Harvesting the "Forbidden Fruit" of Biotechnology Research: Genetic Engineering, International Law and the Patentability of Higher Life Forms in Canada

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As the frontiers of science are constantly redefined by the emergence of new technology, patent law often has to struggle to keep pace with the changing conception of what constitutes a protectable "invention". A key challenge facing patent law in the age of biotechnology lies in ascertaining the extent to which genetically engineered life forms should be protected. A major concern relates to whether such life forms should be excluded from patentability on grounds of ordre public, ethics and morality. This article critically explores the extent to which patent law in Canada protects this "forbidden fruit" of biotechnological innovation, and compares the position in Canada with that of the United States and the European Union. The author argues that recent Canadian jurisprudence in the field of biotechnology law has brought the Canadian position more in line with patent developments in other industrialized nations, although there continue to be differences in the formal definition of "patentable subject matter". The groundbreaking decision by the Supreme Court of Canada in Monsanto v Schmeiser *marks the emergence of a more permissive approach toward the patentability of genetically modified inventions — an approach that is more compatible with patent practices in the United States and the European Union than the position taken earlier by the same court in* Harvard College v Canada*. However, while genetically modified cells and genes are now eligible for patent protection in Canada, entire organisms remain unpatentable under existing Canadian law. Practically speaking, the distinction drawn by the Schmeiser court between genetically modified "components" and genetically modified "life forms" is artificial, because a patent over a genetically modified cell effectively gives a patentee de facto control over the commercial exploitation of the entire organism. This article proposes that Canada should jettison this artificial distinction and explicitly recognize life forms as patentable subject matter if it wishes to play a more influential role in trade agreements such as the Trans-Pacific Strategic Economic Partnership (TPP). Embracing "life forms" as a category of patentable subject matter would also make Canada a more attractive*

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destination for biotechnology investment.

INTRODUCTION

Advances in biotechnology research have the potential to confer tremendous benefits on humanity.[1] From the development of cancer therapies to the production of new crops, the "fruits" of biotechnological innovation offer the possibility of providing solutions to global concerns such as the treatment of illness and the alleviation of human hunger.[2] On the other hand, biotechnology and genetic engineering have also been characterized by some commentators as a means employed by multinational corporations to "reinforce the imbalances of wealth and power which perpetuate malnutrition, hunger and ill health".[3] The startling amount of power that the genetic revolution has placed in the hands of corporations over our health and food supply has prompted debate over the real beneficiaries of biotechnological innovation.[4] The much-touted "contributions" of biotechnology to society accordingly remain tainted by controversy and scepticism. In recent years, biotechnology has raised fresh ethical concerns in equipping humankind with the tools to alter life itself by tinkering with the building blocks of living tissue — the genes contained in the DNA of living organisms.[5]

Inventors and innovators often seek legal protection for their inventions, so that they may lawfully exploit the fruits of their research to the exclusion of their competitors.[6] Modern patent law provides inventors with the right to exploit their

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1 See WR Cornish, *Intellectual Property: Patents, Copyright, Trade Marks and Allied Rights*, 4th ed. (London: Sweet & Maxwell, 1999) at 218, who notes that biotechnology promises many advantages in the cultivation of foodstuff and other natural products, and in combatting illness and generic disorders in humans and animals [*Intellectual Property*].

2 See Industry Canada, "Generic Arguments About Patenting Higher Life Forms", online: <http://www.ic.gc.ca/eic/site/ippd-dppi.nsf/eng/ip00039.html>. In addition, resistance to disease and pests are benefits that are often attributed to genetic engineering. See Iain EP Taylor, "Genetic Engineering of Crops: Science Meets Civil Society's Response", in Iain EP Taylor, ed, *Genetically Engineered Crops: Interim Policies, Uncertain Legislation* (Binghamton, NY: Haworth Press, 2007) at xxvi [*Genetically Engineered Crops*].

3 See Steven P McGiffen, *Biotechnology: Corporate Power versus the Public Interest* (London and Ann Arbor: Pluto Press, 2005) at 198 [*Biotechnology*].

4 See McGiffen, *ibid* at 199, who describes a "juggernaut of corporate-controlled biotechnology" moving and crushing all that stands in its way.

5 DNA, or deoxyribonucleic acid, is an acid that carries genetic information in a living cell, and that controls the development of the qualities that have been passed on to a living thing from its parents. See *Longman Dictionary of Contemporary English*, 3rd ed (Essex: Longman Group, 1995) at 395 and 587.

6 Section 42 of the *Patent Act*, RSC, 1985, c P-4, which defines a patent grant as "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction".

invention in the marketplace for a statutorily defined period of time[7] in exchange for mandatory disclosure of the patent claim and specifications. However, the extent to which patent law should protect genetically altered life forms remains, to this day, a subject of controversy.[8] A chief concern that has often been raised in relation to the patent protection of genetically modified organisms is that life is essentially a product of nature, and that it is unethical to grant legal or property rights in respect of life forms.[9] The idea that patent or property rights may be granted in respect of living organisms or living tissue may be anathema to the view that life is either sacrosanct (from a religious or humanitarian perspective) or a product of nature (from the perspective of legal interpretation).[10]

Other objections raised against the patenting of modified life forms include the environmental hazards of genetic engineering,[11] the disruption of the natural order, hazards to human health and biodiversity, the expropriation of traditional knowledge,[12] as well as the contamination of the world's food supply.[13] In this vein, one might be tempted to characterise genetically altered life forms as the "forbidden fruit" of biotechnology research — with the potential to yield substantial profits, and yet fraught with controversy. Interesting parallels exist between discovering the key to the building blocks of life, and the tree of knowledge, bearing the "forbidden fruit" in the Biblical account of the Garden of Eden. Despite the ethical objections

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7 See for instance section 44 of Canada's *Patent Act*, which defines the patent term as twenty years from the filing date.

8 The scope of patent protection that should be afforded to genetically modified life forms is a subject of contention that has produced a "line of cleavage" among members of Canada's top court. The two most recent judgments by the Supreme Court of Canada on the patentability of life forms were characterised by split decisions. See *Harvard College v Canada (Commissioner of Patents)*, [2002] 4 SCR 45 [*Harvard College*] (with a 5 to 4 split in the decision) and *Monsanto Canada Inc v Schmeiser*, [2004] 1 SCR 902 [*Schmeiser*] (again with a 5 to 4 split in the decision).

9 See for instance Stephanie Chong, "The Relevancy of Ethical Concerns in the Patenting of Life Forms" (1993) 10 CIPR 189; Danish Council of Ethics, Patenting Human Genes: A Report (Copenhagen: Danish Council of Ethics, 1994).

10 Mark W Lauroesch, "Genetic Engineering: Innovation and Risk Minimization" (1988) 57 Geo Wash L Rev 100 at 114, who suggests that such patents might "degrade the sanctity of life and result in extensive and inhumane animal experimentation." See also Robert P Merges, "Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies" (1988) 47 Md L Rev 1051 at 1059-60, who observes that the ownership of life may be considered a form of "secular sacrilege".

11 Michael W Fox, *Killer Foods: When Scientists Manipulate Genes, Better is Not Always Best* (Guilford, CT: Lyons Press, 1999) at 29, who notes that genetic traits in crops can be transmitted to weeds, and pests like the diamondback moth caterpillar can develop resistance to toxin-producing genetically modified crop plants. See also Miguel A Altieri, "Transgenic Crops, Agrobiodiversity, and Agroecosystem Function", in Taylor, ed, *Genetically Engineered Crops*, *supra* note 2 at 46.

12 Burton T Ong, "Patenting the Biological Bounty of Nature: Re-examining the Status of Organic Inventions as Patentable Subject Matter" (2004) 8 Marq Intell Prop L Rev 1 at 2 [Biological Bounty].

13 McGiffen, *supra* note 3 at 188.

to genetic engineering, the United States and the European Union have started to award and recognise patent rights in respect of modified living organisms, as discussed in Section II below.

This paper does not seek to express a detailed view on the ethical or moral sustainability of awarding patents in respect of genetically modified life forms.[14] Rather, its goal is to critically evaluate the extent to which transgenic life forms are considered "patentable subject matter" in Canada, and to compare Canada's approach with patent trends in other developed countries. It will begin with an analysis of the groundbreaking case of *Harvard College v Canada*, in which the Supreme Court of Canada famously denied patent protection for a genetically altered laboratory mouse. It will then consider the qualifying effect of a subsequent decision by the same court in *Monsanto v Schmeiser* on the rule in *Harvard College*.

The ruling in *Schmeiser* and its impact on Canadian patent law have been discussed at some length by other commentators,[15] and the view that *Schmeiser* is generally more favourable to patentees in the life sciences industry is not, of course, a new observation. This paper seeks to add to the existing literature by considering the impact of *Schmeiser* on the compatibility of Canadian biotechnology law with international patent trends. Despite semantic differences in the definition of the phrase "patentable life form", the Supreme Court of Canada has substantially aligned Canada's patent law on biotechnological inventions with that of the United States and the European Union, by opening the door to the protection of life forms with genetically modified components. Although genetically modified life forms *per se* remain unpatentable in Canada, the *Schmeiser* decision appears to allow inventors to obtain *de facto* equivalent protection over life forms by framing the scope of their patent claim as being limited to the genetically modified cells or genes *within* a living organism. The *Schmeiser* ruling supports the proposition that using, breeding or cultivating a living organism containing patented cells or genes amounts to an infringement of the patent.[16] The impact of the *Schmeiser* decision on Canadian patent law is that it has resulted in the *de facto*, but not *de jure*, abolition of the prohibition against patenting life forms in Canada.

This article concludes with some recommendations for patent law in Canada. It proposes that the artificial complexities inherent in the *Schmeiser* decision can be avoided by taking a *clear stand* on the patentability of genetically modified life forms. By extending patent protection to genetically modified "components" of living organisms, the Supreme Court of Canada has effectively already opened the door to the patenting of "life". As such, Canada should jettison the somewhat artificial distinction that it continues to maintain between genetically modified "components" and genetically modified "life forms". Although Canada does not currently

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14 For a general discussion of why animals should not be excluded from patent protection on ethical or economic grounds, see Robert P Merges, "Intellectual Property in Higher Life Forms", *supra* note 10.

15 See generally Bruce Ziff, "Travels with my Plant: Monsanto v Schmeiser revisited" (2005) 2:2 UOLTJ 493; Andrew W Torrance, "Metaphysics and Patenting Life" (2007) 76 UMKC L Rev 363; Keith Aoki, "Seeds of Dispute: Intellectual Property Rights and Agricultural Biodiversity" (2009) 3 Golden Gate U Envtl LJ 79.

16 See the discussion of *Monsanto v Schmeiser*, under Part I, *infra*.

have a formal legal obligation under international law to expand the scope of its patent protection for genetically modified organisms, an explicit recognition of life forms as patentable subject matter would make Canada a more attractive destination for biotechnology investment, and allow it to play a more active role in trade agreements such as the Trans-Pacific Partnership (TPP).

I. ARE LIFE FORMS PATENTABLE SUBJECT MATTER IN CANADA?

As one of the three major branches of intellectual property, patent law seeks to reward innovation and creativity by granting a bundle of exclusive rights in respect of inventions that meet the requirements of patentability under legislation. An "invention" is defined in section 2 of Canada's *Patent Act* as any "new and useful art, process, machine, manufacture or composition of matter, or any new or useful improvement in any art, process, machine, manufacture or composition of matter". In contrast, mere scientific principles and abstract theorems have been expressly excluded from the scope of patentability.[17] Hence the formula $E=mc^2$ would not be patentable on its own, but a nuclear reactor that is designed on the basis on this formula might.[18] In addition, a claimed invention must satisfy other requirements for patentability including novelty[19] and non-obviousness.[20] In exchange for a "limited monopoly" to use, exploit and sell the invention for a twenty year period, the patent applicant is required to correctly and fully describe the operation of the invention such that a person skilled in the relevant art or science would be able to make, construct, compound or use the invention.[21] This requirement of disclosure is designed to enable the patented invention to eventually enter into the public domain after the patent term expires, so that the technology inherent to the invention can then be added to the common pool of knowledge available to research communities, scientists, and the general public.

The technology neutral formulation of "invention" suggests that the *Patent Act* does not discriminate between fields of technology where patentability is concerned. It is also important to note that Canada's *Patent Act* does not contain an *ordre public* bar to patentability, unlike the European Union.[22] However, the emergence of the life sciences industry and biotechnology research has challenged existing conceptions of what constitutes an "invention". The Supreme Court of Can-

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17 Section 27(8) of the *Patent Act*, *supra* note 6.

18 Norman Siebrasse, "Comment on Monsanto Canada Inc v Schmeiser", online: <http://law.unb.ca/Siebrasse/Download/Schmeiser%20Comment.pdf> at 7.

19 See section 28.2(1) of the *Patent Act* on the requirement that the subject matter of invention not be previously disclosed.

20 See section 28.3 of the *Patent Act*: The invention must not be "obvious" to a person skilled in the art or science to which the invention pertains.

21 Section 27(3) *Patent Act*, *supra* note 6.

22 See Article 53(a) of the European Patent Convention: "European patents shall not be granted in respect of inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States".

ada has had to grapple with the interpretation of this word in the context of whether life forms can be considered patentable subject matter, and its interpretive attempts have produced some interesting, though perhaps inconsistent, decisions in the field of biotechnology law.

A traditional argument that has been raised against the patenting of life is that living organisms are capable of natural reproduction, without the need for human intervention.[23] A naturally occurring life form is therefore ineligible for patent protection, because it is a product of nature and not the result of human ingenuity. On the other hand, genetically modified organisms are not naturally occurring, and yet may be capable of reproduction without human intervention. The potential for reproduction through natural means has not, however, prevented courts from conferring patent protection on at least some types of life forms. It is a well-established principle of law in Canada and the United States that lower life forms, such as bacteria and other micro-organisms, can be patented, provided the requirements are satisfied.[24] There is authority, not just in the United States and Canada but also in the United Kingdom, which extends patent protection to genetically altered micro-organisms and processes involving micro-organisms.[25]

Biotechnology law in Canada reached a turning point in 2002, when the Supreme Court of Canada rejected a product patent claim in respect of a genetically engineered *higher* life form — a transgenic laboratory mouse. The claimed invention in question involved injecting a cancer-promoting gene (or "oncogene") into a fertilized mouse egg, and then implanting the egg into a female host mouse.[26] The genetically modified gene would cause some of the host mouse's offspring to develop certain forms of cancer. The "infected" line of mice carrying the oncogene could then be used in animal carcinogenic studies and to facilitate cancer research in laboratories.[27] The patent applicant (Harvard College) sought protection for both the *process* used to produce the genetically altered mice, as well as the end *product* of the process (the modified mice themselves). While a process patent would grant the applicant a monopoly over the use of the described method to implant an oncogene (and therefore the right to prevent others from using the same method to produce genetically altered mice or other onco-animals), a product patent over the mouse, on the other hand, would allow the patentee to prevent others from produc-

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23 See for instance the dictum of Lamer J in the case of *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)*, [1989] 1 SCR 1623 at 1634: "The courts have regarded creations following the laws of nature as being mere discoveries the existence of which man has simply uncovered without thereby being able to claim he has invented them."

24 See for instance *Abitibi Co, Re* (1982), 62 CPR (2d) 81 (Can Pat App Bd & Pat Commr); *Diamond v Chakrabarty*, 447 US 303 (1980) [*Chakrabarty*].

25 See WR Cornish, *Intellectual Property*, *supra* note 1 at 217, who notes that there has never been a general embargo in Britain on patents involving living matter. In as early as the 1970s, the patentability of production techniques for pharmaceuticals which depended upon the use of micro-organisms was accepted with little argument, as seen in decisions like *American Cyanamid Co v Berk Pharmaceuticals Ltd*, [1976] RPC 231 (Eng Ch Div).

26 See *Harvard College*, *supra* note 8 at 7 and 122.

27 *Ibid* at 121.

ing more mice by purchasing and then breeding them.[28] A product patent, generally viewed as a "higher order" variety of patent grants, would enable the patentee to exclude others from making, using, offering to sell, importing or selling a product that embodies the claimed invention, even if the product were developed independently or used for a purpose not contemplated by the original product patentee.[29]

Interestingly, the Supreme Court of Canada, by a narrow majority, upheld the validity of the process claim, while denying the product claim over the mouse itself. In delivering the majority decision of the court, Bastarache J held that a higher life form is not patentable subject matter because it does not constitute a "manufacture" or a "composition of matter" under section 2 of the *Patent Act*.[30] The effect of this majority judgment is that the applicant's laboratory techniques of producing a genetically modified mouse egg through the injection of an oncogene, as claimed in the invention, was indeed eligible for patent protection, but the monopoly granted by such a *process* patent would not prevent a third party from buying and then breeding the *product* (the oncomouse) itself.[31] Bastarache J, writing on behalf of the majority, also expressed the view that the *Patent Act* in its current form was not well suited to address the unique characteristics displayed by life forms, and suggested that issues of such complexity mandated "intricate legal drafting" and a careful balancing of competing interests to be undertaken by Parliament. Bastarache J emphasised that the court lacked the "institutional competence" necessary to engage in such an exercise.[32]

The extremely narrow margin that split the court in *Harvard College* was not the only noteworthy aspect of the case. The forceful dissent expressed by Binnie J in the same case is also instructive in shedding light on some of the complex policy

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28 See George Wei Sze Shun, "Mus Musculus and Homo Sapiens: Murine Metaphysics and the Canadian Supreme Court" (2003) Sing JLS 38 at 41.

29 Ong, Biological Bounty, *supra* note 12 at 30. Ong does note, however, that certain types of process patent, such as a patent on a method of modifying the genetic makeup of living mammals, may enable a process patentee to "lock" a field of technology and shut out further innovation by other researchers unless a licence is first obtained. In such circumstances, even process patents may confer a wide scope of monopoly on the patentee. See also Margaret J Lane, "Patenting Life: Responses of the Patent Offices in the U.S. and Abroad" (1991) 32 Jurimetrics J 89 at 91.

30 See *Harvard College*, *supra* note 8 at 120. See also Wei, *supra* note 28 at 47 and 49-50, who notes that the majority judges in the Supreme Court based their decision principally on statutory interpretation, in ruling that Harvard College's product claims fell outside the scope of patentable subject matter in section 2 of the *Patent Act*. He contrasts the Canadian approach with the US Supreme Court's broad and flexible approach to "manufacture" and "composition of matter" under the US *Patent Act* in *Diamond v Chakrabarty*.

31 One commentator has suggested that only process patents should be made available in respect to organic inventions because they better reflect what the scientist deserves for his or her inventive efforts. See Ong, Biological Bounty, *supra* note 12 at 8 and 59. According to this author, the practice of limiting such patent grants to process patents would be commensurate with the inventor's actual contributions to his or her community, thereby conveying an attitude of respect for "the largess of nature's handiwork".

32 *Harvard College*, *supra* note 8 at 183.

issues that the court had to grapple with. Binnie J noted that the *Patent Act* does not expressly distinguish between higher life forms and lower life forms.[33] In addition, there was nothing unique or distinctive about Canada's patent legislation that set it apart from that of other major industrialized countries, like the United States.[34] Binnie J expressed the concern that Canada's failure to harmonize its patent practices with those of other developed countries might have an adverse impact on biotechnology investment.[35] Further, the phrase "composition of matter" was broad enough to encompass patents on higher life forms and should be interpreted thus. Binnie J emphasized that the existence of separate legislation on plant breeders' rights should not be taken to mean that higher animal life forms are statutorily excluded from patentability.[36] Given that plant breeders' rights are narrower than patent rights and are governed by an entirely different regime, there is no express legislative bar in the *Patent Act* that specifically excludes plants (or animals, for that matter) from patent protection.

The majority decision by the Supreme Court in *Harvard College* appears to have adopted a fairly conservative, and perhaps even rigid, interpretation of "composition of matter", since living tissue consisting of cells and genes, is, scientifically speaking, made up of molecules and atoms. One commentator has gone to the extent of describing the majority decision as not only "strikingly different" from that in the European Union and the United States,[37] but also "pre-scientific",[38] "metaphysical"[39] and "having no basis in science".[40] While Bastarache J, in delivering the opinion of the majority, acknowledged that life forms contain "matter", he was also quick to note that life "transcends" matter and cannot be "created" or "assembled" from scratch by human hands in a laboratory.[41] Yet patent law does in many circumstances afford protection to inventions that are formed by combining different components together in a novel and ingenious way. There is arguably nothing inherent in the phrase "composition of matter" that necessarily leads to the exclusion of life forms from the category of "patentable subject matter".

One possible policy consideration that could have implicitly informed the majority's interpretation of "composition of matter" in section 2 of the *Patent Act* is the ethical objection against conferring proprietary rights over life. The "commodification" of life as a form of protectable property right is troubling from a moral standpoint because it seeks to grant control over the exploitation and use of organisms that can replicate naturally, and might, depending on the species, be capable of movement and sentient thought, including the ability to feel pain and dis-

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33 *Ibid* at 47.

34 *Ibid* at 3: "The truth is that our legislation is not unique."

35 *Ibid* at 18, where Binnie J notes that the "massive investment of the private sector in biotechnology research" is exactly the sort of research and innovation that the *Patent Act* was intended to promote.

36 *Ibid* at 60-61.

37 See Torrance, *supra* note 15 at 368.

38 *Ibid* at 365.

39 *Ibid* at 401.

40 *Ibid* at 402.

41 *Harvard College*, *supra* note 8 at para 163.

tress.[42] Such ethical and moral objections to patent protection might theoretically be accommodated under an "ordre public" bar to patentability, which prescribes that certain classes of invention are not to be granted patent protection — on grounds of public order, safety, morality or environmental concerns — even if they satisfy the traditional requirements for patentability. The TRIPS Agreement and the European Patent Convention allow for such exclusions on *ordre public* grounds. However, Canada does not have an express *ordre public* provision in its patent legislation. Although mathematical formulas and abstract theorems are excluded from patentability under section 27(8) of the *Patent Act*, there is no specific in-built "moral or ethical category" for the exclusion of Canadian inventions that are deemed objectionable or undesirable. The judges for the majority in *Harvard College* could therefore have felt it necessary to express their objections to the patenting of life via the interpretation of "composition of matter" in section 2, given the absence of an *ordre public* provision.

The issue of patenting life again arose for consideration in a subsequent case on agricultural biotechnology that drew worldwide attention. In *Monsanto v Schmeiser*,[43] the Supreme Court was faced with the task of determining the validity of a patent for genetically modified canola plant cells and genes with increased tolerance for glyphosate herbicides (such as "Roundup"). The case concerned a farmer, Percy Schmeiser, who grew the genetically modified strain of canola on his agricultural land without obtaining permission or a licence from the patent owner. Many of the farmers in the area had already switched to "Roundup Ready" canola and were paying a licence fee to use the patented invention. These farmers were also required to sign a "Technology Use Agreement" with Monsanto which forbade them from saving the seeds for replanting or inventory, selling or giving the seeds away, and placed restrictions on the commercial purchasers to whom the harvested crop could be sold.

Interestingly, the Court reiterated its earlier holding in *Harvard College* that higher life forms are not patentable. However, since the patent claim in the *Schmeiser* case was for the genetically modified cells and genes, and not for the canola plant as a whole, the validity of Monsanto's patent was upheld. The court noted that the modified gene that made the plant resistant to herbicides was "chimeric",[44] and did not exist in nature. In addition, Mr. Schmeiser had infringed this patent by "using" the invention in planting, harvesting and collecting the genetically modified crop and seeds. Nevertheless, the court held that despite the finding of infringement, Mr. Schmeiser was not liable to account for any profits, since his profits were not causally attributable to the patented properties of his crop.[45] The

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42 Michael Saunders, "Creating Life from Scratch: The Patentability of Synthetic Organisms" (2008) 11 Tul J Tech & Intell Prop 75 at 88.

43 *Schmeiser*, *supra* note 8.

44 *Ibid* at 20.

45 *Ibid* at 100–105. Monsanto was required to choose between two alternative remedies: damages or an accounting of profits. In light of the fact that Monsanto had elected to seek an accounting of profits from Mr. Schmeiser, it was not entitled to damages. As noted in the majority opinion of the court, an accounting of profits is based on the profits made by the patent infringer, rather than the amount lost by the inventor.

profits that Mr. Schmeiser had made were identical to what he would have made had he grown ordinary canola.[46]

The Supreme Court's decision in *Schmeiser* has inspired some rather interesting commentary from intellectual property scholars in Canada. Torrance observes that while *Schmeiser* did not expressly overrule *Harvard College*, it did vitiate the latter's effect, by establishing the "de facto" patenting of life forms in Canada.[47] In addition, Siebrasse notes that the difference in scope between the Harvard mouse patent claim (which extended to the life form itself) and the Monsanto patent (which limited its scope to the modified cells and genes) might seem like one of form rather than substance, but the consequences are dramatic.[48] He observes that a patent for the cells of a higher life form will now give effectively the same protection as a patent for the life form itself. Ziff observes that a patented gene contained in every cell of a plant confers a form of property right over the entire plant.[49] In the same vein, Gervais and Judge surmise that since a patent can now be infringed by using a higher life form in which a protected invention is embedded, the contrast in scope between the Harvard mouse claim and the Monsanto claim may, for practical purposes, be a "distinction without a difference".[50]

The Supreme Court's holding that a patent for genetically modified cells can now confer rights of exclusivity over the use of an entire life form significantly weakens the rule against patenting life laid down in *Harvard College*. Yet Gervais and Judge emphasize that *Schmeiser* is *not* a reversal of *Harvard College*, since the rule that higher life forms are unpatentable *per se* continues to hold. Interestingly, Siebrasse applauds the majority approach in *Schmeiser* as being compatible with the "broad principles" of patent law, reflective of an intention, by the majority judges, not to be restrained by the rigid technicalities of the *Harvard College* case.[51] However, the expansive approach taken by the court *vis-à-vis* the question of infringement essentially renders nugatory the legal distinction between a patent claim for a genetically modified life form and one that is limited specifically to an "embedded invention" within that life form. The court's insistence in drawing a distinction between these two categories of patent claim introduces an element of artificial complexity, and perhaps even an unjustifiable double standard, into the realm of Canadian biotechnology law.[52] The result of the *Schmeiser* litigation

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46 *Ibid* at 104.

47 Torrance, *supra* note 15 at 369-370.

48 See Norman Siebrasse, "Comment on Monsanto Canada Inc v Schmeiser", *supra* note 8 at 2.

49 See Bruce Ziff, "Travels with my Plant: Monsanto v Schmeiser revisited", *supra* note 15 at 505.

50 Daniel Gervais & Elizabeth F Judge, *Intellectual Property: The Law in Canada*, 2nd edition (Toronto: Carswell, 2011) [Gervais & Judge] at 701.

51 See Siebrasse, *supra* note 18 at 3: "The majority in *Schmeiser* chose consistency with broad principles of patent law at the expense of practical consistency with the Harvard Mouse decision, while the dissent chose consistency with Harvard Mouse at the expense of patent principles."

52 In this vein, Wei suggests that it may be more appropriate to recognize special exceptions to patent rights to allow for agriculture, plant breeders' rights, research and inno-

might very well be an implicit recognition that Harvard College could easily have obtained the same level of protection for a product patent in Canada as in the United States if they had only framed their patent claim to cover the genetically modified cancer gene, rather than the entire oncomouse itself.[53]

Since the conclusion of the *Schmeiser* litigation, and release of the Supreme Court decision, the Canadian Intellectual Property Office (CIPO) has sought to clarify the scope of patentable subject matter for claims involving genetically modified components of animal life forms. In a 2006 "Practice Notice", the CIPO announced that animals at any stage of development, from fertilized eggs onwards (including totipotent stem cells which have the potential to develop into an entire animal), are not patentable under section 2 of the *Patent Act*.[54] This directive is arguably inconsistent with the Supreme Court's holding in *Harvard College* that a fertilized genetically modified mouse egg is patentable subject matter.[55] Nevertheless, the CIPO Practice Notice also indicates that genetically modified cells that do *not* have the potential to develop into entire animals are patentable.[56]

Hence, under the Practice Notice, a modified cancer gene or cell would still be patentable in Canada, as long as it meets the statutory requirements in the *Patent Act*. In addition, the Canadian Biotechnology Advisory Committee (CBAC) has recommended that patents should be allowed in respect of plants and non-human animals that meet the requirements of novelty, non-obviousness and utility, but not on any part of the human body.[57] Although the CBAC's recommendation is not binding on Canadian courts, it is consistent with the general trend in other developed countries to extend patent protection to genetically modified life forms.

Although the CIPO Practice Notice seeks to draw a firm line between "animals at any stage of development", and "genetically modified cells that do not have the potential to develop into entire animals" for the purpose of patentability, this distinction may be a cosmetic one in the case of inventions involving non-totipotent cells, given the Supreme Court's expansive interpretation of "infringement" in the *Schmeiser* decision. The practical effect that this Notice would have on the drafting

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cent bystanders, instead of rejecting patent applications strictly on grounds of scope. See Wei, *supra* note 28 at 77-78.

53 See for instance Keith Aoki, "Seeds of Dispute", *supra* note 15 at 104, who observes that living inventions are now patentable in Canada as long as they are not expressed as a higher life form.

54 See Canadian Intellectual Property Office, "Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues", online: <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00295.html>. See also Gervais & Judge, *supra* note 50 at 702.

55 *Ibid.*

56 *Ibid.* Such cells would include embryonic, multipotent and pluripotent stem cells. See Canadian Intellectual Property Office, "Office Practice Regarding Fertilized Eggs, Stem Cells, Organs and Tissues", online: <http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr00295.html>.

57 Canadian Biotechnology Advisory Committee, "Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee", online: <http://publications.gc.ca/collections/Collection/C2-598-2001-2E.pdf>. See also Torrance, *supra* note 15 at 369 and Wei, *supra* note 28 at 76.

of patent claims is that patent filers seeking protection for genetically modified animals are now encouraged to frame their invention as a "non-totipotent" cellular or genetic "component" of a life form, as was done in the *Monsanto* patent, and *not* as the organism itself, in order to be eligible for patent consideration. Nevertheless, if one were to extend the ruling in *Monsanto* to animals, the interpretation of "use" adopted by the Supreme Court would grant a successful patent applicant *de facto* control over the entire organism, since breeding and selling modified animals containing patented genes would essentially constitute patent infringement.

The corollary of the analysis above is that Canada has aligned itself in *substance* (though not in *form*) with the patent practices of other developed nations in extending patent rights to inventors of genetically modified organisms. Notwithstanding the Supreme Court's decision in *Harvard College*, there had been evidence of growing policy support for extending patent protection to plants and animals prior to December 2002. As mentioned earlier, the Canadian Biotechnology Advisory Committee issued a recommendation in June of 2002 that higher life forms that meet the criteria be treated as patentable.[58] Although there continues to be a formal distinction in Canadian law between the patentability of genetically modified cells and the exclusion of life forms *per se* from the scope of protection, a patent awarded for genetically modified cells confers substantially the same rights as a patent for a genetically modified organism carrying those cells. The next section explores the extent to which this "emerging trend" in Canada comports with general patent practices in other parts of the developed world, and seeks to identify a growing consensus, particularly among developed countries, in favour of treating some forms of genetically modified life as patentable subject matter.

II. PATENT LAW IN THE UNITED STATES AND EUROPE: IS "LIFE" PATENTABLE?

In this section, I discuss the scope of protection patent protection afforded to life forms under United States legislation and the European Patent Convention, and examine the extent to which these patent standards are compatible with the legal position in Canada. Through this comparison, I seek to identify a high degree of consensus in favour of recognizing *lower* life forms as patentable subject matter, and the early signs of an emerging consensus, among these developed nations, that such protection should be extended to *multi*-cellular organisms.

(a) The United States

The United States has a fairly long and established history of recognizing patent protection for non-naturally existing living organisms, which dates back to as early as 1980, when the Supreme Court of the United States held, in *Diamond v*

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58 See Recommendation 2 of Canadian Biotechnology Advisory Committee, "Patenting of Higher Life Forms and Related Issues: Report to the Government of Canada Biotechnology Ministerial Coordinating Committee", online: <http://publications.gc.ca/collections/Collection/C2-598-2001-2E.pdf>, which provides, *inter alia*: "We recommend that higher life forms (i.e., plants, seeds and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable." See also Torrance, *supra* note 15 at 369.

Chakrabarty,[59] that a live, human-made micro-organism was patentable subject matter under §101, as a "manufacture" or "composition of matter" within 35 USC on the patentability of inventions.[60] §101 defines, in language very similar to that contained in the Canadian *Patent Act*, a patentable invention or discovery as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". As is the case in Canada, there are no legislative prohibitions in the United States on the types of subject matter that are patentable based on moral or public policy grounds.[61] The US Supreme Court in *Chakrabarty* emphasized that the claimed invention — a genetically engineered bacterium capable of breaking down crude oil — possessed properties not present in naturally occurring bacteria — and was therefore a product of "human ingenuity", rather than the handiwork of nature.[62] The US Supreme Court adopted a relatively permissive approach to patentability, suggesting, in an oft-quoted line, that "anything under the sun made by man" is patentable, borrowing from language used in the Committee Reports accompanying the *Patent Act of 1952*.[63] While the broad language of §101 does not distinguish between living and non-living inventions, it excludes the laws of nature, physical phenomena and abstract ideas from the scope of patentability.[64] It is also noteworthy that §103 (b) (1) and (3) specifically indicate the circumstances under which a biotechnological process — including the process of genetically altering a single- or multi-celled organism — can be considered to "nonobvious" and eligible for patent protection.

It is interesting to note that although *Diamond v Chakrabarty* upheld the patentability of a genetically modified micro-organism, the broad language used by the Supreme Court in that case has opened the door in the United States for patents in respect of genetically modified life forms *in general*, including multicellular organisms. It has been noted that patents on multicellular life forms are regularly granted in the United States, building upon the precedent set by the Supreme Court in *Chakrabarty*.[65]

The rule that genetically engineered microorganisms may enjoy patent protection is relatively uncontroversial, and has been accepted in many leading industrialised nations, including Canada.[66] However, it is important to note that the United States was one of the first industrialized nations to extend patent protection to higher, multi-cellular life forms, such as plants and animals. The United States patent for the Harvard oncomouse was granted as early as 1988.[67] Patents on the

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59 *Chakrabarty*, *supra* note 24.

60 *Ibid* at 308–318.

61 Gregory R Hagen & Sébastien A Gittens, "Patenting Part-Human Chimeras, Transgenics and Stem Cells for Transplantation in the United States, Canada, and Europe" (2008) 14 Rich JL & Tech 11 at 80.

62 *Chakrabarty*, *supra* note 24 at 308–318.

63 See Michael Saunders, *supra* note 42 at 78.

64 *Ibid.*

65 *Ibid* at 79.

66 *Ibid* at 80, where Saunders notes that Canada, Germany, Australia and Japan have granted patents for genetically engineered lower life forms or microorganisms.

67 Wei, *supra* note 28 at 43.

oncomouse have also been granted in Europe, the United States and Japan.[68]

The patentability of transgenic animals in the United States was further reinforced when the United States Patent and Trademark Office (USPTO) issued a notice in 1987 indicating that non-naturally occurring, non human life forms, including animals, were patentable subject matter under 35 USC 101.[69]

The analysis above indicates that the United States defines the scope of "patentable subject matter" more broadly than Canada. Under the American paradigm of patent protection for biotechnological inventions, genetically engineered life forms — whether consisting of cells, genes, micro-organisms or multicellular organisms — are patentable, as long as they meet the requirements of novelty, nonobviousness and utility.[70] However, human life forms are excluded from the scope of patentability in the United States. It remains a question of some uncertainty as to whether chimeric inventions[71] containing some human genetic material can be patented.[72] The relevance of this issue has become more apparent as new medical technologies enable the insertion of human genetic material into animal organs to facilitate transplantation. The possibility of patenting such "part human materials" would depend on the biological criteria used by legislators and courts to determine the level of human genetic content considered to be acceptable in a patented invention.

While human beings are not patentable in and of themselves in the United States, it appears that certain forms of isolated human elements, such as nucleotide sequences, are generally available for patenting.[73] Yet the maximum amount of human material that can be contained in biotechnology inventions before they can be patented is a question that has not been satisfactorily resolved. The United States Patent and Trademark Office issued a notice in 1987 indicating that a claim which is directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 USC 101.[74] Hence the position in the United States is that human beings at any stage of development are not patentable.[75] This

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68 Saunders, *supra* note 42 at 82.

69 See USPTO, *Manual of Patent Examining Procedure* §2105 (2007), online: <http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2105.htm>; Hagen & Gittens, *supra* note 61 at 46.

70 See 35 USC §103, especially §103(b)(1), which describes the conditions under which a biological process resulting in a novel composition of matter may be considered nonobvious.

71 A chimeric invention is one that contains genetic material from more than one species of living organism. The term "chimeric" is in fact a reference to the "chimera" from Greek mythology, a being with a lion's head, a goat's body and a serpent's tail. See Thomas A Magnani, "The Patentability of Human-Animal Chimeras" (1999) 14 Berkeley Tech LJ 443 at 443; Ryan Hagglund, "Patentability of Human-Animal Chimeras" (2008-2009) 25 Santa Clara Computer & High Tech LJ 51 at 53.

72 Hagen & Gittens, *supra* note 61 at 85.

73 *Ibid* at 3.

74 See Commissioner of Patents and Trademarks, "Animals — Patentability", 1077 OG 24, 21 April 1987.

75 See Hagen & Gittens, *supra* note 61 at 57.

leaves open the possibility that biological inventions that contain some human genetic material, but which do *not* have the potential of developing into a human being, such as a pig's organ containing human DNA, may be patentable in the United States. The line of cleavage between patentable and non-patentable biotechnological inventions in the United States therefore distinguishes between animal or plant life forms and human life forms. The presence of human genetic material in a biotechnological invention that is capable of developing into a human being would render an otherwise patentable invention ineligible for protection in the United States.

(b) The European Union

The position in the European Union with respect to the patentability of genetically modified life forms is not dissimilar to that of the United States. Article 52(1) of the European Patent Convention provides a definition of "patentable subject matter", and Rule 27 of the *Convention's Implementing Regulations* sets out the criteria for patenting biotechnological inventions, with Rule 27(b) extending the patentability of inventions to "plants and animals" if the technical feasibility of the invention is not limited to one single plant or animal variety. Although a European patent for the Harvard Oncomouse was granted in 1992,[76] it is important to note that the European Patent Convention is a multilateral agreement containing minimum standards, and that the individual patent practices of member states may differ considerably. Rule 27(b) embodies a treaty norm, adopted by member states of the European Union, in favour of recognising higher life forms as patentable subject matter, although there are several notable exceptions pertaining to processes involving humans, such as the prohibition of human cloning under Rule 28. However, unlike the United States and Canada, member states of the European Patent Convention take into account *ordre public* considerations when determining issues of patentability.[77] The usefulness of the genetically engineered life form is weighed against any suffering caused to the animal in what is known as a "balancing test".[78]

As in the United States, it is not entirely clear whether part-human chimeras are patentable under the European Patent Convention. In addition, questions of patentability are compounded in the European Union by the jurisdictional complexities of the European patent system. Hagen and Gittens note that there is no such thing as a "European Community patent" and that patents granted by the European Patent Office (EPO) can be revoked under national law.[79] However, the Biotech-

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76 European Patent EP0169672; See also Saunders, *supra* note 42 at 80.

77 See Article 53(a) of the European Patent Convention, which contains "*ordre public*" exceptions to patentability on grounds of morality. See also Hagen & Gittens, *supra* note 61 at 80.

78 Saunders, *supra* note 42 at 85. The European Patent Office has, however, recommended that *ordre public* objections should be limited to "demonstrably abhorrent" inventions. See also Wei, *supra* note 28 at 78.

79 Hagen & Gittens, *supra* note 61 at 82.

nology Directive,[80] which was incorporated into the European Patent Convention in June 1999 by the *Implementing Regulations* to the EPC, provides that *isolated* biological elements may be patentable, even if they are identical in structure to their naturally occurring analogues.[81] Interestingly, Rule 23(e)(1) of the EPC contains an explicit prohibition against the patenting of human bodies at any stage of development.[82] There is also a ban on human cloning in the European Union.[83] Unfortunately, the EPC and the Biotechnology Directive do not provide guidance on the percentage of human genetic material that would be deemed acceptable in a biological invention for the purpose of patentability. State practice among members of the European Patent Convention in this regard varies somewhat — with Sweden and Germany allowing patents for pluripotent stem cells, despite a contrary view expressed by the European Group on Ethics in Science and New Technologies (EGE).[84]

The position vis-à-vis the patentability of life in the European patent system reflects an interesting convergence with patent trends in the United States. Like the US, patent norms in the European Union have extended protection to both unicellular *and* multicellular life forms,[85] but with an explicit prohibition against the patenting of human beings or human bodies. One significant difference, however, is that while the European Patent Convention contains an *ordre public* exception, it does not contain a *specific* list of inventions that are considered contrary to *ordre public*.[86] Some commentators have suggested replacing the prohibition against patenting human bodies with that of patenting "persons", so as to clarify the position with respect to the patentability of part-human chimeras,[87] which consist of inventions combining human and animal genetic material.

The analysis above indicates that intellectual property laws in the United States and the European Union have begun to recognize the patentability of higher

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80 European Community Directive on Biotechnology (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the Legal Protection of Biotechnological Inventions).

81 See Article 5(2) of the Biotechnology Directive.

82 Article 5(1) of the Biotechnology Directive also contains a similar prohibition against the patenting of human bodies at any stage of development. See also Hagen & Gittens, *supra* note 61 at 79.

83 See Rule 23(d) of the European Patent Convention; see also Saunders, *supra* note 42 at 87.

84 Hagen & Gittens, *supra* note 61 at 83.

85 See Torrance, *supra* note 15 at 368, who notes that the European Law is "permissive", allowing patent protection for both microorganisms and multicellular organisms ("macroorganisms").

86 Article 53(a) of the European Patent Convention states that European patents shall not be granted for inventions the commercial exploitation of which would be contrary to "ordre public" or morality, but does not provide examples of what might be considered "immoral". Articles 53(b) and (c) do, however, proscribe patent protection for plant and animal varieties, as well as certain methods of treatment for human beings and animals.

87 Hagen & Gittens, *supra* note 61 at 33.

life forms, extending protection far beyond genetically modified micro-organisms — the subject matter of protection in *Diamond v Chakrabarty*. One can observe the emergence of two patent norms relating to life forms — an older, more established, and more widely recognised one for lower life forms such as bacteria and microorganisms (dating back to *Chakrabarty*), and a newer, more recent one for multicellular organisms, including plants and non-human animals. In the next section, I explore the extent to which these two norms are beginning to find expression in multilateral agreements on trade and intellectual property.

Country / Region	**Patentable**	**Not Patentable**
Canada	Genetically modified micro-organisms, cells and genes	Higher life forms, including plants, animals and human life forms
United States	Genetically modified micro-organisms, cells, genes, higher life forms	Human life forms
European Union	Genetically modified micro-organisms, cells, genes, higher life forms (subject to "*ordre public*" and balancing test)	Human life forms

III. PATENTS AND INTERNATIONAL LAW — THE EMERGENCE OF A NEW INTERNATIONAL LAW NORM FOR THE PATENTABILITY OF HIGHER LIFE FORMS?

(a) International Treaty Norms relating to the Patent Protection of Modified Life Forms

An interesting issue that arises for consideration at this juncture is the extent to which international agreements on intellectual property mandate the protection of modified life forms as patentable subject matter. One of the most important recent developments in the field of international intellectual property law was the entry into force of the TRIPS Agreement in 1995,[88] upon the conclusion of the Uruguay Round of the General Agreement on Tariffs and Trade. The TRIPS Agreement imposed minimum standards of intellectual property protection on all member states of the World Trade Organisation (WTO).[89]

Article 27.1 of the TRIPS Agreement adopts a "technology neutral" approach to "patentable subject matter". Although it does not specifically mention geneti-

88 Agreement on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, 15 April 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 ILM 1197 (1994).

89 For example, Article 33 of the TRIPS Agreement states that the term of patent protection shall not end before the expiration of twenty years from the filing date.

cally modified life forms, it provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application". It also stipulates, among other things, that patent rights are to be made available "without discrimination" as to the field of technology.

The technology neutral thrust of Article 27.1 is perhaps somewhat attenuated by the presence of Articles 27.2 and 27.3, which allow member states to exclude inventions from patentability on *ordre public* or other specified grounds. Judging from the plain text of Article 27.2, one might surmise that the norm against discrimination as to the field of technology is *not* absolute, and that member states are essentially free, within the limits prescribed by the section,[90] to exclude certain technologies or inventions from the scope of patentability. The Article specifically mentions the protection of human, animal and plant life as a possible basis on which to exclude an invention from patentability. A logical inference that can be drawn from the text of Article 27 is that animals and plants are not categorically excluded from patentability under the TRIPS Agreement, although member states are generally free to pass laws excluding such inventions from patent protection. Accordingly, there is *no* clear treaty norm in the Agreement which expressly supports the protection of modified plants or animals as a form of intellectual property. Member states are given a considerable amount of discretion in the extent to which they choose to extend patent protection to animals and plants. One commentator has suggested that the TRIPS Agreement only *implicitly* recognizes the patentability of whole organisms.[91]

Like the TRIPS Agreement, the North American Free Trade Agreement (NAFTA)[92] adopts a technology neutral approach to patentability. Article 1709.1, in particular, states that each Party shall make patents available for any inventions in "all fields of technology", as long as the requirements of novelty, inventive step and industrial application are satisfied. It is noteworthy that NAFTA mirrors the structure of the patent provisions in the TRIPS Agreement in defining exceptions to the patentability of inventions. Article 1709.2 of NAFTA allows a Party to exclude inventions from patentability on grounds of *ordre public* or morality, while Article 1709.3 specifically allow exclusions for "plants and animals" other than microorganisms. The treaty norms established in the patent sections of NAFTA clearly reflect a bifurcated approach in the treatment of genetically modified life forms — a clear standard requiring patent protection for microorganisms, and an optional requirement to extend protection to higher life forms. Based on an analysis of these textual provisions, an argument might be made that the practice of awarding patents for higher life forms has yet to be crystallized as a treaty norm in either the NAFTA or the WTO treaty framework.[93]

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90 Article 27.2 provides that the exclusion from patentability must not be made merely because the exploitation of the invention is prohibited by law in the member state.

91 Torrance, *supra* note 15 at 365.

92 NAFTA, Can TS 1994 No 2.

93 See also Elisabeth A Abergel, "Trade, Science, and Canada's Regulatory Framework for Determining the Environmental Safety of GE Crops", in Taylor, ed, *Genetically Modified Crops*, *supra* note 2 at 194 who notes that the intellectual property rules

On the subject of microorganisms, the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure implicitly recognises the patentability of life forms by establishing an international system for the deposit of patented *lower* life forms. Article 3 of the Treaty, in particular, requires member states to recognize the deposit of such material at any international depository authority.

The norm in favour of extending patent protection to microorganisms appears to be more firmly entrenched in international treaty law (particularly in the text of NAFTA) than that for higher life forms. This implicit distinction in the treatment of organisms based on their classification as higher or lower life forms is similar to the Canadian Supreme Court's "bifurcated approach" in distinguishing between patent applications for modified cells, on the one hand, and patent applications in respect of living organisms in which those cells are embedded, on the other. This dichotomy can perhaps be viewed more accurately as a distinction between unicellular and multicellular inventions, although it has been pointed out that the line between "higher" and "lower" life forms is not always clearly defined in scientific or legal terms.[94]

Yet, it is also important to note that neither the Budapest Treaty nor the TRIPS Agreement expressly mandates the patentability of lower life forms or microorganisms. The Budapest Treaty merely establishes a system by which deposits of microorganisms are to be recognised by contracting parties which allow or require such deposits for the purposes of patent procedure. As such, there is no *express* treaty norm in the major patent law conventions, with the exception perhaps of NAFTA, which specifically supports the protection of lower life forms as patentable inventions. The major international patent treaties appear to confer a significant amount of discretion to contracting parties on the subject of what constitutes "patentable subject matter". While other international conventions and organizations, such as the Cartagena Protocol on Biosafety to the Convention on Biological Diversity,[95] the Agreement on the Application of Sanitary and Phytosanitary Mea-

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under the World Trade Organization stipulate that members may exempt plants and animals from the scope of patentability.

94 See Torrance, *supra* note 15 at 385, who discusses whether there is a basis, in Canadian patent law, for making a distinction between higher and lower life forms, particularly since the Canadian *Patent Act* does not discriminate between "more complex" and "less complex" subject matter. Interestingly, Bastarache J, in delivering the majority opinion in *Harvard College*, has noted that the distinction between higher and lower life forms is widely accepted as valid and is defensible based on the "common sense differences" between the two. See *Harvard College*, *supra* note 8 at 199 and 205.

95 Articles 10.6 and 11.8 of the Cartagena Protocol on Biosafety allude to the "precautionary principle" in international environmental law in allowing countries to deny imports of genetically modified organisms and food products on account of risks to human health. See also Katherine Barrett & Conrad G Brunk, "A Precautionary Framework for Biotechnology" in Taylor, ed, *Genetically Modified Crops*, *supra* note 2 at 134. The full text of the Protocol can be viewed online: <http://bch.cbd.int/protocol/text/>.

sures (the SPS Agreement) of the World Trade Organization,[96] and the Codex Alimentarius Commission[97] lay down rules on trade in modified organisms, they do not provide guidance on their *patentability* as inventions.

Given the lack of an express treaty norm *mandating* the patent protection of genetically modified life forms, the practice in the United States of conferring such protection can be said to be a voluntary "ratcheting up" of domestic patent standards to a level beyond that required by its treaty obligations. The convergent patent practices in the United States and the European Union of protecting modified multicellular life forms as patentable inventions can therefore be said to be *compatible* with, but *not* mandated by, their obligations under international law.

It should nevertheless be borne in mind that these convergent trends are largely confined to developed states in North America and Europe. There is evidence to suggest that at least some developing countries and emerging economic powers are reluctant to accept higher life forms as patentable subject matter.[98] In India, for instance, higher life forms are specifically excluded from the scope of patentable subject matter.[99] In addition, Bolivia submitted a paper at a meeting of the WTO TRIPS Council in 2011 arguing that Art 27.3(b) needs to be amended to prohibit the patenting of life forms and parts thereof.[100] Among the arguments

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96 Agreement on the Application of Sanitary and Phytosanitary Measures, online: <http://www.wto.org/english/docs_e/legal_e/15sps_01_e.htm>.

97 See Codex Alimentarius, online: <http://www.codexalimentarius.net/web/index_en.jsp>.

98 In a discussion paper on the review of Article 27.3 (b) of the TRIPS Agreement in 1999, India submitted that it was unprepared to accept any further strengthening of the protection provided to life forms before assessing, by experience, what standard would be appropriate for Indian society. The paper noted that "developing country laws" in the area of biotechnology were still being developed and that it would take some time for developing countries to acquire experience on the "level of protection necessary and desirable as well as the exceptions and balances necessary for ethical, social and economic needs of their peoples". In addition, the paper proposed excluding patent protection for life forms from national laws till the required experience had been acquired. See Someshwar Singh, "Patents on Life Forms Should be Re-examined, Says India", online: <http://www.twnside.org.sg/title/lifeform-cn.htm>.

99 Section 3(j) of India's *Patents (Amendment) Act of 2005* excludes from patentability "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals". The above provision was added to the *Act* via amendments in 2002 to codify into Indian law the TRIPS-permitted exclusion from patentability of "plants and animals" other than microorganisms and specified biological processes. However, since January 2005, when the TRIPS transitional period in respect of pharmaceutical patents ran out for developing countries, India has granted a handful of pharmaceutical product patents. One commentator has suggested that India's burgeoning domestic pharmaceutical and biotechnology industry is beginning to invent rather than merely reverse-engineer. See Janice M Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" (2007) 68 U Pitt L Rev 491 at 496-8 and 559.

100 See Third World Network Information Service on Intellectual Property Issues, "Bolivia submits detailed paper on TRIPS Article 27.3(b)", 10 March 2011, online:

raised by Bolivia in its written submissions are that patent ownership of life raises serious ethical and moral concerns, is anathema to the sacred conception of life held by indigenous peoples in developing countries, facilitates biopiracy by condoning the appropriation by large multinational corporations of traditional knowledge developed by indigenous communities for centuries, grants monopolistic control to such corporations over key industries such as health, food and agriculture, and allows them to restrict access to essential treatments and medicines. In the paper, Bolivia expressed the view that the patenting of life poses a grave danger to humanity and that amending the TRIPS Agreement to prohibit such patents should be an essential part of the mandate of the Doha Development Round. In a similar vein, Kenya and the Africa Group have expressed opposition to the patenting of life at a seminar on "Current Developments in the WTO" organized in 2000 by the Third World Network, raising the concern that the patenting of life forms might have serious implications for food security in the developing world.[101]

Based on the above analysis, there is no uniform consensus, among members of the international trading community that patent protection should be extended to genetically modified life forms. Even Canada, a highly developed nation with a fairly mature intellectual property system, is somewhat hesitant and qualified in its acceptance of genetically modified inventions as patentable subject matter. This can be deduced from Canada's refusal to *formally* extend patent protection to higher life forms, despite having shifted its policy stance favourably in recent years toward such protection. Canada's approach may be said to be entirely consistent with its legal obligations, both nationally and internationally speaking, since nothing in international patent law or domestic law specifically mandates extending patent protection to *higher* life forms. Furthermore, it might be observed that the emerging state practice in the United States in regard to patenting higher life forms are a result of perceived compliance with national law, rather than with an international obligation. Without adequate evidence of favourable state practice in the field of biotechnological patents for life forms in developing nations, it is difficult to extrapolate any sign of sufficiently widespread support for an emerging norm in favour of protecting higher life forms.

The evidence appears to be clearer, however, that there is greater support among developed countries for the treatment of genetically modified *lower* life forms as patentable subject matter. The treaty norm in favour of patent protection for lower life forms is more clearly defined in both NAFTA and the European Patent Convention. In addition, the majority decision of the Supreme Court of Canada in *Harvard College* observed that "it is now accepted in Canada that lower life forms are patentable".[102] A stronger argument can therefore be made that the state

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<http://www.twnside.org.sg/title2/intellectual_property/info.service/2011/ipr.info.110305.htm>.

101 See Martin Khor, "Why Life Forms Should Not Be Patented", online: <http://www.twnside.org.sg/title/2103.htm>.

102 See *Harvard College*, *supra* note 8, at 201. The majority judges did note, however, at para 197, that *Abitibi Co, Re*, *supra* note 24 was in fact a Patent Appeal Board decision and that the patentability of lower life forms "was in fact never litigated in Canada." They were quick to add, at para 201, that the accepted position with respect to the

practice in these developed countries of extending patent protection to microorganisms arises from a legal obligation that is grounded in precedent and regional treaty provisions. A preliminary conclusion that can be drawn from this analysis is that normative evolution in respect of patenting *lower* life forms appears to be more advanced than that for *higher* life forms, and the practice of awarding protection to genetically modified microorganisms is closer to becoming crystallised as an international patent norm — subject, of course, to more widespread explicit acceptance by other players in the international community, especially developing countries. On the other hand, the patenting of *higher* life forms continues to be objected to with more strongly-voiced ethical and moral concerns, rendering it a less likely candidate for crystallization into international treaty law, at least in the foreseeable future.

IV. IMPLICATIONS FOR CANADA — WHICH WAY FORWARD FOR THE PROTECTION OF GENETICALLY MODIFIED LIFE FORMS?

While one might observe some degree of convergence in the patent practices of developed countries, the patentability of modified life forms remains a question of some controversy. As discussed in the previous section, the protection of modified higher life forms is not currently mandated by international conventions on patent law. As a member of NAFTA, Canada is not obliged to extend patent protection to genetically modified plants or animals, as long as it invokes either the *ordre public* provision or one of other exceptions for higher organisms contained in the Agreement.

Quite interestingly, however, Canada's *Patent Act* does not specifically mention plants or animals, nor does it contain an *ordre public* exception. To further compound matters, the *Schmeiser* legacy has left Canadian patent law in a state of some uncertainty. The *Schmeiser* decision has opened the door to biotechnological patents by recognising the patentability of genetically modified components of living organisms, while denying protection for entire organisms. As mentioned earlier, this distinction introduces an element of artificial complexity into the analysis of patentability, since the effect of *Schmeiser* is to grant *de facto* protection over the entire organism to a successful patentee with a valid claim in respect of genetically modified genes or cells.

A more coherent approach for Canada would be to jettison the "halfway house" or the "door half open" position represented in *Schmeiser*, and to either recognize the patentability of genetically modified organisms outright, or to restrict their protection to process patents, as at least one commentator has suggested.[103] The first option would be more compatible with the current trends in the developed world, and represent an explicit recognition of the more permissive and liberal approach adopted by Binnie J in his dissenting opinion in *Harvard College*. If, on the other hand, the second option is chosen, the *Patent Act* should be modified to in-

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patentability of lower life forms did *not* necessarily lead to the conclusion that higher life forms were also patentable in Canada.

103 Ong, Biological Bounty, *supra* note 12 at 8 and 59.

clude an express exclusion for plants and animals, so as to fulfill Canada's obligations under NAFTA. Both options would be compatible with Canada's international obligations, but concrete action is required to clarify the position in Canada with respect to genetically modified higher organisms, so as to adequately address the ambiguities that would otherwise continue to plague the *Schmeiser* decision and its interpretive legacy in future cases.

It is submitted, however, that recognizing genetically modified life forms as patentable subject matter would be a more favourable strategy for Canada to adopt as a major trading nation. It has been suggested that Canada needs to take more concrete steps to harmonize its intellectual property standards with those of the European Union and the United States if it wishes to be taken seriously by its trading partners.[104] One of the main challenges facing Canada in its negotiations for admission to the proposed Trans-Pacific Strategic Economic Partnership Agreement (TPP), lauded as potentially the world's most important trade pact,[105] has reportedly been Canada's uncertain commitment to strengthening its intellectual property standards, particularly in the field of the life sciences.[106] Originally comprising Chile, New Zealand, Singapore and Brunei, the TPP seeks to further liberalize multilateral trade in the Asia-Pacific region, and the list of countries involved in negotiations has grown to include Mexico, Peru, Malaysia and the United States.[107] The United States announced in 2008 that it would commence negotiations with the original four members to join the TPP.[108] Although Canada had joined the TPP talks as an observer in 2010, the United States and New Zealand had objected to Canada's admission to the Agreement, citing concerns over agricultural policy and intellectual property rights protection.[109] While Canada has announced that it has recently joined the TPP negotiations at the invitation of President Barack Obama,[110] its stand on the issue of intellectual property protection is likely to have a significant impact on its prospects for membership in this multilateral free trade agreement.

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104 Peter Harder, "Canada must take necessary steps to clinch European Trade Agreement", *The Globe and Mail* (14 August 2012) at 5.

105 Michael Geist, "What's Behind Canada's Entry to the Trans-Pacific Partnership Talks?" online: <http://www.thestar.com/business/article/1216011 — what-s-behind-canada-s-entry-to-the-trans-pacific-partnership-talks> at 1.

106 Harder, *supra* note 104 at 5.

107 Geist, *supra* note 105 at 1.

108 Office of the United States Trade Representative, "Trans-Pacific Partners and United States Launch FTA Negotiations", online: <http://www.ustr.gov/trans-pacific-partners-and-united-states-launch-fta-negotiations>.

109 CD Howe Institute, "Can Canada Join the Trans-Pacific Partnership? Why Just Wanting it is Not Enough", online: <http://www.cdhowe.org/pdf/Commentary_340.pdf>, at 8: "A review of US official statements and speeches for 2010 makes it clear that strengthened copyright protection was the major trade reform the US was seeking from Canada".

110 Office of the United States Trade Representative, "US Trade Representative Kirk Welcomes Canada as a New Trans-Pacific Partnership Negotiating Partner", online: <http://www.ustr.gov/about-us/press-office/press-releases/2012/june/ustr-kirk-welcomes-canada-as-new-tpp-partner>.

Some critics of the TPP have complained that the negotiations thus far have been conducted behind closed doors, and shrouded in secrecy, reminiscent of the Cold War era.[111] It has also been suggested that involvement in the TPP negotiation process may come at a heavy price, with membership in the Agreement being contingent upon meeting the demands of its most powerful participant, the United States.[112] In particular, the "entry costs" for Canada have been argued to be particularly steep, given its rather "late entry" into the TPP process, and the lack of input from Canada in the early stages of the negotiations.[113] In this vein, the United States' invitation to Canada to join the negotiations has been described as an attempt to bring about regulatory changes, including changes to intellectual property standards, in Canada's domestic economy through the "back door" of trade negotiations.[114] The economic benefits of membership in the TPP to Canada may also be limited by the fact that Canada already has free trade agreements with four of the ten participants, namely the United States, Mexico, Chile and Peru.[115] Admission to the TPP Agreement would therefore only grant access to a few relatively small economies, including Vietnam, New Zealand, Malaysia and Brunei, which represent less than 1% of Canadian exports.[116]

It is indeed important to look beyond the patent law issue when weighing the costs and benefits of membership in the TPP, and to consider the overall impact of participation in these negotiations on Canada's regulatory sovereignty and domestic economy. Although it is true that Canada already has access, through free trade agreements, to the markets of some of the participants in the TPP negotiations, economic factors may form only part of the rationale for joining the Agreement. Membership in the TPP may help Canada improve its diplomatic and cultural ties with emerging economies in the Asia Pacific, increase the level of foreign direct investment, and strengthen Canada's political leverage in the region. It is also noteworthy that the TPP is still in its early stages of development, and as it matures as a free trade agreement, its future membership may include powerful players in the Asia Pacific region, such as South Korea and China.[117] Already, Japan has expressed preliminary interest in joining the Agreement, and along with Canada and Mexico, would bring participation in the regime to 12 states, culminating in what would be known as the "TPP-12".[118] It is accordingly important for Canada to include these considerations into its "calculus" of the costs and benefits of seeking admission to the TPP.

Substantively aligning its patent practices with other major industrialized

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111 Eric Stadius & Elizabeth Briggs, "The Trans-Pacific Partnership: Free Trade at What Costs?", Eurasia Review, 22 August 2012, online: <http://www.eurasiareview.com/22082012-the-trans-pacific-partnership-free-trade-at-what-costs-analysis/>.

112 Geist, *supra* note 105 at 4-5.

113 *Ibid* at 4.

114 *Ibid* at 3.

115 *Ibid* at 2.

116 *Ibid* at 7.

117 See Stadius & Briggs, *supra* note 111 at 29.

118 *Ibid*.

countries may also bring about additional economic benefits for Canada through other free trade agreements. For example, economic studies have suggested that the successful conclusion of the Comprehensive Economic and Trade Agreement (CETA), a proposed free trade and copyright agreement with the European Union, would result in a boost of $12 billion dollars in economic activity for Canada, and grant access to the world's largest common market of 500 million consumers.[119] While the CETA's intellectual property provisions relate primarily to copyright standards, the importance of strengthening trade relations with other developed nations and emerging economies suggests that it would be in Canada's economic interest to harmonize its intellectual property standards with those of the United States and the European Union, and to recognize genetically modified life forms as patentable subject matter — a practice that Canada has already begun to adopt in *substance* if not in *form*.

CONCLUSION

As biotechnology research continues to make inroads into the realm of the life sciences, patent examiners and other policy makers will continue to grapple with the ethical and legal implications of extending protection to increasingly novel and unique inventions. As the frontiers of biotechnology law are constantly defined and redefined by national laws and state practices, so too will the norms of international patent law be reshaped by ongoing dialogue between states and other stakeholders in the international community.

This article has sought to highlight an interesting trend among developed nations to extend patent protection to genetically modified higher life forms, and to situate Canada's position within this trend. Led by the United States and the European Union, this trend has been gaining momentum in recent years with the modification of Canada's approach toward the patentability of genes and cells within higher life forms. I have argued that the Supreme Court's groundbreaking interpretations of "patentable subject matter" and the infringement doctrine in *Schmeiser* have substantially (though not formally) aligned Canada's position with that of the United States and the European Union.

Despite this growing trend toward support for the patent protection of higher life forms in major industrialized countries, this practice has yet to crystallize into an international treaty norm. However, the normative growth in the field of biotechnology law appears to be following a "bifurcated" model — a more mature norm in favour of accepting the patentability of lower life forms, and a less established one for higher life forms. In view of the more established consensus in favour of protecting microorganisms and bacteria as forms of patentable subject matter, it would appear that such a practice is closer to becoming accepted as a norm of international patent law, while the patenting of higher life forms will need to garner more support from the international community, especially developing countries, before it is likely to be incorporated into treaty provisions relating to trade and intellectual property rights in genetically modified life forms.

The practical implications of this "bifurcated model" is that patent filers should be circumspect about their prospects of obtaining patent protection for mod-

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119 Harder, *supra* note 104 at 4.

ified life forms in newly industrialising economies, and to some extent, even in mature intellectual property systems like Canada. While a patent claim for higher life forms is more likely to succeed in the "developed West", prospective patentees should be aware that the success or failure of their patent application may very well depend on *how* their claim is drafted. In Canada, for instance, patentees would be well advised to frame their patent claim in respect of modified cells or genes, rather than over entire organisms, for as long as *Schmeiser* remains good law. In addition, the prospect of obtaining patent protection for life forms in general is uncertain at best in emerging economies with fledgling research and development sectors. The extent to which patent norms are accepted across various regimes in the international legal landscape is therefore a key factor that ought to be taken into account by R&D firms and inventors in crafting their patent drafting strategies to suit individual markets and intellectual property systems.

Despite the strides that Canada has made in the field of biotechnology law, *Schmeiser* remains, at best, a half-hearted embrace of genetically modified life forms as patentable subject matter. Yet the practical effect of the *Schmeiser* decision is that patented cells and genes now confer *de facto* control over the entire organism, owing to the broad approach to "use" and "infringement" adopted by the majority in the Supreme Court of Canada. The distinction that the court continues to maintain between the patenting of cells and the patenting of organisms is, for practical purposes, indefensible. By recognizing genetically modified components as patentable, Canada has already taken a bold step forward — some might say a step across an ethical boundary — by granting property rights in life. It is therefore illogical, and perhaps even intellectually dishonest, to grant patent rights over modified genetic components embedded in life forms, while in the same breath denying patent rights over the life forms themselves. It is perhaps time for Canada to liberate itself from the artificial interpretive constraints of the *Harvard College* ruling, and to more explicitly allow inventors to reap the *fruits* of their biotechnological innovations. Doing so would place Canada in step with the patent practices of its major trading partners, and enable it to play a more influential role in ongoing trade negotiations.