notice* appears simply to generalise the prohibition contained in Article 5(1) so that it applies to all animals when it says that "…animals at any stage of development, from fertilised eggs on, are higher life forms and are thus not patentable subject matter under section 2 of the *Patent Act*."[119] Article 5(1) reflects a concern to provide "ethically appropriate boundaries" behind the *Biotechnology*

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[111] CIPO, "Human Development" (On file with the author).

[112] *Ibid.*

[113] See note 108.

[114] E-mail from Barney de Schneider, Assistant Commissioner of Patents, to Ron Marchant, UK patent office.

[115] E-mail from Barney de Schneider, Assistant Commissioner of Patents, to David Campbell, Michael Gillen, Chairperson, Patent Appeal Board, and Alan Trociuk, Counsel, Legal Services (On file with the author).

[116] CIPO, "Is it Patentable Subject Matter?" (On file with the author).

[117] *Biotechnology Directive*, Article *6(1);* 53(a) *EPC; Guidelines for Examination in the EPO,* ch 4.1.

[118] Article 5(1) *Biotechnology Directive*; *Rule* 23(e)(1) *Regulations; Guidelines for Examination in the EPO,* ch 4.5.

[119] See note 2.

Directive made explicit in Article 6(1) of the *Biotechnology Directive.*[120] The question, thus, arises as to whether the *Stem Cell Notice* imports a patentability principle based upon ethical reasoning analogous to, and borrowed from, European legislation.

As for totipotent animal stem cells, the Canadian *Stem Cell Notice* bears strikingly similarity to the UK's *Inventions Involving Human Embryonic Stem Cells*.[121] Indeed, internal e-mails reveal that the Canadian deliberation was informed by some discussion with the UK patent office regarding its position on the patentability of totipotent stem cells.[122] In its *Inventions Involving Human Embryonic Stem Cells,* the UK Intellectual Property Office takes the position that totipotent human stem cells *are not* patentable because they represent a stage of development for the human body, which is not patentable.[123]

> *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.*

Pluripotent stem cells, on the other hand, are patentable.[124]

Why does the CIPO adapt – as it appears to – the UK's position to Canadian circumstances? Is it more than convenience and expediency? More importantly, does the adaptation import the ethical assumptions embodied in the UK's patent law and practice that are not embodied in Canadian law? Why, for example, does the CIPO not adapt the position of the EPO, which does not allow patenting on either fertilised eggs or totipotent stem cells as provided in the *EPO Guidelines for Examination,*[125] but also does not allow patents on pluripotent stem cells (as confirmed in the Edinburgh patent case[126] and the WARF patent case[127]). Why is European reasoning

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[120] *OJ C 159 of 26.6.1989, quoted in* A Plomer, *The Patentability of Human Embryonic Stem Cells in Europe*, available at http://www.nottingham.ac.uk/law/StemCellProject/reports.htm (accessed 17 October 2008).

[121] See note 18.

[122] Internal untitled documents numbered 36-39 (On file with the author).

[123] See note 18.

[124] *Ibid.*

[125] Chapter 4.54, see note 17, above, reads: "In addition, the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions (see, however, IV, 3.2). Such stages in the formation or development of the human body include germ cells (EU Dir. 98/44/EC, rec. 16). Also excluded from patentability under Art. 53(a) are processes to produce chimeras from germ cells or totipotent cells of humans and animals (EU Dir. 98/44/EC, rec. 38)." See also EPO, "The EPO follows the EU's Directive on biotechnology patents" (2005) available at http://www.epo.org/about-us/press/releases/archive/2005/27102005.html (accessed 17 October 2008).

[126] Decision of the Opposition Division of 21 July 2003 on European Patent No. EP0695351 (Univ. of Edinburgh). The Opposition Division of the European Patent Office rejected European patent No. EP 0695351, titled "Isolation, selection and propagation of animal transgenic stem cells" (the "Edinburgh patent") as a violation of EPO Rule 23(d)(c) [implementing Biotechnology Directive 6(2)(c)] which

applicable at all? None of these points are discussed by the CIPO in the record of its internal deliberations.

A basic problem with the CIPO notice is that – even if it is based upon a moral principle that totipotent animal stem cells are not patentable because they are a stage of development of a higher life form – it is not clear that totipotent *stem cells* are, in fact, a stage of human development. There is a widespread assumption in Europe that fertilised human eggs are stages of development of the human body. As Aurora Plomer puts it, "[t]he natural reading of Article 5(1) is that patenting of human embryos is precluded, since a human embryo constitutes one of the stages in the formation and development of the human body."[128] Furthermore, the Commission of the European Communities thought that it was "clear" that totipotent stem cells are unpatentable, "…since each cell could develop into a human being on its own…" [129] At the same time, this broad statement against the patentability of totipotent stem cells is in tension with the broad scope of patentability of biological materials under the *Biotechnology Directive.*[130] In fact, the European Group on Ethics in Science and New Technologies ("EGE") – an advisory group to the European Commission – issued a non-binding opinion that human embryonic stem cell lines that are modified

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prohibits the "uses of human embryos for industrial or commercial purposes." 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.

[127] Wisconsin Alumni Research Foundation (T1374/04 - 3.3.08) (referral by the Technical Board of Appeal to the Enlarged Board of Appeal). 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. As 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 necessarily involved the destruction of the human embryos from which the stem cells were derived, if the method was not part of the claims. NOTE: during revisions of this paper, the Enlarged Board of Appeals released a decision. See EPO, "No European patent for WARF/Thomson stem cell application," available at http://www.epo.org/topics/news/2008/20081127.html (accessed December 3rd, 2008).

[128] See A Plomer, *The patentability of human embryonic stem cells in Europe*, available at http://www.nottingham.ac.uk/law/StemCellProject/reports.htm (accessed 17 October 2008).

[129] Commission of the European Communities. "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" (2005) available at http://eurlex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexplus!prod!DocNumber&lg=en&type_doc=COMfinal&an_doc=2005&nu_doc=312 (accessed 17 October 2008).

[130] *Biotechnology Directive* Article 3(1) states that "For the purposes of this Directive, 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." Comparable wording is used in Article 52(1) EPC. *In Harvard/Oncomouse* [1990] O.J. EPO 476 (T 0019/90 - 3.3.2), 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."

for specific industrial application fulfil the legal requirements for patentability,[131] but isolated stem cell lines do not since they are "so close to the human body."

Notwithstanding the view of the Commission of the European Communities, it may seem obvious that *on its own*, no totipotent stem cell can develop into an animal. Hence, it makes little sense to consider a totipotent animal stem cell, *per se*, to be a stage of development of an animal. As K Vrotovec and B Vrotovec explain:[132]

> *Human totipotent stem cells located outside the human body, regardless of their way of derivation (e.g. zygote explanted from a woman's fallopian tube or a totipotent cell created in vitro by somatic cell nuclear transfer [SCNT] technique, do not have the capability to differentiate into an entire human body on their own when left in an in vitro setting. …Therefore, human totipotent cells located outside the human body cannot be qualified as a human body at the earliest stage of its formation and development and should not be excluded from patentability solely on the basis of Article (5) of the Biopatent Directive.*

The basis of the Vrotovec objection in developmental biology will be discussed in more detail in the following section. For now, however, the possibility that such a principle is held by the CIPO for moral reasons cannot be easily discounted.

Whatever the grounds for the *Stem Cell Notice*, particularly problematic for the CIPO is the fact that – while the US appears to abide by the principle that humans at any stage of development are not patentable for moral reasons – human totipotent stem cells *are* considered by it to be patentable subject matter. So, even if the CIPO did import moral assumptions from Europe, why do they necessarily imply that totipotent animal stem cells are not patentable? The patentability of stem cells in the US is rooted in 35 USC s 101 which provides that "[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 therefor, subject to the conditions and requirements of this title." Section 101 had been interpreted broadly in *Diamond v. Charkabarty,* holding that "anything under the sun made by man" is patentable subject matter.[133] In 1999, the Director of the United States Patent and Trademark Office (USPTO), Q. Todd Dickinson, told Congress that "…purified and isolated stem cell lines are patentable subject matter under 35 USC s 101."[134]

The USPTO *Manual of Patent Examining Procedure* states that:

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[131] European Group on Ethics in Science and New Technologies, "Opinion on the ethical aspects of patenting inventions involving human stem cells" (2002) available at http://europa.eu.int/comm/european_group_ethics/docs/avis16_en.pdf (accessed 17 October 2008).

[132] K Vrotovec and B Vrotovec, "Is Totipotency of a Human Cell sufficient Reason to Exclude its Patentability Under the Europan Law?" (2007) *Stem Cells* 25, 3026-3028 at 3027.

[133] *Diamond v Chakrabarty,* 447 U.S. 303, 308 (1980).

[134] T Dickinson, "Statement of Q. Todd Dickinson Acting Assistant Secretary of Commerce and Acting Commissioner of Patents and Trademarks before the Subcommittee on Labor, Health and Human Services, Education and Related Agencies of the Senate Appropriations Committee January 12, 1999 (1999) available at www.uspto.gov/web/offices/ac/ahrpa/opa/bulletin/stemcell.pdf (accessed 17 October 2008).

> *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.*[135]

This prohibition exists for moral reasons. First of all, property rights in humans are contrary to the U.S. Constitution.[136] Second, they are contrary to the so-called "moral utility" requirement that inventions not be frivolous or injurious to the well-being, good policy, or sound morals of society.[137] In addition, the Weldon Amendment – introduced in 2003 and carried forward to the present – prohibits funding to the USPTO for the purposes of the patenting of human organisms.[138] Weldon was of the view that the destruction of human embryos that could occur when detaching human embryonic stem cells from human embryos was bad.[139] At that time, the USPTO's Director Rogan wrote that "[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."[140] Nevertheless, during debate on the Weldon Amendment, the House of Representatives agreed at one point 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[141] although an amendment to such an effect was eventually rejected by the House of Representatives

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[135] U.S. Patent and Trademark Office, "Manual of Patent Examining Procedure § 2105" (2007) available at http://www.uspto.gov/web/offices/pac/mpep/mpep_e8r3_2100.pdf (accessed 17 October 2008).

[136] See DJ Quigg, Patent and Trademark Office Notice: Animals- Patentability, 1077 Off. Gazette 24 (1987), available at http://www.justinhughes.net/patentingpeople/papers/Quigg.pdf (accessed 17 October 2008).

[137] 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 (accessed 17 October 2008).

[138] The Science, State, Justice, Commerce, and Related Agencies Appropriations Act of 2007, H.R. 5672, 109th Cong. § 618 (2006) 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."

[139] As Weldon put it, "… Clinton … was essentially allowing the destruction of human embryos for the purpose of this kind of research, and I think that would be a bad thing." See PBS Transcript of "Interview with Dave Weldon," available at http://www.pbs.org/newshour/bb/health/july-dec04/weldon.html (accessed 17 October 2008).

[140] J Rogan, "Letter from James E. Rogan, to the U.S. Senate Committee Comm. on Appropriations" (2003), available at http://www.nrlc.org/killing_embryos/Human_Patenting/patentletter112003.html (accessed 17 October 2008). Emphasis added. In addition, the USPTO's 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)."

[141] American Bar Association, Special Committee on the Weldon Amendment. "Report of the Special Committee on the Weldon Amendment to the H.R. Amendment to H.R, 2799, The Appropriation Bill for the Departments of Commerce, Justice and the Judiciary" available at http://www.abanet.org/intelprop/summer2004/spec_comm.pdf (accessed 17 October 2008).

in Conference Committee.[142] In agreement, Weldon himself observed that "a human embryo is an 'organism' but a stem cell clearly is not."[143]

In the US, the issue of the patentability of totipotent stem cells seems to have been resolved at the level of practice in favour of their patentability as two fundamental US patents have been issued that encompass totipotent stem cells. The CIPO does not point this out in its internal documents but instead puts a question mark in a chart indicating doubt about whether totipotent stem cells are patentable in the US.[144] US Patent 5,843,780, invented by James Thomson and assigned to WARF, claims a "purified preparation of primate embryonic stem cells" and issued on December 1, 1998.[145] U.S. Patent 6,200,806 invented by James Thomson, also assigned to WARF, claims a "purified preparation of pluripotent *human* embryonic stem cells."[146] The '780 patent impliedly claims human stem cells while the '806 patent explicitly claims human embryonic stem cells. *Totipotent* human stem cells are not explicitly claimed (using the terminology "totipotent") in it either, but in the '780 patent, "pluripotent" is defined to mean that "… the cell has the ability to develop into any cell derived from the three main germ cell layers *or an embryo itself*."[147] Hence, the '780 patent is the clearest of the two in its claim to *totipotent* human stem cells.

The US position raises issues for the CIPO. First, the CIPO needs to explain why it regards totipotent stem cells as stages of animal development while the US would not (by analogy with its treatment of totipotent human embryonic stem cells). Second, it needs to explain why its prohibition on patenting totipotent stem cells is relevant to stem cell technology. Consider the claim to a purified preparation of primate embryonic stem cells from the '780 patent. These stem cells are intended to be useful for generating transgenic non-human primates for models of specific human genetic diseases and for tissue transplantation.[148] That claim is also contained in Canadian patent application no. 2190528.[149] It has been argued that, since the claimed cells must maintain their capability to differentiate in vitro for over a year, they are not

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[142] *Ibid.*

[143] D Weldon, "Patent Amendment" (2003) available at www.house.gov/hensarling/rsc/doc/Weldon111003.DOC (accessed 17 October 2008). The ABA Special Committee on the Weldon Committee, see note 141, above, was rightly concerned that "… this terminology could be interpreted as broadening the current USPTO prohibition to prescribe also the patenting of human cells or human cell lines, such as embryonic stem cell lines."

[144] CIPO, "Is It Patentable Subject Matter?" (On file with the author.) To be fair, the question mark might indicate the uncertainty that existed regarding the validity of James Thomson's WARF patent.

[145] J Thomson *"Primate Embryonic Stem Cells"* (1996) 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=5,843,780.PN.&OS=PN/5,843,780&RS=PN/5,843,780 (accessed 17 October 2008).

[146] J Thomson. *Primate Embryonic Stem Cells* (1998) available at http://patft.uspto.gov/netacgi/nph-Parser?Sect2=PTO1&Sect2=HITOFF&p=1&u=%2Fnetahtml%2FPTO%2Fsearch-bool.html&r=1&f=G&l=50&d=PALL&RefSrch=yes&Query=PN%2F6200806 (accessed 17 October 2008).

[147] See note 145.

[148] *Ibid.*

[149] J Thomson. *Primate Embryonic Stem Cells* (1996) available at http://patents.ic.gc.ca/cipo/cpd/en/patent/2190528/summary.html (accessed 17 October 2008).

totipotent.[150] If this is correct, then the *Stem Cell Notice* does not prohibit the patenting of one of the strongest possible claims in stem cell technology.[151] Thus, the *Stem Cell Notice* would be irrelevant to very useful and fundamental stem cell technology.

The strongest evidence that the CIPO is not intentionally basing its views on ethical principles is the differing rationale provided by the UK and the CIPO on the patentability of pluripotent stem cells. The *Stem Cell Notice* makes a distinction regarding the patentability of totipotent and pluripotent stem cells.[152]

> *Human embryonic pluripotent stem cells, which arise from further division of totipotent cells, do not have the potential to develop into an entire human body... Thus, the Office is ready to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability.*

Unlike the CIPO *Stem Cell Notice*, the UK *Inventions Involving Human Embryonic Stem Cells* includes a statement about the value of human embryonic stem cell research. It states:[153]

> *Moreover, although there is some opposition in the United Kingdom to research involving embryonic stem cells, a number of reports from influential UK political, medical and scientific bodies in recent years has emphasised the enormous potential of stem cell research, including embryonic stem cell research, to deliver new treatments for a wide range of serious diseases. This indicates that on balance the commercial exploitation of inventions concerning human embryonic pluripotent stem cells would not be contrary to public policy or morality in the United Kingdom. Thus, the Office is ready to grant patents for inventions involving such cells provided they satisfy the normal requirements for patentability.*

The decision not to mimic the UK wording is evidence that it is not the intent of the CIPO to base the *Stem Cell Notice* on moral considerations. More to the point, the CIPO is quick to deny that the *Stem Cell Notice* was influenced by moral considerations. In its document, "Stem Cell Patenting," the following question is asked:[154]

> *The isolation and use of stem cells has raised a number of moral and ethical questions. Why has the Patent Office decided to grant patents on pluripotent embryonic stem cells including those from humans?*

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[150] RR Mandra & AA Russo, *Stem Cells and Patenting and Related Regulatory Issues: A United States Perspective*, (2004-5) 7 B.S.L. Rev. 143, 144-5.

[151] *Ibid*, at 145.

[152] See note 2.

[153] See note 18.

[154] See note 15.

Obviously, the background to this question is that many persons believe that the patenting of human stem cells is morally prohibited. The question challenges the CIPO to justify how it can, therefore, grant patents on pluripotent stem cells of higher life forms, including humans. The CIPO's response is the bare legalistic one that "…there is no section of the *Patent Act* relating to morals or ethics and patent applications cannot be refused on this basis,"[155] clearly implying that it views the policy in the *Stem Cell Notice* as not properly based upon moral considerations. Since there are no explicit legal provisions prohibiting the patenting of totipotent cells, this response makes the issue of the legal grounds for the *Stem Cell Notice* all the more urgent.

Furthermore, the response is somewhat misleading, since some patent applications are refused on ethical grounds in Canada. It is just that those grounds also have to be explicitly legal grounds. Obviously, the decision to patent inventions in the first place is the result of an ethical choice to provide incentives for the creation of inventions. Further examples include the fact that, in Canada, "invention" has been interpreted not to include a method of cross-examination used by a barrister[156] (partly for the ethical reason that lawyers already enjoy a monopoly on practice without obtaining one through the patent system).[157] The prohibition against patenting humans in Canada is itself not explicit in the *Patent Act* but, according to the Supreme Court, is based upon the common law principle that people cannot own people.[158] Obviously, that legal principle also embodies a moral principle prohibiting the ownership of people and would prevent the granting of such a patent as contrary to law.[159] So, the issue is not whether the *Stem Cell Notice* embodies ethical assumptions, but whether any ethical assumptions that it does embody go beyond those contained in Canadian law. If the CIPO's policy does not embody a moral principle identifying potential and actual higher life forms at all, what is the basis of its identification of potential and actual higher life forms?

5.2 Animal embryos and totipotent stem cells are preformed animals

If one accepts that the CIPO did not identify totipotent animal cells with higher life forms for moral reasons, whether intentionally or not, then another option is that it identified them based upon a particular theory of animal development. This position is suggested by analogy with the Australian jurisprudence on the patentability of human stem cells.

In its internal review, the CIPO did a cursory one-page review of the patentability of human beings under Australian legislation. It quotes section 18(2) of the *Australian Patent Act* 1990 which states that "[h]uman beings, and the biological process for

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[155] *Ibid.*

[156] *Lawson v Commissioner of Patents* (1970) 62 C.P.R. 101, 109 (Ex. Ct.); see also *Tennessee Eastman Co. v Commissioner of Patents* [1974] S.C.R. 111.

[157] See note 11, at 291.

[158] *Harvard*, see note 5, at para 54, citing *Somerset v. Stewart* (1772), Lofft 1, 98 E.R. 499 (K.B.).

[159] *Patent Act*, R.S., 1985, c P-4, s 40.

their generation, are not patentable inventions."[160] It also quotes Part 2.9.5 of the Australian Patent Office *Manual of Practice and Procedure* ("MPAP") which draws the following implications:[161]

> *It follows that exclusion under sec 18(2) of human beings from patentability extends inter alia to: fertilised human ova and equivalents, zygotes, blastocysts, embryos, fetuses, and totipotent human cells including those that are the products of nuclear transfer procedures.*

The *MPAP* provides that human totipotent stem cells are excluded from patentability whereas pluripotent stem cells are not excluded from patentability.[162] The CIPO notes that the *MPAP* states that:

> *A totipotent cell can be derived from fertilized oocytes, and cells of embryo up to about the eight-cell stage, and have the inherent capacity to generate an entire human organism, therefore, these cells and methods or processes of obtaining human totipotent cells are not patentable under s18(2).*[163]

What, according to Australian law, is the basis of the identification of human beings with potential human beings such as "fertilised human ova and equivalents, zygotes, blastocysts, embryos, fetuses, and totipotent human cells?" Can this be adapted more generally to animals? The relevance of moral considerations external to the legislation has been ruled out by the Australian Patent Office as it has said that "arguments based solely on matters of ethics or social policy are not relevant in deciding whether particular subject matter is patentable."[164] Moreover, in *Anaesthetic Supplies Pty Limited v Rescare Limited*, Wilcox J noted that courts have no special expertise in matters of ethics and social policy and to resort to ethical principles would usurp the role of Parliament.[165] The citation of Australian law by the CIPO could potentially bolster a claim by it that a reason for the identification of potential and actual higher life forms is biologically-based rather than ethically-based.[166] Unfortunately, it does

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[160] *Australian Patent Act* 1990, s 18. See also Australian Law Reform Commission, "Genes and Ingenuity: Gene Patenting and Human Health" (2004) available at http://www.austlii.edu.au/au/other/alrc/publications/reports/99/ (accessed 17 October 2008).

[161] Australian Patent Office, Manual of Practice and Procedure (2008) available at http://www.ipaustralia.gov.au/pdfs/patentsmanual/WebHelp/Patent_Examiners_Manual.htm (accessed 17 October 2008).

[162] *Ibid,* part 2.9.5.1.

[163] See note 161, part 2.9.5.1.

[164] See note 161, part 2.9.1.2.

[165] *Anaesthetic Supplies Pty Limited v Rescare Limited* (1994) AIPC 91-076, 28 IPR 383.

[166] The Australian Government and its Advisory Council has been clearer than the Canadian Patent Office on the issue of the role of ethics in patentability issues. As the Australian Government Advisory Council on Intellectual Property has said that "the reason for this exclusion is ethical. In the Second Reading Speech for the Patents Bill 1990, the Government stated that the Bill took into account certain concerns expressed in the Senate on the issue of the patentability of human beings. These concerns related to the ethics of patenting life forms, particularly humans, and community standards on the issue. Various proposed amendments to address these issues culminated in s18(2)." See Australian

not take the opportunity to explain the relevance of the Australian law to the Canadian context. What then is the relevance of the Australian law to the Canadian legal context? This paper speculates that the Canadian position relies on similar assumptions as the Australian position.

The Australian *MPAP* takes its view from *Fertilitecentrum AB v Luminis PTY Ltd.*[167] In that case, the Deputy Commissioner, D. Herald, distinguished between a human life form and a human being. For the Deputy Commissioner, a human life form is one "… that has the inherent capacity to grow to a mature human being."[168] This, then, is a potential human being. For the Deputy Commissioner, "…there is little doubt that a human life form is created at fertilisation."[169] For him the correct approach to interpreting the scope of "human being" in s. 18(2) of the *Patent Act* involves accepting human beings as being in a process of development from fertilised ovum to birth.[170]

> *The correct interpretation of s. 18(2) is ascertained by recognising a human being as being in the process of generation from the time of the process that create a fertilised ovum (or other process that give rise to an equivalent entity) up until the time of birth.*

Unfortunately, this does not tell one when the developing embryo should be considered a human or, more generally, an animal. In fact, the Deputy Commissioner says that his approach is "…to explicitly recognise that there is no agreement about when in the reproductive process a human being [as opposed to a human life form] comes into existence".[171] It is odd, therefore, that he then takes the position that a human being is an "… entity that might reasonably claim the status of a human being, including a fertilised ovum and all its subsequent manifestations."[172] The CIPO quotes this passage from the Deputy Commissioner in its one-page review of Australian patent law and – without saying it – seems to adapt it to conclude that fertilised eggs and their subsequence manifestations are higher life forms, but it never says whether it has applied the "reasonableness" criterion.[173]

In fact, it appears *unreasonable* to claim that a totipotent cell is a persistent individual that can be identified with a later animal. While the DNA may be the same for each, it has been argued by some that the relatively homogenous cells that comprise the early embryo do not form an individual because the cells do not function in a coordinated

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Government Advisory Council on Intellectual Property, "Patentable Subject Matter" at 29 available at http://www.acip.gov.au/library/Patentable%20Subject%20Matter%20Issues%20Paper.pdf (accessed 17 October 2008).

[167] *Fertilitecentrum AB v Luminis PTY Ltd* [2004] APO 19 (13 July 2004). (*Fertilitecentrum)*

[168] *Ibid*, at para 31.

[169] *Fertilitecentrum*, see note 167, above, at para 32. Herald does not even mention, let alone deal with, the obvious problems with his view that twinning and fusion of cells makes it difficult to identify the individual with the cell. See the discussion below.

[170] *Fertilitecentrum*, see note 167, at para 36.

[171] *Fertilitecentrum*, see note 167, at para 31.

[172] *Fertilitecentrum,* see note 167, at para 37.

[173] See note 15.

way to regulate and preserve a single life.[174] Furthermore, these live cells only become individuals or parts of individuals when there is substantial cell differentiation and coordination, which occurs around day-sixteen after fertilisation.[175] More specifically, it is not easy to identify a persistent individual with a given blastomere given the possibility of fusion of two blastomere cells into one individual.[176] It is not easy to identify a persistent individual with a given blastocyst because of the possibility of twinning of the blastocyst.[177] Nor is it easy to identify a persistent individual with a totipotent cell that is detached from a four-eight cell embryo since, if the *identical* totipotent cell had not detached, it would not be considered a separate individual.[178]

The essence of the Deputy Commissioner's equation of potential human life and actual human life, as he explains, is that a human life form (a potential human being) must have "some of the characteristics"[179] of the animal and the human embryo and, therefore, "…has all that it needs to go on and develop as a human being."[180]

> *And as a human life form that has the inherent capacity to grow to a mature human being, I consider it has at least SOME of the characteristics that go to make up a human being - such that it properly falls within the ambit of the term `human being'. And to the extent that there can be a significant difference in time between when a sperm enters an ovum, and the entanglement of the DNA, I think it is appropriate to take the starting point as being when the sperm enters the ovum - for at that time the ovum has all it needs to go on and develop as a human being.*

In this core passage the Deputy Commissioner appears to succumb to the temptation to hold that a human being – or at least some key characteristics of the human being – is already present in its earliest embryonic form of human life. This old idea- usually dubbed preformationism – is motivated by the need to answer the ancient question of how a formed animal develops from an apparently unformed one – how can the egg with no tissue or organs become an animal with tissue and organs?[181] The preformationist answer is that the animal *already exists* in its earliest manifestations.[182] As late as 1694, Hartsoeker used the image of a tiny, coiled man contained in the sperm,[183] while ovists placed the preformed-being in the egg.[184] The

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[174] See note 92.

[175] *Ibid.*

[176] M Brown, "The Potential of the Human Embryo" (2007) 32 *Journal of Medicine and Philosophy* 585–618 at 608.

[177] *Ibid,* at 609.

[178] See note 176, at 607-8.

[179] *Fertilitecentrum,* see note 167, at para 32.

[180] *Ibid.*

[181] See note 19.

[182] *Ibid.*

[183] See J Maienschein, "Epigenesis and Preformationism" in E. Zalta (Ed.) *Stanford Encyclopedia of Philosophy* (2008) *available at* http://plato.stanford.edu/archives/fall2006/entries/epigenesis/.

preformationist view is usually contrasted with epigenesis, which casts development as genuine change from, for example, a fertilised egg without organs to an animal with organs, rather than merely the growth of a preformed-being.[185]

No credible modern biologist now believes that tiny animals exist inside sex cells. Nowadays, genetic preformationism (the modern version of the old doctrine) holds that genes alone direct the development of embryos. As Oyama describes this view, "…genetic information, by virtue of the meanings of in-formation as 'shaping' and 'animating', promised to supply just the cognitive and causal functions needed to make up a heap of chemicals into a being."[186] Modern day preformatiomists, Robert George and Christopher Tollefsen, unpersuasively assert that there is "[n]othing extrinsic to the developing organism itself acts on it to produce a new character or new direction of growth."[187] So, on this view, one could characterise totipotent cells as higher life forms on the basis that they have the DNA of a higher life form.

The CIPO does not quote or discuss the core passage from *Fertilitecentrum*. However, given that the CIPO denies that it equated potential and actual higher life forms for moral reasons, the only remaining option – at least, from the two possibilities considered here – appears to be that the CIPO *is assuming a form of genetic preformationism*. Let it be granted that there is much discussion in developmental biology that speaks as if genes are the *only* directing force in development and differentiation.[188] In fact, however, the modern consensus construes development as "a matter of the epigenetic activation of preformed genetic information,"[189] a "synthesis of epigenesis and preformation."[190] As Jane Maienschein puts it, "… genetics provides information about the range of possibilities. But clearly, regulation of the genetic expression involves interpretation. And this is epigenetic."[191] Or as Mayr puts it, "[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."[192] Since genes alone are clearly not the sole determinant of development, genetic preformationism cannot be correct.

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[184] *Ibid.*

[185] JS Robert, *Embryology, Epigenesis and Evolution: Talking Development Seriously* (Cambridge: Cambridge University Press, 2004) at 36.

[186] S Oyama, The Ontogeny of Information: Developmental Systems and Evolution (Cambridge: Cambridge University Press, 1985), quoted in JS Robert, see *ibid* at 44.

[187] RP George and C Tollefsen, *Embryo: A Defence of Human Life*, quoted in W Saletan, "Little Children" (2008) available at http://www.nytimes.com/2008/02/10/books/review/Saletan-t.html?ex=1360299600&en=88ddd52cd403cf5a&ei=5088&partner=rssnyt&emc=rss (accessed 17 October 2008).

[188] Ernest Mayr, *This is Biology* (Cambridge: Harvard University Press, 1987) at 123, writes that "the genetic program is the underlying factor of everything organisms do. It plays a decisive role in laying down the structure of an organism, its development, its functions, and its activities."

[189] *Ibid* at 56.

[190] See note 188, at 157-158.

[191] See note 183.

[192] See note 188, at 157-8.

Beyond the brute fact that without the right environmental conditions totipotent cells simply cannot develop into animals, modern developmental biology has revealed subtle ways in which non-genetic, environmental factors play a crucial role in development.[193] The environment provides nutrition and numerous cues that ensure the development of the embryo and fetus.[194] Without the hormonal cues of the mother, for instance, the embryo will not implant.[195] The position of the cell in the blastocyst will determine whether it will ultimately be part of the placenta or the embryo and whether it becomes skin, eye, bone or another part of the body.[196] Robert makes the broader philosophical point:[197]

> *... epigenetic events are developmental interactions within the whole cell-organism in its developmental context, between any an all of such factors as cytoplasmic structure, DNA sequences, mRNA, histone – and non-histone proteins, enzymes, hormones, positional information, parental effects, termperature cues and metabolites.*

Similarly, stem cells do not behave independently of their immediate microenvironment i.e. the stem cell niche.[198] This stem cell niche is the collection of external signals that influence stem cell fate.[199] External signals include secreted chemical factors, cell-cell interactions and relationships between cells and the surrounding tissue.[200] Stem cells that are removed from their original niche and placed in a new environment can differentiate into the cell type(s) typical of that new environment. In experiments, human neural stem cells, for example, produced muscle cells when introduced into skeletal muscle.[201]

Some scientists have drawn the implication that, because the totipotency of an embryo depends upon implantation in the uterus, "blastocysts within the laboratory are only 'potentially totipotent', in contrast to their counterparts within the body."[202] If this reasoning is correct, then no stem cells or fertilised eggs would be deemed unpatentable in Canada based upon their totipotency, as the most that could be said is that they are potentially totipotent rather than (actually) totipotent. As a result, the *Stem Cell Notice* would be irrelevant and inapplicable to the patenting of stem cells for therapeutic and research purposes.

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[193] CR Town and DG Jones, "Stem cells, embryos, and the environment: a context for both science and ethics," (2004) 30 J. Med. Ethics 2004, 410-413 at 411.

[194] *Ibid,* at 411.

[195] Christopher Thomas Scott, *Stem Cell Now* (Plume: New York, 2006), at 29.

[196] See note 22, at 95.

[197] See note 185, at 74.

[198] See note 193.

[199] FM Watt and BL Hogan, "Out of Eden: stem cells and their niches" (2000) 287 *Science* 1427–30.

[200] See note 23, at 5.

[201] *Ibid.*

[202] See note 193, at 412.

Creating an iterated modality[203] of potency seems to be an unhelpful way of understanding the fact that laboratory embryos cannot grow into adult animals and stem cells cannot differentiate into various cell types without the requisite environmental factors being present. More accurately, it can be said that a totipotent cell has a degree of potency that is *relative to its environment*. One cannot say that a cell itself is objectively totipotent since its totipotency is highly relative to, for instance, whether the cell is implanted in a womb or whether it is maintained in a culture of cells. Similarly, one cannot say that a cell is objectively pluripotent because- given the right technological environment e.g. the use of somatic cell nuclear transfer or other reprogramming methods- virtually *every* human cell could- again with the right environment- develop into an entire animal.[204]

Fundamentally, the problem with the *Stem Cell Notice* is that it appears to assume a view of development and stem cell differentiation according to which the degree of potency is objective rather than relative to the environment. This creates a problem for the *Stem Cell Notice* because it draws an objective distinction between patentable pluripotent cells and unpatentable totipotent cells. The fact that the relativity of potency undermines the importance of totipotency has not been lost in the ethical debate about stem cell research.[205]

> *Given the role that external factors — including technological interventions — play in an embryo's realizing its potential, one can question whether there is a morally relevant distinction between an embryo's and somatic cell's potential...*

The consequence of the relativity of potency is that the *Stem Cell Notice* is unable to draw an objective distinction between patentable pluripotent cells and unpatentable totipotent cells. The result is that an examiner cannot correctly object to an application for a patent on a fertilised animal egg or stem cell on the basis that it is totipotent without a consideration of the environment in which the subject matter exists. More particularly, embryonic stem cells derived from, for example, the eight-cell stage that are *used for therapeutic or research purposes* are not totipotent at all – since, given *that* environment, the claimed cells do not have the potential to develop into a higher life form.

6. Refusals of patents on totipotent cells are not justified

The CIPO must justify any refusal to grant a patent for totipotent cells. Section 42 of the *Patent Act* mandates 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…" So, if the Commissioner is satisfied that a totipotent cell is not

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[203] Such as the case where potentially totipotent does not collapse into totipotent.

[204] This is, of course, because the doctrine of nuclear equivalence means that virtually every human cell contains the same genetic material. The single exception is mature sperm which contain half the number of chromosomes of all other cells, leading to equal populations of X-bearing (female) and Y-bearing (male) sperm. See note 23, above, at 11.

[205] A Siegel, "Ethics of Stem Cell Research", (2008) in E Zalta (ed), *The Stanford Encyclopedia of Philosophy* (2008) available at http://plato.stanford.edu/archives/fall2008/entries/stem-cells / (accessed 17 October 2008).

patentable by law, then the application shall be refused. In *Harvard*, Bastarache J cited with approval Duff CJ's (as he then was) statement that the Commissioner of Patents ought not to refuse an application unless it is clearly without substantial foundation.[206] Furthermore, the Supreme Court had earlier held that it was important that an *adequate* statement of the reasons for such an administrative decision be provided.[207] The Commissioner has noted that these reasons must be "…based on an interpretation of the *Patent Act* and applicable jurisprudence."[208]

When rejecting a claim on a totipotent cell, an examiner will cite the reason given in the *Stem Cell Notice*: that totipotent cells are unpatentable because they are higher life forms. But is this reason adequate to reject a claim to a totipotent cell, especially given contrary pronouncements given by the Supreme Court of Canada? The Supreme Court of Canada made its view clear in *Harvard* that "courts are as well placed as the Commissioner to determine whether a higher life form fits within the definition of "invention."[209] It also took the position that courts are just as well placed to determine whether a given higher life form, such as a genetically modified mammal, is a composition of matter.[210] According to the Supreme Court, these are questions that approach "…a pure determination of law" and are of "…great, even determinative import for future decisions."[211] At the same time, it refused to alter the line drawn by the CIPO between higher and lower life forms, saying that any alteration must be done by Parliament.[212] The Supreme Court said as well that the scientific question of whether some organism, such as a fungus or a totipotent cell, is a higher life form is something that is within the CIPO's expertise and such decisions of the Commissioner should be accorded deference by courts.[213]

The problem with rejecting a claim on totipotent cells – that is based upon the view that such cells are higher life forms – is that it conflicts with the Supreme Court of Canada's view that fertilised oncomouse eggs are compositions of matter. The CIPO directly found that a fertilised mouse egg is a composition of matter and is therefore patentable.[214] The Supreme Court also found that higher life forms are not patentable.[215] Hence, on its reasoning, a fertilised mouse egg cannot be a higher life

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[206] Bastarache J at para 144 of *Harvard*, citing Duff C.J. (as he then was) in *Vanity Fair Silk Mills v Commissioner of Patents* [1939] S.C.R. 245 at 246.

[207] *Pfizer Company Limited v Deputy Minister of National Revenue*, [1977] 1 S.C.R. 456.

[208] *Harvard*, see note 5, at para 128.

[209] *Harvard*, see note 5, at para 148.

[210] *Harvard*, see note 5 above, at para 119. Bastarache J for the majority wrote that "… the question of whether a higher life form can be considered a 'manufacture' or 'composition of matter' approaches a pure determination of law. There is no disagreement in this case regarding the nature of the specific invention: if it is determined that higher life forms are 'manufacture[s]' or 'composition[s] of matter', then the oncomouse is an invention."

[211] *Harvard*, see note 5, above, at para 150. Bastarache J for the majority at para 150 writes that "… though the Commissioner does possess considerable expertise in the areas of science, medicine and engineering, this expertise must be considered in the context of the problem under review."

[212] *Harvard*, see note 5, at para 199.

[213] *Harvard*, see note 5, at para 151.

[214] *Harvard*, see note 5, at para 162-3.

[215] *Harvard*, see note 5, at para 155.

form. This conclusion conflicts, of course, with the position of the CIPO in the *Stem Cell Notice*, that a fertilised egg is a higher life form which is, therefore, unpatentable. It appears, then, that the CIPO position that fertilised eggs and, by implication, all totipotent cells are higher life forms is incorrect in the Supreme Court's view.

From the perspective of the CIPO (one can only speculate) totipotent cells are *more* than mere compositions of matter since they have the potential to develop into a higher life form. It could say that the Supreme Court has made a factual error in considering a fertilised egg to be a composition of matter. It could claim that genetic preformationism is the correct theory of development and differentiation to apply to the issue of patenting totipotent cells. If the CIPO does assume a form of genetic preformationism, it is open to it to claim that the potentiality that is possessed by a totipotent cell is the extra *attribute* that makes the totipotent cell something more than a mere composition of matter. This attribute is the genetic blueprint of a higher life form that is already present in the totipotent cell. The problems with genetic preformationism as a theory of development and totipotency have already been discussed. The more general problem is that, while the CIPO might be tempted to claim that its views should be granted deference based upon its scientific expertise, the nature of totipotency appears to be sufficiently uncertain, philosophical and complex that no deference should be accorded to it.

Even if the CIPO's view that fertilised eggs and totipotent stem cells are higher life forms should be given deference, the reasons it gives for its policy of the patentability of totipotent cells cannot be considered to be adequate. As this paper has emphasised, the CIPO gives no reason for *why* it equates potential higher life forms with actual higher life forms. Furthermore, the two possible rationales – moral equivalence and ontological equivalence – fail. Finally, even if the standard is one of reasonableness rather than correctness, the *Stem Cell Notice* does not meet that standard. In *Dunsmuir*, the Supreme Court of Canada set out criteria for the reasonableness standard:[216]

> *A court conducting a review for reasonableness inquires into the qualities that make a decision reasonable, referring both to the process of articulating the reasons and to outcomes. In judicial review, reasonableness is concerned mostly with the existence of* ***justification****,* ***transparency*** *and* ***intelligibility*** *within the decision-making process. But it is also concerned with whether the decision falls within a range of possible, acceptable outcomes which are defensible in respect of the facts and law.*

If an examiner is to base the decision whether to issue a patent on totipotent cells on the *Stem Cell Notice*, one must, therefore, look at the process and outcomes of the development of the *Stem Cell Notice*. Was there *intelligibility* in the process of developing the *Stem Cell Notice*? The CIPO engaged in internal discussions and in limited external discussions with the UK Patent Office but did not rely upon any formal consultation process in arriving at the *Stem Cell Notice.* The CIPO has said that the new policy "… was the result of prolonged discussions at all levels of the organization through a very reasoned process… [in which] [a]ll relevant jurisprudence

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[216] *Dunsmuir v New Brunswick*, 2008 SCC 9, at para 47. Emphasis added.

was considered."[217] However, a review of internal documents used to develop the *Stem Cell Notice* show that its review was cursory, incomplete and lacking in analysis. It just touches upon the underlying scientific issues. There is no discussion of the relevance of foreign patent law to the Canadian context and no engagement with the deeper issues that foreign legislation, cases, policies and reports reveal. Most importantly, it did not engage in any substantive discussion about *why* it identifies potential higher life form with actual higher life forms. In short, there was a lack of intelligibility in the process of the development of the *Stem Cell Notice.*

Was the process *transparent*? On February 15, 2008, the CIPO announced new *Guidelines for Formal Consultation ("Guidelines")*.[218] While the *Guidelines* were not in effect during the development of the *Stem Cell Notice*, they give a sense of the formalities that could be required when making changes to patent office practice. The *Guidelines* indicate that consultation may occur for changes to office practice, operational issues and amendments to legislation and regulations and sometimes consultations have been undertaken for such purposes.[219] Formal consultation can take the form of web consultation, joint liaison committee meetings and working groups.[220] Importantly, formal consultation procedures are not required when issuing a practice notice.[221] There was no formal consultation done in relation to the development of the *Stem Cell Notice*. While one method of consultation is to interact with the Joint Liaison Committee, the interaction relating to the *Stem Cell Notice* appears to have been merely a response to a submission of a Committee member months after the *Stem Cell Notice* was adopted.[222]

Is the *Stem Cell Notice* justified? Under the CIPO's *Guidelines for Formal Consultation*, in the exceptional circumstance that the CIPO does *not* engage in external consultations, as in this case, the CIPO will publish an explanation of its decision.[223] The only explanation for its policy in the *Stem Cell Notice* is contained in it. As argued, however, the *Stem Cell Notice* does not address the fundamental issue of why potential higher life forms are deemed to be actual higher life forms. Internal documents are brief, incomplete and do not address the reasoning in behind the equivalence of potential and actual. While it is true that the *Guidelines* were not in effect at the time of the development of the *Stem Cell Notice*, and it is commendable that they have now been implemented, the CIPO did not satisfy the now-existing

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[217] See note 71.

[218] CIPO, "New Guidelines for Formal Consultations" (Guidelines) available at http://www.cipo.ic.gc.ca/epic/site/cipointernet-internetopic.nsf/en/wr01225e.html (accessed 17 October 2008).

[219] *Ibid.*

[220] See note 218.

[221] See note 218. In contrast, formal consultation is required when amending intellectual property regulations. In the latter case, the CIPO is required to demonstrate that Canadians have been consulted and that they have had an opportunity to participate in developing or modifying regulations. (accessed 17 October 2008). See Government of Canada. "Cabinet Directive on Streamlining Regulation" available at http://www.regulation.gc.ca/directive/directive01-eng.asp .

[222] Indeed, the submission seems to have been dealt with in a perfunctory way after the adoption of the *Stem Cell Notice* and with no opportunity for the feedback to make any difference to the outcome of the policy regarding patenting totipotent cells.

[223] See note 218.

requirements of the *Guidelines* for an explanation. There is a lack of justification for the CIPO's policy on patenting totipotent cells. Independently of the requirements in the *Guidelines*, the CIPO did not satisfy the requirements for making a reasonable decision provided in *Dunsmuir.* Thus, rejecting a claim on totipotent cells based upon the CIPO *Stem Cell Notice* is unjustified.

This paper has been concerned primarily with examining the CIPO's view that potential higher life forms are actual higher life forms. It is worth emphasising, however, that its view that totipotent stem cells are unpatentable rests upon its assumption that higher life forms are themselves unpatentable. Although not the focus of this paper, the CIPO's view that higher life forms are unpatentable and its distinction between higher and lower life forms have both been subject to severe criticism. Most often this criticism has been directed at the Supreme Court of Canada because of its decision in *Harvard* to uphold both the CIPO's views concerning the patentability of higher life forms as well as its distinction between higher and lower life forms.

For example, Dan Burk, claims that the distinction between lower and higher life forms is "rationally indefensible."[224] In his unsympathetic reading of *Harvard*, however, Burk mistakenly attributes to the Supreme Court the doctrine of vitalism as the reason why higher life forms are more than mere compositions of matter.[225] In a different critique, Andrew Torrence has criticised the distinction between higher and lower life forms as having no basis in biological science.[226] For Torrence, by using the terminology of "higher" and "lower," the Supreme Court has mistakenly and naively adopted the view that humans and other so-called "higher life forms" have a more privileged evolutionary status than lower life forms.[227] In reality, the Supreme Court does not explicitly make such a claim nor does its argument that higher life forms are unpatentable turn on them having a privileged evolutionary status. More importantly, Torrence attributes to the Supreme Court the view that the principle that genotype does not determine phenotype only applies to higher life forms and not to lower life forms.[228] As Torrence points out, this is plainly false, as there are some spectacular examples of phenotypic plasticity, where genotype does not determine phenotype, amongst so-called "lower life forms."[229] As Torrence seems to recognise, nonetheless, in *Harvard*, the Supreme Court did not attempt to make a biological distinction but rather a *metaphysical* distinction between life forms that are mere compositions of matter and those that are constituted by more than their bodily matter – e.g. by a mental component.[230] So Torrence blunts his own basic criticism. But that does not imply the distinction between higher and lower life forms that is accepted by the Supreme Court should be regarded as useful or justified. Indeed, it is problematic that the distinction between unicellular and multicellular is not at all equivalent to the

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[224] D Burk, "Reflections in a Darkling Glass: A Comparative Contemplation of the Harvard College Decision" (2003) 40 *Canadian Bus LJ* 219 – 237 at 221.

[225] *Ibid.*

[226] A Torrence, "Metaphysics and Patenting Life" (2007) 76 *UMKC Law Review* 363-403.

[227] *Ibid*, at 389.

[228] See note 226, at 394.

[229] *Ibid.*

[230] *Ibid.*

metaphysical distinction between those things that are compositions of matter and those that are more than mere compositions of matter. Furthermore, while Torrence is wrong to dismiss such a metaphysical distinction as merely religious and an impermissible intrusion into Canadian law,[231] his criticism raises the issue as to why the CIPO could be regarded as having the expertise to deal with issues of a metaphysical nature or scientifically uncertain. Moreover, to the extent that Torrence's criticism – that the CIPO distinction between higher and lower life form is based upon basic scientific mistakes – is correct, how does this reflect upon the CIPO's scientific competence?

More generally, the criticisms of the reasoning in behind the *Stem Cell Notice* raise the question of which body can most effectively deal with issues of the patentability of fundamentally new technology. Are courts, intellectual property offices or governments best suited to decide such issues? It is beyond the scope of this paper to do anything but mention some prominent opinions. For Dan Burk, it is the courts. He has expressed optimism that "…the flexible US approach, favouring ongoing judicial oversight, will better accommodate new and different technologies within the general framework of a patent statute."[232] The Supreme Court of Canada is more circumspect than Burk, indicating that it does not possess the institutional competence to deal with issues as complex as the patentability of human life forms, suggesting that it is within the competence of government.[233] As for patent offices, David Vaver has pointed out that some jurisdictions "implicitly recognize that intellectual property offices do not necessarily possess institutional competence to deal with broader public policy issues."[234] He remarks that:

> *With growing public concern about new technologies and the pace of their introduction and dissemination; it is increasingly important for the public to be involved on an operational level in the grant of patents and not merely to be consigned to a sideline role.*[235]

If this is so, then the introduction of recent *Guidelines* may result in more public input, but this case study suggests that at present- despite the presence of highly qualified individuals in the CIPO – there are legal, practical and scientific limits to its ability, like other patent offices, to apply patent legislation wisely to fundamentally – new technology. Additional research is required in order to determine how effective the *Guidelines* are in increasing public input into the patent granting process.

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[231] See note 226, above, at 395. Most of his criticisms are rooted in an outmoded theory that courts should not deal with any matter that cannot be falsified even, apparently, if that is the issue that the court is bound to address. Unfalsifiable views, such as the idea that persons have minds in addition to bodies, are deemed religious by Torrence, and therefore not to be dealt, with even though they may in fact be independent of any religious view. Furthermore, exaggerations, such as that the Supreme Court's judgment in *Harvard* endorses creationism and intelligent design, undermine the credibility of his analysis.

[232] See note 224, at 235.

[233] *Harvard*, see note 5, at para 183.

[234] See note 11.

[235] *Ibid.*

7. Conclusion

The CIPO says that totipotent animal cells are not patentable because they are higher life forms, but it provides no reason why totipotent animal cells – which are potential higher life forms – *are* higher life forms. During internal deliberations, it reviewed jurisdictions, such as Europe, in which moral considerations are relevant to patentability, but denies that moral considerations are relevant to its view that fertilised eggs and totipotent stem cells are higher life forms. It also reviewed Australian law in which a preformationist theory of development and stem cell differentiation is assumed, but does not comment on that aspect of their legal context. It has been conjectured in this paper that the CIPO's position is based upon genetic preformationism, according to which kinds of higher life forms are individuated by means of their genetic blueprints. On such a view, a totipotent cell is a higher life form, it seems, just because it contains the same DNA as a higher life form. This view runs counter to the fact that modern biologists have recognised an increasingly important role for non-genetic, environmental factors in both development and stem cell differentiation. The modern interactive account of development and stem cell differentiation make it difficult to say that there is an objective account of totipotency which can support the position in the *Stem Cell Notice*. Because of this, it is difficult to consider a totipotent cell to be an *individual animal* in a stage of development and to say that stem cells derived from, for example, an eight-cell embryo that is being used for therapeutic purposes is totipotent. Finally, in order to justify the rejection of a patent application, adequate reasons must be provided. While an examiner could refer to the *Stem Cell Notice* as deeming totipotent animal cells to be higher life forms, there is nothing in the *Stem Cell Notice* or in the CIPO's internal documents that provides a reason for identifying potential and actual higher life forms. Given that its views on development and differentiation appear to be erroneous (i.e. no explanation of its views was provided in order to justify its position and the process was unintelligible and opaque) the CIPO cannot justifiably reject an application for a fertilised egg or totipotent stem cell on the basis of the *Stem Cell Notice* according to the criteria in *Dunsmuir*. This decision suggests that, despite the presence of highly qualified individuals within the CIPO, there are legal, practical and scientific limits to the ability of it, like other patent offices, to apply the *Patent Act* to fundamentally new technology.