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Harvard Onco-Mouse NOT Patentable in Canada

In 1985, the President and Fellows of Harvard College applied for a patent on a transgenic mouse that had an oncogene inserted into its genome - the mouse had been genetically engineered for susceptibility to developing cancer. In August 2000, the Federal Court of Appeal ruled in a 2-1 decision that a patent may be granted on the Harvard onco-mouse, thereby reversing a long-standing practice of the Patent Office in refusing to grant patents for animals. On 5 December 2002, the Supreme Court of Canada in a split 5-4 decision held that the Federal Court of Appeal was wrong and that the "Harvard mouse", being a higher animal life form, is not a patentable "invention" in Canada. This ruling leaves Canada out of step with the law in most other developed countries.

Before this decision, Canadian patents for some years had been granted for lower life forms such as bacteria. The Patent Office had also for some time granted patents for methods to create genetically engineered organisms. In particular, method claims covering introduction of the oncogene into the mouse genome had been allowed by the Patent Office in the *Harvard Mouse* patent application; the Commissioner's decision to allow the method claims was not in issue before the courts.

In ruling that a patent should not be granted for the mouse *per se*, the Court rejected the argument that the genetically engineered mouse constitutes either a "manufacture" or a "composition of matter" within the statutory definition of "invention" in the *Patent Act*, notwithstanding that the onco-mouse resulted at least in part from human ingenuity. Interestingly, the majority of the Supreme Court appeared to accept that the genetically altered egg obtained by injecting the oncogene into a fertilized egg would satisfy the definition of "composition of matter".

In both the majority judgment and in the dissenting judgment, the Court recognized the competing public policy issues, but considered it proper to leave to Parliament the policy question whether patents should be granted on higher life forms. The majority were satisfied that on the present wording of the Act, higher animal life forms are outside the ambit of the definition of "invention", requiring Parliament to address the policy issues before patents may be granted on higher life forms. The minority took the opposite approach, noting that by its very nature, invention leads technologists into previously unexplored areas, and that the definition of "invention" in the *Patent Act* should therefore be given an expansive interpretation. On this view, the patent should be granted, and the policy implications later resolved by Parliament, who might in their wisdom amend the legislation to exclude higher life forms. Excerpts from both the majority and minority opinions are appended.

Excerpts from the Majority Reasons for Judgment, delivered by BASTARACHE J. --

To refuse a patent, the Commissioner must be satisfied that the applicant is not "by law" entitled to the patent, wording which indicates that the Commissioner has no discretion independent of the *Patent Act* to consider the public interest when granting or denying a patent.

Given that there is no discretion on the part of the Commissioner to deny a patent on a particular subject matter of invention, the sole question is whether Parliament intended the definition of invention, and more particularly the words "manufacture" or "composition of matter", within the context of the Patent Act, to encompass higher life forms such as the oncomouse. In my opinion, Parliament did not intend higher life forms to be patentable. Had Parliament intended every conceivable subject matter to be patentable, it would not have chosen to adopt an exhaustive definition that limits invention to any "art, process, machine, manufacture or composition of matter". In addition, the phrases "manufacture" and "composition of matter" do not correspond to common understandings of animal and plant life. Even accepting that the words of the definition can support a broad interpretation, they must be interpreted in light of the scheme of the Act and the relevant context. The *Act* in its current form fails to address many of the unique concerns that are raised by the patenting of higher life forms, a factor which indicates that Parliament never intended the definition of invention to extend to this type of subject matter.

...the Commissioner expressed the view that the words "manufacture" and "composition of matter" as found in §2 apply to something that has been made under the control of the inventor. At the same time, the resulting product must be reproducible in a consistent manner. Considering the invention in question, the Commissioner determines that there are two distinct phases. The first phase involves the preparation of the genetically engineered plasmid. The second involves the development of a genetically engineered mouse in the uterus of the host mouse. The Commissioner concluded that while the first phase is controlled by human intervention, in the second phase it is the laws of nature that take over to produce the mammalian end product. He was therefore unwilling to extend the meaning of "manufacture" or "composition of matter" to include a non-human mammal. In his view, the inventors do not have full control over all of the characteristics of the resulting mouse, and human intervention ensures that reproducibility extends only so far as the cancer-forming gene.

The sole question in this appeal is whether the words "manufacture" and "composition of matter", in the context of the *Patent Act*, are sufficiently broad to include higher life forms. If these words are not sufficiently broad to include higher life forms, it is irrelevant whether this Court believes that higher life forms such as the oncomouse ought to be patentable... there are a number of reasons why Parliament might want to encourage the sort of biomedical research that resulted in the oncomouse. But there are also a number of reasons why Parliament might want to be cautious about encouraging the patenting of higher life forms. In my view, whether higher life forms such as the oncomouse ought to be patentable is a matter for Parliament to determine. This Court's views as to the utility or propriety of patenting non-human higher life forms such as the oncomouse are wholly irrelevant.

I conclude that Parliament did not intend to include higher life forms within the definition of invention found in the *Patent Act*. In their grammatical and ordinary sense alone, the words "manufacture" and "composition of matter" are somewhat imprecise and ambiguous. However, it is my view that the best reading of the words of the Act supports the conclusion that higher life forms are not patentable. As I discuss below, I do not believe that a higher life form such as the oncomouse is easily understood as

either a "manufacture" or a "composition of matter". For this reason, I am not satisfied that the definition of "invention" in the *Patent Act* is sufficiently broad to include higher life forms. This conclusion is supported by the fact that the patenting of higher life forms raises unique concerns which do not arise in respect of non-living inventions and which are not addressed by the scheme of the Act. Even if a higher life form could, scientifically, be regarded as a "composition of matter", the scheme of the *Act* indicates that the patentability of higher life forms was not contemplated by Parliament. Owing to the fact that the patenting of higher life forms is a highly contentious and complex matter that raises serious practical, ethical and environmental concerns that the *Act* does not contemplate, I conclude that the Commissioner was correct to reject the patent application. This is a policy issue that raises questions of great significance and importance and that would appear to require a dramatic expansion of the traditional patent regime. Absent explicit legislative direction, the Court should not order the Commissioner to grant a patent on a higher life form.

[In the Federal Court of Appeal, whose decision is here reversed]...Rothstein J.A. concluded that the oncomouse was a "composition of matter", and therefore did not find it necessary to consider whether it was also a "manufacture". In coming to this conclusion, he relied on the following definition of "composition of matter" adopted by the majority of the U.S. Supreme Court in *Chakrabarty*:

... all compositions of two or more substances and ... all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.

In *Chakrabarty*, the majority attributed the widest meaning possible to the phrases "composition of matter" and "manufacture" for the reason that inventions are, necessarily, unanticipated and unforeseeable. Burger C.J. also referred to the fact that the categories of invention are prefaced by the word "any" ("any new and useful process, machine, manufacture, or composition of matter"). Finally, the Court referred to extrinsic evidence of Congressional intent to adopt a broad concept of patentability, noting that: "The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to `include anything under the sun that is made by man'".

I agree that the definition of invention in the *Patent Act* is broad. Because the Act was designed in part to promote innovation, it is only reasonable to expect the definition of invention to be broad enough to encompass unforeseen and unanticipated technology. I cannot however agree with the suggestion that the definition is unlimited in the sense that it includes "anything under the sun that is made by man". In drafting the *Patent Act*, Parliament chose to adopt an exhaustive definition that limits invention to any "art, process, machine, manufacture or composition of matter". Parliament did not define "invention" as "anything new and useful made by man". By choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the *Act*. This should be kept in mind when determining whether the words "manufacture" and "composition of matter" include higher life forms.

With respect to the meaning of the word "manufacture" (fabrication), although it may be attributed a very broad meaning, I am of the opinion that the word would commonly be understood to denote a non-living mechanistic product or process. For example, the Oxford English Dictionary defines the noun "manufacture" as the action or process of making by hand... The action or process of making articles or material (in modern use, on a large scale) by the application of physical labour or mechanical power. In *Chakrabarty*, "manufacture" was defined as the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.

In my view, while a mouse may be analogized to a "manufacture" when it is produced in an industrial setting, the word in its vernacular sense does not include a higher life form...In my opinion, a complex life form such as a mouse or a chimpanzee cannot easily be characterized as "something made by the hands of man".

As regards the meaning of the words "composition of matter", I believe that they must be defined more narrowly than was the case in *Chakrabarty*, namely "all compositions of two or more substances and ... all composite articles". If the words "composition of matter" are understood this broadly, then the other listed categories of invention, including "machine" and "manufacture", become redundant. This implies that "composition of matter" must be limited in some way. Although I do not express an opinion as to where the line should be drawn, I conclude that "composition of matter" does not include a higher life form such as the oncomouse.

Patenting higher life forms would involve a radical departure from the traditional patent regime. Moreover, the patentability of such life forms is a highly contentious matter that raises a number of extremely complex issues. If higher life forms are to be patentable, it must be under the clear and unequivocal direction of Parliament. For the reasons discussed above, I conclude that the current Act does not clearly indicate that higher life forms are patentable. Far from it. Rather, I believe that the best reading of the words of the Act supports the opposite conclusion -- that higher life forms such as the oncomouse are not currently patentable in Canada.

The patenting of higher life forms raises special concerns that do not arise in respect of non-living inventions. Unlike other inventions, biologically based inventions are living and self-replicating. In addition, the products of biotechnology are incredibly complex, incapable of full description, and can contain important characteristics that have nothing to do with the invention. In my view, the fact that the *Patent Act* in its current state is ill-equipped to deal appropriately with higher life forms as patentable subject matter is an indication that Parliament never intended the definition of invention to extend to this type of subject matter.

The existence of the *Plant Breeders' Rights Act* is relevant to the issue of whether Parliament intended higher life forms to be patentable under the Patent Act for several reasons. First, it is argued that had plants been patentable under the Patent Act, it would have been unnecessary for Canada to pass a *Plant Breeders' Rights Act* to begin with. A related argument was put forward by the appellant, who submits that although Parliament passed "special legislation" to provide protection for plant breeders, it made no move to amend the *Patent Act* or to adopt other special legislation to provide for the protection of forms of animal life. In addition, in the face of Marceau J.A.'s opinion in *Pioneer Hi-Bred* (speaking for a majority of the Federal Court of Appeal) that the Patent Act had never been intended or understood to include crossbred plants -- one form of higher life -- in patentable subject matter, Parliament did nothing to alter that intention or understanding. A final point is that the *Plant Breeders' Rights Act* was passed in recognition that the *Patent Act* was not tailored to plants due to their unique characteristics. Since other higher life forms share many of these characteristics, it is reasonable to assume that Parliament would choose to protect these life forms through legislation other than the *Patent Act* or through an amended *Patent Act* that is better suited to the subject matter.

The respondent notes that the Commissioner of Patents has since 1982 accepted that lower life forms come within the definitions of "composition of matter" and "manufacture" and has granted patents on

such life forms accordingly. It adds that the Patent Act does not distinguish, in its definition of invention, between subject matter that is less complex (lower life forms) and subject matter that is more complex (higher life forms). It submits that there is therefore no evidentiary or legal basis for the distinction the Patent Office has made between lower life forms such as bacteria, yeast and moulds, and higher life forms such as plants and animals.

The patentability of lower life forms is not at issue before this Court, and was in fact never litigated in Canada. In *Abitibi*, the Patent Appeal Board rejected the prior practice of the Patent Office and issued a patent on a microbial culture that was used to digest, and thereby purify, a certain waste product that emanates from pulp mills. The decision, in this regard, was based largely on the U.S. Supreme Court's decision in *Chakrabarty*, and on the practice in Australia, Germany and Japan. Having noted that judicial bodies in these countries altered their interpretation of patentable subject matter to include micro-organisms, the Board observed: "[o]bviously the answer to the question before us, which once had seemed so clear and definite has become clouded and uncertain". The Board was careful to limit the subject matter to which the decision would apply:

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

Though this Court is not faced with the issue of the patentability of lower life forms, it must nonetheless address the respondent's argument that the line between higher and lower life forms is indefensible. As discussed above, I am of the opinion that the unique concerns and issues raised by the patentability of plants and animals necessitate a parliamentary response. Only Parliament has the institutional competence to extend patent rights or another form of intellectual property protection to plants and animals and to attach appropriate conditions to the right that is granted. In the interim, I see no reason to alter the line drawn by the Patent Office. The distinction between lower and higher life forms, though not explicit in the *Act*, is nonetheless defensible on the basis of common sense differences between the two. Perhaps more importantly, there appears to be a consensus that human life is not patentable; yet this distinction is also not explicit in the *Act*. If the line between lower and higher life forms is indefensible and arbitrary, so too is the line between human beings and other higher life forms.

[On the question of patentability of lower life forms] it is difficult to say whether the Canadian courts would have followed the approach of the majority of the U.S. Supreme Court in *Chakrabarty*, or whether the approach of the minority would have been preferred. Regardless of the wisdom of the decision, it is now accepted in Canada that lower life forms are patentable. Nonetheless, I agree with the appellant that this does not necessarily lead to the conclusion that higher life forms are patentable, at least in part for the reasons that it is easier to conceptualize a lower life form as a "composition of matter" or "manufacture" than it is to conceptualize a higher life form in these terms. First, as noted in *Abitibi*, micro-organisms 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". The same cannot be said for plants and animals. [Citing *In Re Bergy, Coats, and Malik*, 195 USPQ 344 (1977)] "The nature and commercial uses of biologically pure cultures of microorganisms ... are much more akin to inanimate chemical compositions such as reactants, reagents, and catalysts than they are to horses and honeybees or raspberries and roses ..."

Excerpts from the Dissenting Reasons for Judgment, delivered by BINNIE J.- -

The biotechnology revolution in the 50 years since discovery of the structure of DNA has been fuelled by extraordinary human ingenuity and financed in significant part by private investment. Like most revolutions, it has wide ramifications, and presents potential and serious dangers as well as past and future benefits. In this appeal, however, we are only dealing with a small corner of the biotechnology controversy. We are asked to determine whether the oncomouse, a genetically modified rodent with heightened genetic susceptibility to cancer, is an invention. The legal issue is a narrow one and does not provide a proper platform on which to engage in a debate over animal rights, or religion, or the arrogance of the human race.

The oncomouse has been held patentable, and is now patented in jurisdictions that cover Austria, Belgium, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, The Netherlands, Portugal, Spain, Sweden, the United Kingdom and the United States. A similar patent has been issued in Japan. New Zealand has issued a patent for a transgenic mouse that has been genetically modified to be susceptible to HIV infection. Indeed, we were not told of any country with a patent system comparable to Canada's (or otherwise) in which a patent on the oncomouse had been applied for and been refused.

If Canada is to stand apart from jurisdictions with which we usually invite comparison on an issue so fundamental to intellectual property law as what constitutes "an invention", the respondent, successful everywhere but in Canada, might expect to see something unique in our legislation. However, one looks in vain for a difference in definition to fuel the Commissioner's contention that, as a matter of statutory interpretation, the oncomouse is not an invention. The truth is that our legislation is not unique. The Canadian definition of what constitutes an invention, initially adopted in pre-Confederation statutes, was essentially taken from the United States Patent Act of 1793, a definition generally attributed to Thomas Jefferson. The United States patent on the oncomouse was issued 14 years ago. My colleague, Bastarache J., acknowledges that the fertilized, genetically altered oncomouse egg is an invention under our *Patent Act*. 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. Subject matter patentability, on this view, is lost between two successive stages of a transgenic mouse's genetically pre-programmed growth. In my opinion, with respect, such a "disappearing subject-matter" exception finds no support in the statutory language.

A patent, of course, does not give its holder a licence to practise the invention free of regulatory control (any more than an unpatented invention enjoys such immunity). On the contrary, the grant of a patent simply reflects the public interest in promoting the disclosure of advancements in learning by rewarding human ingenuity. Innovation is said to be the lifeblood of a modern economy. We neglect rewarding it at our peril. Having disclosed to the public the secrets of how to make or use the invention, the inventor can prevent unauthorized people for a limited time from taking a "free ride" in exploiting the information thus disclosed. At the same time, persons skilled in the art of the patent are helped to further advance the frontiers of knowledge by standing on the shoulders of those who have gone before.

It is true, of course, that in 1869, when the post-Confederation *Patent Act* was passed, Parliament did not contemplate genetically engineered "higher life forms". Parliament in 1869 did not contemplate genetically engineered "lower life forms" either, although in recent years Canadian patents have regularly

been issued for such inventions. (My colleague, Bastarache J. affirms that "lower life" forms will continue to be patentable.) Nor did Parliament in 1869 contemplate moon rockets, antibiotics, telephones, e-mail or hand-held computers. The proper question is not whether Parliament intended to include "oncomice" or "higher life forms" or biotechnology generally in patent legislation, but whether Parliament intended to protect "inventions" that were not anticipated at the time of enactment of the *Patent Act*, or indeed, at any time before the claimed invention.

...healthcare is the major beneficiary of biotechnology. "More than 90 percent of the advanced biotechnology products on the world market are related to health. It is expected that about three-quarters of global biotechnology demand will continue to be in this area". Medical research inevitably relates to life, and its products will often impinge, directly or indirectly, on "higher life forms". The practical application of biotechnology is in large measure the preoccupation of enterprises that need to profit from their successes to finance continued research on a broader front. These successes are few and far between. It seems Du Pont spent about US \$15 million to fund the oncomouse. The patent system offers the only protection available for the intellectual product of this research, and thus, the only hope of a fair return against the great financial risks that investment in biotechnology entails.

The majority of the Federal Court of Appeal in this case found persuasive the interpretative principles applied by the United States Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In that case the inventor had genetically engineered bacteria capable of breaking down crude oil spills. The invention was environmentally useful but the bacteria, necessarily, were alive.

The proper distinction was not living versus inanimate but between the discovery of a product of nature (whether living or not) versus a human-made invention. Burger C.J. did not subscribe to the notion that patents could be obtained for "anything under the sun that is made by man". In fact, he specifically states that "[T]his is not to suggest that [the *Act*] has no limits or that it embraces every discovery". On the contrary, the patent issued because its subject matter was held to be a "manufacture" or "composition of matter" within the statutory test laid down by Congress.

The appellant Commissioner says the Federal Court of Appeal erred by allowing a patent on a "higher intelligent life form", but he himself offers no definition of an "intelligent" life form, much less does he identify a dividing line between a "higher" intelligent life form and a "lower" intelligent life form. The *Patent Act* does not distinguish, in its definition of invention, between subject matter that is less complex ("lower life forms") and subject matter that is more complex ("higher life forms"). The degree of complexity is not a criterion found in the Act or in the jurisprudence in determining patentability. The distinction between "lower life forms" and "higher life forms" in its application to s. 2 is the invention of the Patent Office.

While refusing to issue a patent for a higher animal life form in this case, the Commissioner has issued patents under the *Patent Act* for higher plant life forms...much of the Commissioner's argument turned on the lack of the regulatory framework that is necessary, he says, to address the ethical and scientific issues raised by genetic research. The argument is that because in his view genetic patents should be regulated, and because the Patent Act fails to do the job, Parliament cannot in 1869 have intended to grant patents for genetically engineered "higher" life forms. With respect, I do not agree.

First, we all probably have strong views that certain activities or things should be regulated. Some say contraceptive devices should not be patented because their use is immoral and unregulated. Others might wish to deny patents to environmentally risky chemical compositions for which, in their view, there is no adequate regulation. On the other hand, others feel that the use of potentially dangerous inventions like explosives and firearms should not be regulated. I do not think patents should be denied as a protest against perceived shortcomings in regulatory structures. The opponents of such patents should address themselves to Parliament, not the courts.

If a certain subject matter is unpatentable as a matter of law, inventors who do carry on inventing will gravitate toward alternative sources of protection. The most obvious would be trade secrets protection. The problem with this alternative, in terms of the public interest, is that the public would lose the *quid pro quo* of public disclosure that they receive under patent law.

Lacking legal protection against unauthorized appropriation of ideas, ingenious people may tend to hide and hoard the products of their ingenuity rather than disclose them for others to build on that knowledge. The "hide and hoard" mentality was the very mischief the *Patent Act* was aimed at.

There are, in other words, many policy implications of excluding patent protection as well as the policy implications of inclusion relied upon by the appellant Commissioner. The balance between the competing interests is for Parliament to strike.