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MUS MUSCULUS AND *HOMO SAPIENS*: MURINE METAPHYSICS AND THE CANADIAN SUPREME COURT

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This article examines the patentability of genetically engineered higher life forms in Canada and Singapore by reference to the recent decision of the Canadian Supreme Court on the patentability of a genetically engineered laboratory mouse. The Canadian Supreme Court, rather than examining the policy behind patent protection, addressed this question primarily through the lens of statutory interpretation. This article discusses the reasoning of the Canadian Supreme Court and considers its application in Singapore.

I. INTRODUCTION

The year 2002 turned out to be quite a year for life sciences, genetic engineering and the humble and overworked laboratory mouse.[1] In December that year, the draft genome of "Black 6", a type of laboratory mouse was published in *Nature*.[2] The elucidation of the mouse genome caused enormous excitement. It represented, in many ways, the culmination of the mouse in the service of mankind in the field of medical and scientific research. Knowledge of the mouse genome, it has been said, will help scientists, through comparative genomics, to unravel the mysteries of the human genome, the first draft of which was produced only one year earlier.[3] That the first draft of the mouse genome should be completed so quickly after the first draft of the

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1 *Mus musculus.*

2 *Nature*, No. 420, 5 December 2002. See also *New Scientist*, Vol. 176, No. 2372, 7 December 2002, for a short report on the mouse genome.

3 See *Nature*, No. 409, 15 February 2001 for the publication of the human genome. The Mouse Genome Sequencing Consortium in its report published in *Nature, supra* note 2, states at 520 that "the sequence of the mouse genome is a key informational tool for understanding the contents of the human genome and a key experimental tool for biomedical research . . ." See also Wade, *Life Script. How the Human Genome Discoveries Will Transform Medicine and Enhance your Health* (United States: Simon & Schuster, 2001) at 55.

human genome is testimony to the importance that the project represented to the scientific community in the new millennium.[4]

But the story that led to the achievement in 2002 started much further back.[5] The humble mouse, first a pest, became a pet around the 18th century or possibly earlier still. The creation of fancy, hybrid mice by hobbyists and the observation of the manner in which traits such as colour were passed on to succeeding generations contained tantalizing hints of genetics and the natural laws of inheritance.[6] By the early 20th century, fancy mice were already being bred as experimental animals for laboratory use and the long service of the mouse in aid of man had begun.[7] The discovery, which more than any other, helped to jump start the modern biotechnology revolution came in 1953 with the publication of the structure of the DNA molecule.[8] That breakthrough, together with other discoveries relating to the coding and the cell protein transcription mechanism, led to the development of modern genetic engineering techniques that have now resulted in the development of transgenic animals[9] and plants, gene therapy, stem cell technology, cloning and the elucidation of the human and mouse genome. The ever broadening scope for industrial and practical applications of the new knowledge has in turn raised difficult questions of law and policy. Some of these are concerned with the need to control and regulate the use of the new science and technology, while others are concerned with the need to ensure adequate protection of new practical applications from unauthorised use and exploitation by third parties. Still others are concerned with the impact of the technology together with intellectual property rights on third world poverty, the environment and issues pertaining to globalisation.

This article looks at the patentability of genetically modified life forms from the perspective of the recent decision of the Canadian Supreme Court

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4 In fact the Human Genome Project which started in 1990 identified the mouse as one of the central model organisms. The Mouse Genome Sequencing Consortium was set up in 1999 with the goal of sequencing the mouse genome. See *Nature, supra* note 2 at 520.

5 The common evolutionary ancestor of mice and humans, *Eomaia scansoria*, is thought to have lived some 75–125 million years ago. It is the animal from which modern placental animals are thought to have evolved.

6 See *Nature*, *supra* note 2 at 520. The laws of inheritance were in fact discovered by Gregor Mendel in the mid-19th century by observing how characteristics of peas were passed on and inherited.

7 For a detailed timeline of the history of the mouse in genetics, see the website of *Nature*, online: Nature <http://www.nature.com/nature/mousegenome/archive.html>.

8 Watson and Crick, *Nature*, 2 April 1953. Given the important role that the mouse has played in life sciences research and the development of biotechnology, it is fitting that in the penultimate year before the 50th anniversary of the discovery of the structure of DNA, the genome of the mouse was published to the world.

9 The first transgenic mouse was produced in 1982 by a team led by Richard Palmiter and Ralph Brinster. This mouse had a gene inserted whilst an embryo which resulted in increased size. See the mouse time-line at the website of *Nature, supra* note 7.

on the "oncomouse" and discusses whether such transgenic animals might be patentable in Singapore.

II. The Onco-Mouse Invention

The oncomouse was developed in the early 1980s by researchers at Harvard.[10] The invention involved the insertion of a gene associated with the development of malignant tumors into the genome of a laboratory mouse. The idea behind this was to produce a line of "oncomice" with a much increased propensity to the development of cancer.[11] Once transgenic oncomice were produced, they could be used in carcinogenicity studies to test for carcinogenic substances as well as to aid in the evaluation of the efficacy of cancer-treating products.

The process whereby this was achieved involved the construction of an "activated oncogene sequence." An oncogene is a gene which expresses a protein involved in growth and division of cells.[12] Elevated amounts of the protein result in an increased likelihood that the mammal will develop cancer. In essence, the inventors developed an oncogene that was "active" or "switched on" so that the incorporation of the oncogene into an animal's genome would lead to an increase in the production of the protein. The activated oncogene sequence was made by fusing a promotor sequence of DNA from a virus with the oncogene so as to produce the activated oncogene.[13] The next step was to insert the activated oncogene sequence into a suitable

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[10] Namely, T. Stewart and P. Leder.

[11] Cancer (malignant tumor) essentially involving abnormal cell division and growth.

[12] There are many different types of oncogenes. Oncogenes are often present in the body as "protooncogenes". Mutations in the protooncogene results in malignancy. Examples of oncogenes include the *myc* gene and the *ras* gene. See the explanation by Bains, *Biotechnology From A to Z* (United Kingdom: Oxford University Press, 1998) [Bains] at 276.

[13] See the description of an activated oncogene sequence by the Canadian Court of Appeal in *President and Fellows of Harvard College v. Commissioner of Patents* [2000] 4 F.C. 528 at fn. 62 [*Harvard College* (C.A.)]. A promotor is the section of DNA in a gene that signals the start of transcription (protein synthesis). It is the part at which RNA polymerase binds at the start of transcription. RNA polymerase is the enzyme that separates the two strands of the double helix DNA molecule as a prelude to transcription of a complementary mRNA strand during protein synthesis. See definitions in *Oxford Dictionary of Biology*, 1996 and the *McGraw Hill Dictionary of Bioscience*, 1997. The oncogene in question is the *myc* gene and the promotor is taken from the MMTV virus. See Bains, *supra* note 12 at 277 where it is explained that the activated oncogene expresses itself in the mammary gland of the mouse. See also the patent claims filed in Canada. Claim 6 related to "a mammal wherein said oncogene sequence comprises a coding sequence of the *c-myc* gene". Claim 8 related to a mammal wherein "said viral promotor sequence comprises a sequence of an MMTV promotor sequence". The patent claims are set out in the appendix to the Canadian Court of Appeal decision, *infra*. Note that the invention was not restricted to use of the *myc* oncogene as other activated oncogenes could also be used. Indeed, Claim 17 specifically refers to 33 different activated oncogene sequences.

carrier as a prelude to its incorporation into the genome of the mouse. The carriers used by the inventors were "plasmids".[14] The DNA of the plasmid was cut using restriction enzymes[15] and the activated oncogene spliced into the DNA of the plasmid.[16] The transformed plasmid was then injected into a fertilized mouse egg at a site called "the male pronucleus".[17] It was preferable for the transformed plasmid to be injected into the fertilized egg whilst the egg was still in the one cell (zygote) stage and in any case no later than the eight cell stage. This was because if the transformed plasmid was able to incorporate the activated oncogene into the genome of the fertilized mouse egg at the one cell stage, it should result in every cell of the mouse, which developed from that zygote, having the activated oncogene.[18] The next step was to transfer the transformed fertilized egg to a female "host" or "surrogate" mouse and to allow the embryo to develop to full term. After the mouse was born, its cells were examined to see if they had taken up the activated oncogene. If all the cells had the activated oncogene, the mouse, termed a founder mouse,[19] was mated with an uninjected mouse. Following the natural rules of Mendelian inheritance, 50% of the resulting mice would have all of their cells affected by the activated oncogene. These oncomice could then be subject to laboratory controlled carcinogenicity studies.[20]

The patent claims filed in Canada mirrored the inventive pathway described above. From the perspective of the inventors, it was important to obtain protection for both the process used to obtain oncomice as well as the oncomice themselves. A patent over the process but not oncomice would mean that there would be little that the patentee could do to stop a person producing more oncomice by simply breeding oncomice. It was also important to claim protection for the use of the process to produce other types of oncomammals—otherwise the patent could be bypassed simply by substituting another mammal for the mouse. Further, since the inventive

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[14] Plasmids are small circular bits of DNA found inside bacteria. They have the ability to move out of one bacterium and into another. This ability makes them useful as vectors to carry foreign genes into host organisms.

[15] These are enzymes that act as "molecular scissors" in that they have the ability to cleave strands of DNA at particular sites.

[16] This is usually done with the help of an enzyme called DNA ligase.

[17] The male "pronucleus" refers to the nucleus of the sperm which for a short time exists as a separate entity in the egg after fertilization. See the description in the Canadian patent disclosure set out in the judgment Nadon J. in *President and Fellows of Harvard College v. Canada (Commissioner of Patents)* [1998] 3 F.C. 510 [*Harvard College*].

[18] Claim 1 of the Canadian Oncomouse patent covered: "A transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage."

[19] It appears that only two males out of 28 mice had successfully incorporated the oncogene—a success rate of about 7%. See the Canadian Court of Appeal decision in *Harvard College* (C.A.), *supra* note 13 at fn. 64.

[20] See the Court of Appeal of Canada judgment in *Harvard College* (C.A.), *supra* note 13.

process could also be applied to other oncosequences and promotors aside from the *myc* gene and the promotor from the M.M.T.V. virus that typified the invention, it was important that these were also covered. Broad claims were necessary, otherwise, given the nature of the invention, it would be relatively easy to bypass the patent through substitution.[21] The claims fell into two groups. The first group (claims 1 to 12) covered various forms of transgenic non-human mammals (essentially the founder mammal and its progeny that were affected by the oncogene). Some of these are set out below to illustrate the width of the product claims.

> Claim 1 covered "[a] transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence introduced into said mammal, or an ancestor of said mammal, at an embryonic stage."
> Claim 2 covered "[t]he mammal of claim 1, a chromosome of said mammal including an endogenous coding sequence substantially the same as a coding sequence of said oncogene sequence."
> Claim 3 covered "[t]he mammal of claim 2, said oncogene sequence being integrated into a chromosome of said mammal at a site different from the location of said endogenous coding sequence."
> Claim 4 covered "[t]he mammal of claim 2 wherein transcription of said oncogene sequence is under the control of a promoter sequence different from the promoter sequence controlling the transcription of said endogenous coding sequence".
> Claim 6 covered "[t]he mammal of claim 1 wherein said oncogene sequence comprises a coding sequence of the c-myc gene".
> Claim 8 covered "[t]he mammal . . . wherein said viral promoter sequence comprises a sequence of an M.M.T.V. promoter".
> Claim 10 covered "[t]he mammal of claim 1 wherein transcription of said oncogene sequence is under the control of a synthetic promoter sequence".
> Claims 11 covered "[t]he mammal of claim 1, said mammal being a rodent".
> Claim 12 covered "[t]he mammal of claim 11, said mammal being a mouse."

The second group (claims 13–26) essentially set out claims relating to the process of producing transgenic non-human oncomammals as well their use in carcinogenicity studies. Some of these claims are also set out below to further illustrate the scope of the claimed inventions.

> Claim 13 covered "[a] method of testing a material suspected of being a carcinogen comprising exposing the mammal of claim 1 to said material and detecting neoplasms as an indication of carcinogenicity."

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[21] The Canadian patent claims are taken from the appendix to the Canadian Court of Appeal decision in *Harvard College* (C.A.), *supra* note 13.

Claim 14 covered "[a] method of producing a transgenic cell culture comprising: a) introducing an activated oncogene sequence into pluripotent cells of a mammalian embryo; b) allowing said embryo to develop into an adult animal; and c) culturing somatic cells of said animal".
Claim 15 covered "[a] method of producing a transgenic mammal having an increased probability of developing neoplasms, said method comprising introducing into a mammal embryo an activated oncogene sequence".
Claim 17 covered "[t]he method of claim 15 wherein said activated oncogene sequence comprises a DNA sequence from one of the oncogene sequences: src, yes, fps, abl, ros, fgr, erbB, fms, mos, raf, Ha-ras-1, Ki-ras 2, Ki-ras 1, myc, myb, fos, ski, rel, sis, N-myc, N-ras, Blym, mam, neu, erbA1, ra-ras, mht-myc, myc, myb-ets, raf-2, raf-1, Ha-ras-2, erB".
Claim 18 covered "[u]se of the transgenic mammal of claim 1 in a method of testing a material suspected of altering neoplastic development, said method comprising treating said mammal with said material and detecting a reduced or increased incidence of development of neoplasms, compared to an untreated mammal of claim 1, as an indication of said alteration".
Claim 24 covered "[p]lasmid having ATCC Accession No. 39749."[22]
Claim 26 covered "[u]se of a transgenic mammal according to any one of claims 1 to 12 to test a material suspected of altering neoplastic development in a mammal."

III. The History of the Oncomouse Litigation in Canada

The oncomouse was developed in the early 1980s. The first patent claims were filed in the United States where a patent was granted as early as 1988. Patent applications were also filed in other countries including the member states of the European Patent Convention, Japan and Canada.[23] The

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[22] This is likely to be a reference to the accession number of a culture deposit made to facilitate disclosure. See generally the Budapest Treaty on the International Recognition of the Deposit of Micro-organisms for the Purposes of Patent Procedure 1977.

[23] The European application process commenced in 1985 and has yet to be concluded! In July 1989, the Examining Division rejected the application on the basis of Article 53(b) and 83 of the European Patent Convention 1973 ("E.P.C.") Article 53(b) prevents the patenting of plant or animal varieties or essentially biological processes for the production of plants or animals not being microbiological processes or the products thereof. Article 83 requires the invention to be disclosed in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art. An appeal was then brought to the Board of Appeals. In October 1990, the Board of Appeal allowed the appeal on the Article 83 finding. It also remitted the application back to the Examining Division for further examination as to whether the oncomouse was an animal variety within Article 53(b) of the E.P.C. At the re-examination, the Examining Division also had to consider the application of the *ordre public* bar in Article 53(a). In 1991, the Examining Division granted the patent on the basis that the invention did not relate to an

Canadian oncomouse application was filed in June 1985 and originally comprised 24 claims. The patent examiner rejected the bulk of the claims (18 out of 24) which then led to a request for a review. At the review, the number of claims was increased to 26. The patent examiner rejected all of the product claims (claims 1 to 12) but allowed all of the process related claims (claims 13 to 26). The product claims were rejected on the basis that they did not cover inventions and therefore were bad for claiming non-statutory subject matter. The decision was affirmed by the Commissioner of Patents of the Patents Appeal Board. From here, the matter reached the Canadian courts. In 1998, the Federal Court Trial Division dismissed the appeal and affirmed the Commissioner's decision.[24] The case was then taken to the Court of Appeal where a majority, in 2000, allowed the appeal in respect of the product claims.[25] This legal victory for the oncomouse product claims was, however, short-lived for the oncomouse patent soon found itself before the Canadian Supreme Court. In December 2002, a bare majority of the Supreme Court allowed the appeal and restored the decision of the Patent Commissioner.[26] All in, 13 judges had sat on the *Oncomouse* case in Canada. Seven agreed with the Patent Commissioner's decision whilst six did not! In this way, the judicial position of the product patent claims in the oncomouse litigation was finally resolved—but only by the barest of majorities.

IV. The Legal Issues Raised by Oncomouse

Given the invention pathway that led to the oncomouse and the scope of the patent claims that were filed, it is easy to see how a broad range of patent issues might have arisen. The case, especially in respect of the product claims, might have been fought on any number of fronts. In the first place there is the basic issue as to whether all or any of the claims related to "inventions". Any claim which did not cover an invention would be

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animal variety and did not offend against *ordre public*. See [1990] E.P.O.R. 501 and [1991] E.P.O.R. 525. Subsequently, opposition proceedings were commenced. The European Patent Office ("E.P.O.") Opposition Division ruled in November 2001 that whilst the oncomouse patent was valid, the patent was to be limited to transgenic rodents containing the additional cancer gene. This decision can in turn be taken to the E.P.O. Technical Board of Appeals. For a discussion, see Wei, *An Introduction to Genetic Engineering, Life Sciences and the Law* (Singapore: Singapore University Press, 2002) at para. 4.25 [Wei, *An Introduction to Genetic Engineering*].

24 *Harvard College, supra* note 17, Nadon J.

25 *Harvard College* (C.A.), *supra* note 13, Linden and Rothstein JJ.A., Isaac J.A. dissenting.

26 *Commissioner of Patents v. President and Fellows of Harvard College* [2002] S.C.C. 76 [*Harvard College* (S.C.)], L'Heureux-Dube, Gonthier, Iacobucci, Bastarache and LeBel JJ., Mclachlin C.J., Major, Binnie and Arbour JJ. dissenting. References to the Supreme Court decision follow the neutral citation format.

fundamentally bad as patentability is obviously restricted to inventions.[27] What is not so obvious, however, is just what is encompassed by the term "invention". Second, issues could have arisen as to whether policy might be relied upon, either as an aid to understanding the term "invention" or as an external matter that might justify or allow the refusal of a patent to things which otherwise would have satisfied the requirement of patentability.[28] Third, even if the product claims passed the threshold of invention, there might be tricky issues of patentability relating to novelty, inventive step (non-obviousness) and utility.[29] Fourth, even if there was patentable subject-matter, there might have been problems as to whether the disclosure requirements had been met. Disclosure of how the claimed invention works in the patent specifications is the *quid pro quo* for the grant of the patent monopoly. Whilst the patentee may not always be under a duty to disclose *all* information pertaining to the claimed invention, he will, at least, be under a duty to disclose *sufficient* information to enable a person skilled in the relevant art to perform the invention. In general terms, the wider and broader the claims, the more explanation that needs to be set out in the patent application. Claims which appear to stretch beyond what has been invented (or that which has been disclosed to have been invented) will naturally be viewed with suspicion.[30]

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[27] In Canada, subject matter to be patentable must be an invention according to the definition set out in section 2 of the Patent Act, R.S.C. 1985. Similarly, in Singapore, patentable material is confined to inventions. See section 13(1) of the Patents Act (Cap. 221, 1995 Rev. Ed. Sing.)

[28] One approach might be to define invention by reference to the broad policy objectives of patent law. Here, policy is internalised into the debate of what is covered by the expression "invention". Another may be to argue that policy considerations are external to the question of what is an invention and operates as a sort of bar to patentability. In Canada, there are no express statutory provisions which deny the grant of a patent on the grounds that the invention is contrary to policy or because it is against *ordre public*, for example, because of ethical or environmental or other concerns. As will be seen later, the Canadian courts have taken the view that under the current Canadian provisions, there is no room for policy considerations in deciding what is an invention under the Patent Act. Further, there are no *ordre public* type provisions in the Canadian legislation. In Singapore, whilst the approach to the meaning of invention is considered below, it is worth pointing out that there is a public policy bar against offensive, immoral or anti-social inventions set out in section 13(3) of the Singapore Patents Act.

[29] In Canada, a novelty and utility requirement is set out within the definition of invention in section 2. A requirement of non-obviousness is set out in section 28.3. In Singapore patentable subject-matter is defined in section 13(1) as an invention that is new, inventive and capable of industrial application. At first sight it appears as if utility or industrial applicability in Singapore are external to the question—what is an invention. In fact, it will be hard to construct a general definition of invention without incorporating some notion of practical applicability. See also footnote 117, *infra*.

[30] In Canada, section 27 provides that: "(1) The Commissioner shall grant a patent for an invention . . . if an application . . . is filed in accordance with this Act and all other requirements for the issuance of a patent under this Act are met. . . . (3) The specification of an invention must (a) correctly and fully describe the invention and its operation or use as contemplated by

Whilst some of these issues can overlap, the *Oncomouse* decision in the Supreme Court of Canada was eventually decided on a narrow basis: namely, whether there was patentable subject-matter in respect of the product claims. In short, were any of the product claims, inventions, within the meaning of the Patent Act of Canada?[31] This issue is considered below followed up by a discussion of what might be the position in Singapore should a similar case arise for consideration.

V. The Oncomouse Product Claims before the Canadian Supreme Court

A. *The Apparent Common Ground*

The ambit of the disagreement between the majority and minority decisions in the Canadian Supreme Court was of narrow compass. Both agreed that the question as to whether genetically engineered higher life forms such as the oncomouse *ought* to be patentable was irrelevant. The question was simply whether the statutory definition of invention was broad enough to cover higher life forms. This question was viewed essentially as a matter for statutory interpretation uncluttered by policy concerns—be these ethical, religious or environmental in nature. Under the Canadian Patent Act, section 2 states: "[I]nvention means any new and useful art, process, machine,

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the inventor; (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it; (4) The specification must end with a claim or claims defining distinctly and in explicit terms the subject-matter of the invention for which an exclusive privilege or property is claimed." In Singapore, this can be contrasted with section 25(4) which states that "the specification of an application shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art."

31 Note that the dissenting minority in the Supreme Court who would have upheld the patentability of the oncomouse product claims (claims 1–12) expressly stated that this did not mean that the claims must be allowed. Specifically, they held that claims 1–12 "ought to be considered by the Commissioner in accordance with the usual patent principles (note, for example, that the European Patent Office ultimately modified claim no. 1 to include only 'transgenic rodents' rather than, as claimed, 'transgenic non-human mammals')." See *Harvard College* (S.C.), *supra* note 26 at para. 115. Note that there was also a question as to the standard of review applicable to the Patent Commissioner's decision to refuse the product patent claims. Was the commissioner's decision to be accorded deference or was the standard simply one of correctness? The majority in the Canadian Supreme Court was of the view that on the actual facts, the appropriate standard was that of correctness: see para. 119. See also the Court of Appeal decision in *Harvard College* (C.A.), *supra* note 13, where the majority also preferred the less deferential standard of correctness. The majority in the Court of Appeal would have found for the inventors even if the more deferential standard of reasonableness simpliciter had been applied: see at para.179.

manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter."

The case turned largely on the interpretation of this statutory provision. Thus, Bastarache J. for the majority states that

> . . . 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.[32]

Bastarache J. continued:

> The sole question in this appeal is whether the words 'manufacture' and 'composition of matter' . . . 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. The grant of a patent reflects the interest of Parliament to promote certain manifestations of human ingenuity. As Binnie J. indicates . . . 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 . . .[33]

Similar views were expressed on this point by the dissenting minority in the Canadian Supreme Court. Binnie J., for the minority, agreed that the Commissioner of Patents was given no discretion to refuse a patent on the grounds of morality, public interest, public order, or any other ground if the statutory criteria are met.[34] The difference between the majority and

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[32] See *Harvard College* (S.C.), *supra* note 26 at para. 120. The majority also disagreed with the argument that section 40 of the Patent Act conferred on the Commissioner of Patent a discretion to deny a patent on public interest grounds. Section 40 provides that "whenever the Commissioner is satisfied that an applicant is not by law entitled to be granted a patent, he shall refuse the application . . ." In the Court of Appeal, Isaac J.A. (dissenting) held that one of the purposes of the Patents Act is that "the Commissioner must always be aware of, and take into account, the public interest in granting a patent. In a morally divisive case such as this, this Court should defer to the Commissioner's decisions where they are informed by considerations of public policy." See *Harvard College* (C.A.), *supra* note 13 at para. 54. The Canadian Supreme Court disagreed with this in Harvard College (S.C.), *supra* note 26 at para. 152.

[33] *Ibid*. at para. 153.

[34] *Ibid*. at para. 11. At para. 14, Binnie J. also points out that the failure of the Canadian Parliament to introduce an *ordre public* type bar (covering public morality, environmental

minority decision is that whilst both accepted that the matter was one of statutory interpretation, they came to diametrically opposite conclusions as to the scope of the definition of invention in its application to life forms.

As can readily be appreciated, the proper interpretation of the scope of ambiguous statutory words, which have potentially broad meanings, when the statute was enacted a long time ago, in the light of new unanticipated developments, is never easy. However unattractive this may be, much may inevitably depend on the point of view taken on the broad question of what is the policy objective of patent law. Indeed, Binnie J. took the view that the decision of the Patent Commissioner to adopt a restrictive definition (so as to exclude higher life forms) was one that was taken "for policy considerations unrelated to the Patent Act or its legitimate role or function".[35] Binnie J. continued that:

> The appellant Commissioner contends that the Federal Court of Appeal showed no understanding that this case is a 'harbinger of a new era'. The majority judgment, he says, looked narrowly at the case but failed to consider the broader context. What may have appeared as a small step for the oncomouse was, so to speak, a very large policy leap for patentability. Nevertheless, we must deal with the Patent Act as it is. Change ought to come through statutory amendment, not by the Court reading down the Patent Act to exclude non-human 'higher life forms' from patentability by creative statutory interpretation.[36]

How the majority and minority in the Supreme Court of Canada were able to reach such contradictory conclusions in the *Oncomouse* case on the meaning of invention, in the face of so much apparent common ground, is discussed next.

B. *The Majority Decision in the* Oncomouse *Case*

The statutory definition of invention in section 2 of the Canadian Act sets out five categories of invention: art, process, machine, manufacture and

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or health protection concerns) meant that Parliament was signaling "however passively that these important aspects of public policy would continue to be dealt with by regulatory regimes outside of the Patent Act."

[35] *Ibid*. at para. 35. Some support for this criticism of the majority's approach can be found in the fact that Bastarache J. for the majority did state at para. 155 that "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".

[36] *Ibid*. at para. 75.

composition of matter. It was accepted that in order for a higher life form to fit within the definition of invention, it had to be either a "manufacture" or a "composition of matter". A number of overlapping arguments were put forward in support of the decision that transgenic higher life forms were not "manufactures" or "compositions of matter". These are summarized below.

To begin with, there were arguments based on a close reading of the language and structure of section 2. The claimants naturally had tried to persuade the Canadian Supreme Court to follow *Diamond v. Chakrabarty*. In that case, the United States Supreme Court, also in a majority decision, adopted a broad flexible approach towards interpreting the phrases "composition of matter" and "manufacture" set out in the United States Patents Act.[37] In particular, the majority held that "composition of matter" should be given its ordinary dictionary meaning and that, thus construed, the expression covered "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."[38] In taking such a broad approach, the United States Supreme Court found strong support in the legislative history behind United States patent legislation. The Patent Act of 1793 was said to have embodied Thomas Jefferson's philosophy that "ingenuity should receive a liberal encouragement" and it was also noted that the reports accompanying the Patents Act 1952 informed that Congress intended statutory subject matter to include anything under the sun that is made by man.[39] Bastarache J. for the majority in the Canadian Supreme Court disagreed. Whilst the definition of invention under the Canadian Act was broad and extended to unforeseen and unanticipated technology, it was not unlimited and did not include anything under the sun made by man. It was reasoned that if this had been the intention of Parliament, the definition of invention would not have been limited to the five categories. In this way, the majority appear to have subscribed to the view that not all useful things made by man are necessarily to be regarded as inventions.[40] On this basis, the majority found that "manufacture" would commonly be understood as referring to a "non-living mechanistic product

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37 65 L. Ed. 2d 144.

38 65 L. Ed. 2d 144 at 149.

39 *Chakrabarty's* case involved a human made genetically engineered bacteria that was capable of breaking down crude oil. The U.S. Supreme Court held that since the claim was more than a discovery or a natural phenomenon that it was plainly patentable subject matter. The genetically altered bacteria was a non-naturally occurring manufacture or composition of matter that was a product of human ingenuity.

40 Bastarache J. at para. 187 concluded that "[i]t simply does not follow from the objective of promoting ingenuity that all inventions must be patentable regardless of the fact that other indicators of legislative intention point to the contrary conclusion."

or process". Manufacture, it was said, related to articles or materials, things whose vernacular meaning did not include higher life forms.[41]

Similarly, even though the majority accepted that invention was to be given a broad meaning, they held that the expression "composition of matter" had to be given a narrower definition than was the case in *Chakrabarty*. A number of reasons, internal to the construction of section 2, were offered in support. To begin with, there was the argument that the *Chakrabarty* definition of composition of matter was so broad that the other categories of invention would be redundant. To avoid redundancy a line had to be drawn. The majority did not, however, indicate where or how that line was to be drawn: instead it was content with the conclusion that wherever the line was, composition of matter did not include a higher life form such as an oncomouse.[42] In addition, there was an argument based on *ejusdem generis* type reasoning. The meaning of questionable words and phrases in a statute could be ascertained by reference to associated words and phrases and a collective term that completes an enumeration should be restricted to the same genus as the other words in the enumeration.[43] The majority accepted that since "machine" and "manufacture" did not ordinarily cover a "conscious sentient living creature", it could be inferred that "composition of matter" was best read as also not covering such life forms.[44] Further, there

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[41] The majority also referred to the old English case of *Hornblower v. Boulton* (1799) 101 E.R. 1285 which defined manufacture as "something made by the hands of man"—a definition not so far removed from the American idea of anything under the sun that is made by man. The majority doubted that a complex life form such as a mouse or chimpanzee could be characterized as something made by the hands of man. But, with respect, this surely was not the issue! The patent claims were limited to genetically transformed oncomammals. The scope of the claimed product inventions were limited in a way that excluded protection for mammals in their natural state. If the question is framed as: "whether a transgenic non-human mammal whose germ cells and somatic cells contain an activated oncogene sequence, introduced into the said mammal, or an ancestor of said mammal, at an embryonic stage, is something that could be characterized as made by the hands of man"—an affirmative answer is much more likely. After all, properly construed and *limited*, the claim is for a transgenic mammal, not occurring naturally in nature, and whose existence as a *transgenic* mammal depended on technical intervention by man.

[42] But query whether the redundancy argument can still be relied on if the expression "composition of matter" is intended to be general words that whilst encapsulating earlier words opens the door to other things. Are these things to be limited to things which are of the same or similar mould or might the intention be to leave the meaning at large? Much will depend here on whether some principle of *ejusdem generis* applies. This is considered below.

[43] See *Harvard College* (S.C.), *supra* note 26 at para. 161, citing Cote, *The Interpretation of Legislation in Canada*, 3rd ed. (Ontario Canada: Carswell, 2000).

[44] But what about "art" and "process"? A process may amount to invention even if the process involves use of living organisms. Indeed, the process patent claims in the *Oncomouse* case were accepted as valid by the Canadian courts. Query whether *ejusdem generis* type reasoning is applicable where there is no clear genus underlying the enumerated list of things. In any case, with due deference to the position under Canadian law, a view may be taken, at least in other jurisdictions, that *ejusdem generis* type reasoning does not apply if it is clear from the

was the argument that since "composition" involved the making of some form of "mixture" or "combination", it was not unreasonable to assume that it had to be the inventor who combined or mixed the various ingredients. The point behind this being that the majority were willing to draw a distinction between the making of the transformed fertilized egg through micro injection of the activated oncogene near the pronucleus and the subsequent development of that egg into an oncomouse. The former, might be a mixture and therefore a composition of matter in the context of patent law, the latter was not, because "the body of a mouse . . . does not consist of ingredients or substances that have been combined or mixed together by a person".[45] Continuing in this vein, the majority also held that a mouse, even an oncomouse, was more than mere composition of matter. As a higher life form, the common understanding would be that it possessed "qualities and characteristics that transcend the particular genetic material of which [it] is composed."[46]

Moving on, there was a series of arguments against patentability of higher life forms that went beyond the language of section 2.[47] Patenting of higher life forms was said to involve "special concerns that do not arise in respect of non-living invention". What, then, were these concerns? First, it was said that, unlike other inventions, biological inventions are living and

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context or the scope of the Act that Parliament did intend a broader meaning to be used and that the rule must give way "to the basic duty of the Courts to have regard to the mischief aimed at by the statutory provisions." See Cross, *Statutory Interpretation* (United Kingdom: Butterworths, 1976) at 116–7.

45 See *Harvard College* (S.C.), *supra* note 26 at para. 162. In so holding, the majority accepted that whilst the making of the fertilized oncoegg was a but-for cause of a mouse predisposed to cancer, the development of the oncomouse from the egg was a complex process that did not call for human intervention. Whilst this may be so, a definition of composition of matter that requires the inventor to have mixed or combined all the ingredients out of which the invention is made (or incorporated into) seems overly restrictive in the light of the general goal of patent to law to encourage industrial and technological development.

46 *Ibid*. at para. 163. Thus, even if the inventors were responsible for the "composition of matter" out of which the body of the oncomouse was made, the oncomouse was still not composition of matter because as a higher life form it was composition of matter *plus* other qualities and characteristics. Whilst this "composition plus" argument may well have a lot going for it in the context of religious or philosophical discussion, it is queried whether it fits in with the scheme of patent legislation. After all, the majority accepted at para. 185 that "there is no doubt that two of the central objects of the Act are to "advance research and development and to encourage broader economic activity." The majority did not, however, accept that this meant that anything under the sun made by man is patentable. In particular they were of the view that if Parliament had wanted patents to be available for higher life forms that they would have used words in the definition of invention that would in common usage have referred to higher life forms.

47 The majority reiterated that statutory interpretation cannot be based solely on the wording of the legislation and that the words of an Act are "to be read in their entire context and in their grammatical and ordinary sense harmoniously with the scheme of the Act, the object of the Act, and the intention of Parliament. *Ibid*. at para. 154.

self-replicating[48] Second, the products of biotechnology are complex and incapable of full description and can contain important characteristics that have nothing to do with the invention.[49] Developing this theme further, the majority found that there were broader concerns that did relate to patentability and the scheme of the Patent Act. One such concern was the impact of patent protection on Canada's agricultural industry. Since higher life forms self-replicate: the grant of a product patent on the life form will cover not just the particular plant, seed or animal sold, but all of its progeny that contains the patented invention. Concerns that this could lead to a significant increase in the scope of patent rights had in fact been voiced by the Canadian Biotechnology Advisory Committee (C.B.A.C.) which recommended that a farmers' privilege provision be included in the Patent Act.[50] Another concern related to the fact that self-replicating higher life forms could result in cases of innocent infringement as replication might occur without the knowledge of the defendant in possession of the life form. This led the

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[48] This is a variant of the composition of matter "plus" argument. But what about lower life forms? Even the simplest and smallest bacteria or virus is alive, at least in the sense that it seeks replication.

[49] Query whether complexity *per se* is a reason for holding that something is not patentable. Query also the problems with description. Written description may be especially difficult with genetically engineered micro-organisms. This is why a deposit system to facilitate disclosure has been established by the Budapest Treaty for the Deposit of Micro-organisms 1977. See generally, Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology, Fundamentals of Global Law, Practice and Strategy* (Oxford: Oxford University Press, 1999) at 228–9. In any case, it should be stressed that the Canadian courts had no difficulties with accepting the process patent claims in the *Oncomouse* case. Same or similar difficulties with full description are likely to have occurred. See, for example, claim 13 set out above which was found to be patentable and which related to a method of testing carcinogens on oncomammals as set out in claim 1, claim 1 being one of the product claims found to be unpatentable! Further, claims 20–24 (accepted as patentable) related to plasmids, disclosed by reference to accession numbers. As to the point that life forms may have characteristics (physical or otherwise) that have nothing to do with the invention, a response might be that those characteristics are irrelevant to patent law if the claimant is not intending to cover those characteristics *per se*.

[50] Note that the C.B.A.C. in fact concluded that higher life forms should be patentable and that a farmers privilege be introduced so that a farmer can collect and reuse seeds harvested from patented plants and to breed patented animals for their own use, so long as these were not sold for commercial breeding purposes. The C.B.A.C. report, whose full title is "Patenting of Higher Life Forms and Related Issues. Report to the Government of Canada Biotechnology Ministerial Coordinating Committee", was published in June 2002. The C.B.A.C. Report is summarised later in this article. Conversely, the claimants in the *Oncomouse* case must have felt it vital to obtain protection over the oncomammals as otherwise there would be little that could be done to prevent a person breeding copies from the oncomammals. Such an act of breeding is unlikely to infringe the process patents. In any case, might it be said that issues relating to the appropriateness of the scope of patent rights in their application to biotechnology are more a matter for law reform rather than a matter from which inferences can be drawn as to whether higher life forms are covered by existing law in the first place?

C.B.A.C. to recommend that provisions be enacted to protect the "innocent bystander" in the case of plants, seeds and animals capable of reproduction. Still yet another concern was the danger that patent protection on higher life forms might deter further innovation by third parties in the area covered by the patent. To reduce this possibility, the C.B.A.C. recommended that a research and experimental use exception be introduced into the Patent Act.[51] An even more fundamental worry was the danger that patents for higher life forms held, via slippery slope reasoning, for human life. The majority felt that concerns that patents for higher life forms might open the door for patents over human life were not adequately met by section 7 of the Canadian *Charter of Rights and Freedoms*. The latter did not deal specifically with invention and simply provided that everyone has the right to life, liberty and security of the person.[52] In any case, even if section 7 prevented the patenting of whole human beings, the majority were quick to point out that this left open problems with human beings at earlier stages of development such as foetuses and so forth. Indeed, the C.B.A.C. in its report had recommended that no patent should be granted over human bodies at any stage of development.[53] Such a recommendation, the majority felt, was not adequately secured by reference to section 7 of the *Charter*.[54] The point behind these observations was to reinforce the argument of the majority that the Patent Act of Canada was not in its present form "well suited to address the unique characteristics possessed by higher life forms". In short, rather than hold that genetically engineered higher life forms can be patentable subject matter and to leave it to courts and Parliament to develop

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[51] In Singapore, a statutory experimentation defence can be found in section 66(2)(b) of the Patents Act (Cap. 221, 2002 Rev. Ed. Sing.). Whilst there is much to be said for such a defence (and indeed a clearer and more detailed defensive provision), the question as to whether there should be such a defence and its scope should not affect the question as to whether higher life forms are patentable. Further, the fact that broad product patent claims may mean that subsequent innovation in that field will need to be licensed is not new. The majority recognised this but felt that the impact may be more severe in the case of products of biotechnology. But, query whether this is true in any breakthrough technology that opens new areas for exploitation. Such problems are likely to have been common in many chemical and pharmaceutical areas.

[52] See *Harvard College* (S.C.), *supra* note 26 at paras. 177–80. The dissenting minority took a different view on this holding in that "it has been established for over 200 years that people cannot at common law own people. . .The issue of whether a human being is a composition of matter does not therefore arise under the Patent Act. If further reinforcement is required, ss. 7 and 15 of the Canadian Charter of Rights and Freedoms would clearly prohibit an individual from being reduced to a chattel of another individual." See *Harvard College* (S.C.), *supra* note 26 at para. 40.

[53] See also the European Directive on Biotechnology, Directive 98/44/EC which sets out a similar bar in Article 5.

[54] *Ibid*. at paras. 177–183. Other problems with allowing patents for higher life forms were said to be the problems of patents for body parts and genes.

refinements, qualifications and exceptions, the majority preferred to disallow patents on higher life forms in their entirety.[55] This conclusion could not be justified on policy grounds (since it was accepted that whether or not higher life forms should be patented was irrelevant). Instead, it had to be justified on the basis that because special provisions on qualifications and exceptions were not there, Parliament could not have intended higher life forms to be patentable under the current Patent Act.

The majority's conclusion that Parliament did not intend higher life forms to be patentable under the current Canadian Patent Act was further reinforced by the enactment of the Plant Breeders' Rights Act in 1990 to protect plant varieties.[56] That Act was passed in Canada at least in part because of the decision in *Pioneer Hi-Bred Limited v. Commissioner of Patents*.[57] In that case, an application had been made to patent a new variety of cross-bred soybean that had been cultivated naturally. The new variety was not the product of modern genetic engineering techniques involving gene splicing and direct manipulation of the soybean genome. The patent office examiner rejected the application on the basis that the new soybean variety was not an invention.[58] The rejection was affirmed by the Patent Appeal Board and the matter was then appealed to the courts. The Federal Court of Appeal subsequently held that the new cross-bred soybean variety (but cultivated naturally) was not an invention within the Patent Act.[59] Further, the application also failed on the grounds of inadequate disclosure. The appellant had deposited seed samples with various governmental agencies. The Federal Court of Appeal, whilst accepting that the new plant variety could be grown from the deposited seeds, was not satisfied that this in itself complied with the disclosure requirements.[60] On further appeal, the Canadian Supreme Court, on the question of invention, drew a distinction between two types of

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55 The majority felt that if higher life forms were patentable, it "would not be an appropriate judicial function for the courts to create an exception from patentability for human life given that such an exception requires one to consider both what is human and which aspects of human life should be excluded." *Ibid*. at para. 181.

56 For discussion of Canadian Plant Breeders Act, see Derzko, "Plant Breeders' Rights in Canada and Abroad: What are These Rights and How Much Must Society Pay for Them?" (1993–1994) Vol. 39 McGill Law Journal at 144.

57 [1989] 1 S.C.R. 1623.

58 Apparently, the examiner applied the Canadian Patent Office guideline that a process for producing a new genetic strain or variety of a plant or animal is non-patentable.

59 [1987] 3 F.C. 8 at 14 *per* Marceau J.: "given that plant breeding was well established when the Act was passed, it seems to me that the inclusion of plants within the purview of the legislation would have led first to a definition on invention in which words such as 'strain', 'variety' or 'hybrid' would have appeared, and second to the enactment of special provisions capable of better adapting the whole scheme to a subject-matter, the essential characteristics of which is that it reproduces itself as a necessary result of its growth and maturity."

60 The Federal Court of Appeal in *Pioneer Hi-Bred* disagreed with *Re Application of Abitibi Co* (1982) 62 C.P.R. (2d) 81, a decision of the Patent Appeal Board which had held that

genetic engineering of plants. First, there was genetic engineering involving selective cross-breeding. Second, there was genetic engineering which required a change in the genetic material resulting in an alteration of the genetic code affecting all hereditary material. This second type of genetic engineering was said to involve change at the "molecular" level with the creation of a new gene by way of a "chemical reaction", which new gene will lead to a change in the trait controlled by the gene. The genetic engineering in issue in the *Pioneer* case was of the first kind. Was the resultant hybrid "an invention"? Lamer J., whilst accepting that there was a degree of human intervention even with the first type of genetic engineering, doubted that would be sufficient to constitute invention. This was because it was said that the intervention did not appear to alter the basic soybean reproductive process, which continued in accordance with the laws of nature. Lamer J. noted that earlier decisions in Canada did not allow such a method to be the basis for a patent. Instead, the Canadian courts regarded creations following the laws of nature as being mere discoveries the existence of which man has simply uncovered without being able to claim he has invented them. Ultimately, the Supreme Court in the *Pioneer* case found it unnecessary to decide the issue as to whether one or both genetic engineering scenarios described involved invention. This was because the matter could be, and was in fact, disposed of solely on the basis of inadequacy of the disclosure.[61]

As a result of the failure of the application in the *Pioneer* case, the Canadian Parliament enacted the Plant Breeders' Rights Act in 1990. The Patent Commissioner in the *Oncomouse* case argued that this supported the conclusion that higher life forms were not patentable subject matter. If plants were patentable, the Plant Breeders' Rights Act would not have been necessary. Further, Marceau J.A. in the Federal Court of Appeal in the *Pioneer* case specifically held that Parliament did not intend cross-bred plants (a type of higher life form) to be patentable. If cross-bred plants were not patentable, the same must be so for genetically engineered oncomice! And, to cap it off, whilst Parliament saw fit to introduce a new statutory scheme to protect plant breeders on account of the special characteristics of plants, nothing was done about animals. If Parliament wanted to protect genetically engineered animals, it would surely have enacted special legislation or amended the Patent Act to deal with the special character of animal based inventions—or so it was argued.

These arguments received a sympathetic treatment by the majority in the *Oncomouse* case. In particular, Bastarache J. noted that the enactment of

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deposit of a new micro-organism in a publicly accessible cell culture depository was sufficient compliance with the disclosure requirements.

61 The Supreme Court found that the written disclosure did not enable a person skilled in the art to arrive at the same result without further explanation. Further, under the Canadian Patent Act, there was no provision covering disclosure by deposit of sample.

special legislation on plant varieties demonstrated that patent law was not the only way to encourage innovation in the field of biotechnology. Special legislation on biotechnology could be tailor-made to meet the special needs and concerns of the technology and public at large.[62]

In coming to the decision that the Patent Act in its current form did not extend to higher life forms, the majority did accept that the position was different for lower life forms. Genetically engineered lower life forms were capable of forming patentable subject matter. Indeed, Bastarache J. noted that in *Re Application of Abitibi*,[63] a patent was issued "on a microbial culture that was used to digest, and thereby purify, a certain waste product that emanates from pulp mills." That decision was however limited to "micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa".[64] What then was the difference between these and other life forms? The answer appears to be that micro-organisms and the like can be produced "en masse" in the same way as chemical compounds and because they are produced in such large numbers, any measurable quantity will possess uniform properties and characteristics.[65] In short, lower life forms in the nature of micro-organisms bear a much closer resemblance to chemical compounds. The claimants in the *Oncomouse* case naturally argued that the distinction between lower and higher life forms was indefensible. The majority disagreed, holding that the distinction was defensible on "the basis of common sense differences between the two". Tucked into this argument was the point that whereas micro-organisms can be produced *en masse* with uniform properties, the same was not true of higher life forms. Genetically engineered multicellular higher life forms do not replicate into exact copies of each other. Although 50% of the offspring of a founder oncomice will possess the activated oncogene in their genome, the chances are they will look different in terms of many bodily characteristics: hair length, colour and so forth.[66] Reproducibility and uniformity were felt

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62 See *Harvard College* (S.C.), *supra* note 26 at para. 196. Note that the *Pioneer* case was ultimately decided on the point of adequacy of disclosure and not on the question of patentability of higher life forms. An alternative view is that the Plant Breeders' Rights Act 1990 was a limited legislative response to the difficulties of satisfying technical criteria in the Patent Act in the case of plant varieties, and that it did not necessarily indicate any legislative recognition that higher life forms were not patentable. This alternative view was recognised by the majority in the *Oncomouse* case: see *Harvard College* (S.C.), *supra* note 26 at para. 192. The majority nevertheless felt that if Parliament had intended the Patent Act to cover higher life forms, some legislative action would have been taken. The minority in the *Oncomouse* case, on the other hand, preferred the more limited reading of the significance of the Plant Breeders' Rights Act. See below.

63 (1982) 62 C.P.R. (2d) 81.

64 See *Harvard College* (S.C.), *supra* note 26 at para. 198.

65 *Ibid*.

66 Indeed, it appears that even where an animal is cloned, the clonee may look different from the clonor, quite apart from having different behavioral characteristics. See "Same Genes,

to be important hallmarks of something that was "composition of matter" or "manufacture".[67]

C. *The Minority Decision in the* Oncomouse *Case*

Binnie J. for the minority, whilst agreeing that the matter was one essentially of statutory interpretation, found that the oncomouse was an inventive "composition of matter" within section 2 of the Patent Act. At the heart of the difference between the majority and minority conclusion in the *Oncomouse* case was that whereas the majority preferred to stress the question—did Parliament in enacting the Patent Act intend to cover oncomice or higher life forms?—the minority preferred to stress the question whether Parliament intended to protect inventions that were not anticipated at the time of the enactment of the Patent Act.[68] Given that patent legislation inevitably dealt with new unforeseen, inventive technological developments, there is much to be said for the minority approach. Both parties accepted that the oncomouse was new, useful and non-obvious. Given the objective of patent legislation "to encourage new and useful inventions without knowing what such inventions would turn out to be and to that end inventors who disclosed their work should be rewarded for their ingenuity",[69] the minority conclusion, that invention should be given a broad interpretation (without fixed

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but cloned kitty shows she's no copycat" *The Straits Times* (23 January 2003) for an article about a cat, "Rainbow", and her clone, "CC." Apparently whereas Rainbow was a "typical calico" with brown, tan and gold splotches, CC had a striped grey coat on white!

67 The majority also noted that higher life forms may differ from lower life forms in that they have a capacity to display emotion and to show more complex reactions to stimuli. They also noted (but did not necessarily endorse) the views of animal welfare groups that higher life forms are different as they are sentient and conscious. See *Harvard College* (S.C.), *supra* note 26 at para. 204. The majority accepted that the line between higher and lower life form was a difficult one to define, but were reassured by the fact that even if the claimants view was accepted, a line still had to be drawn between higher life forms and human beings. That in turn would raise hard issues as to what is meant by a "human being".

68 See *Harvard College* (S.C.), *supra* note 26 at para. 10 and compare the majority's formulation at para.120. Curiously, Bastarache J. for the majority at para. 187 put the matter slightly differently when he stated that "it is reasonable to assume that Parliament did not intend the monopoly right inherent in the grant of a patent to extend to *inventions* of this nature. It simply does not follow from the objective of promoting ingenuity that all inventions must be patentable, regardless of the fact that other indicators of legislative intention point to the contrary conclusion [emphasis added]." If oncomouse was an invention, it would, with respect, have been patentable if requirements of novelty, inventive step *etc*. had been met. The critical question was whether oncomouse was to be regarded as an invention in the first place.

69 *Ibid.* at para. 11.

preconceived non-statutory limits) and that the oncomouse was a type of "composition of matter", has its attractions.[70]

In some ways, the majority's decision, that the oncomouse (indeed any genetically engineered higher life form) was not "composition of matter" and therefore not an invention, appears to be based on thinly veiled policy arguments.[71] Thus, as summarised earlier, the majority placed stress on the fact that the current Patent Act was ill-suited to protect higher life form based inventions—after all, there were problems with the weight and scope of the protection conferred by existing patent law on living inventions. In the light of the ability of the oncomouse to replicate, product patent protection would reach through the generations and into the great, great, great grand children *etc.* of the founder mice. Then again, there were the problems of inadequate exceptions and qualifications, especially in the area of farmers' rights, innocent bystanders and research and experimentation. Even further down the slippery slope lay the spectre of patents on human beings—in whole or in part—a prospect that comes ever closer with reports of human cloning attempts increasing in frequency. All these are very real, legitimate and pressing concerns, but they do not necessarily affect the question whether the oncomouse was a "composition of matter" and therefore an invention given the context and purposes of the Patent Act. Patenting of human beings was not in issue in the *Oncomouse* case and in any event, as the minority point out, there were other methods of dealing with this problem.[72] If the

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[70] *Ibid*. at para. 59: "the definition of invention should be read as a whole and expansively with a view to giving protection for what is new and useful and unobvious."

[71] *Ibid* at para. 35, where Binnie J. for the minority states that "[t]he Commissioner seeks to restrict the legislative definition of invention and he does so (in my view) for policy reasons unrelated to the Patent Act or to its legitimate role and function".

[72] The minority pointed out that the claims specifically excepted humans. In any case, section 7 of the *Charter of Rights and Freedoms* was said to prevent one person owning another: see *Harvard College* (S.C.), *supra* note 26 at para. 40. Note that the majority pointed out that even if there is some bar against patenting human beings, other issues may arise over the body of a human at early stages of development: see *Harvard College* (S.C.), *supra* note 26 at para.180. This is true, but perhaps this points more to the need for external legislation regulating the use of genetic engineering technology. In any case, even countries that have introduced a patent bar on human beings are likely to face the same issues over the detailing of exemptive provisions. For example, under the Patents Act 1990 (Australia), section 18(2) simply states that "human beings, and the biological processes for their generation are not patentable." Contrast this with the more detailed provision in the European Directive on the Legal Protection of Biotechnological Inventions, Directive 98/44/EC, Article 5(1), which states that "the human body, at the various stages of its formation and development, and the simple discovery of one of its elements, including the sequence or partial sequence of a gene, cannot constitute patentable inventions." But even this exclusion is not itself without qualification as Article 5(2) goes on to provide that "an element isolated from the human body or otherwise produced by means of a technical process, including the sequence of partial gene sequence of a gene, may constitute a patentable invention, even if the structure is identical to that of a natural element."

minority were not swayed by the arguments that the Patent Act could not have been intended to cover higher life forms because there were many points of detail that needed clarification,[73] they were even less impressed by other even more general arguments which were clearly rooted in policy objections to certain aspects of life sciences technology. These included: religious objections,[74] the lack of a regulatory framework governing the use of biotechnology,[75] animal rights,[76] environmental protection[77] and globalization.[78]

Aside from these general policy objections to the grant of the oncomouse product patent claims, there was a clutch of arguments based on the fact that the inventors had little control over the characteristics of the oncomouse as

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[73] See *Harvard College* (S.C.), *supra* note 26 at para. 113: "My colleague, Bastarache J. suggests that the absence of such provisions supports his conclusion that the oncomouse is unpatentable, but this approach, with respect, simply substitutes the Court's notion of good public policy for the judgment of Parliament, whose members are well aware of these and similar proposals ... The respondent is entitled to have the benefit of the Patent Act as it stands."

[74] Aside from differences over religious views, the minority pointed out that the court is not the forum "that can properly debate the mystery of mouse life": see *Harvard College* (S.C.), *supra* note 26 at para. 78. The reluctance of the minority to take religious arguments into account is supported by the fact that there is no residual discretion in the Patent Act of Canada to deny a patent to an invention on grounds of *ordre public*.

[75] Regulation, licensing and control of biotechnology and its applications are of course extremely important. But, as the minority pointed out, regulation necessarily followed invention and in any case health and safety issues are not the focus of patent legislation: see *Harvard College* (S.C.), *supra* note 26 at para. 82. In any case, a patent does not give the patentee an *ipso facto* license to exploit as the patentee will have to comply with any relevant health, safety and other regulations governing use: see *Harvard College* (S.C.), *supra* note 26 at para. 65, citing the C.B.A.C. Interim Report on Biotechnology that "it is crucial for rational debate on questions related to what should or should not be patentable to recognize that patents confer only prohibitive rights. The Canadian patent system is not designed to decide about what uses of technology are permissible nor is the Patent Act designed to prevent dangerous or ethically questionable inventions from being made, used, sold or imported. The responsibility and tools for dealing with such matters resides elsewhere (eg. through regulatory approval or product safety processes)." Canadian Biotechnology Advisory Committee, Biotechnology and Intellectual Property: Patenting Higher Life Forms and Related Issues (Interim Report): Ottawa, Canadian Biotechnology Advisory Committee, November 2001 at vi.

[76] Rejected because mice had already been commodified and if a patent was not granted, the only difference would be that anyone would be entitled to make and use the oncomouse! See *Harvard College* (S.C.), *supra* note 26 at para.100.

[77] These included arguments relating to the danger of contamination of the natural gene pool as a result of escaped animals mating with those in the wild. Rejected because the patent system would not be able to prevent this environmental risk. Instead, it would be better dealt with though environmental protection legislation. See *Harvard College* (S.C.), *supra* note 26 at para. 103.

[78] Rejected because the anti-globalization attack was, at heart, an attack on intellectual property rights in general. The minority recognised that the concerns of developing countries had rightly received wide attention but felt that this was not an issue that arose for consideration.

a whole. Their sole technical contribution lay in the creation of an activated oncogene sequence that was spliced into a plasmid and micro-injected near the pronucleus of a fertilized mouse egg. From then on, nature essentially took over with the oncomouse presenting a range of characteristics (phenotype) that had nothing to do with the presence of the oncogene: hair length, eye colour, body colour, length of whiskers and even possibly character, being controlled by other genes and environmental factors. As a matter of scientific fact this was of course perfectly true, but what should be the impact of this on the legal issue as to whether the oncomouse was a patentable invention? A number of approaches were apparent. First, it might be said that the lack of control over all the characteristics of the oncomouse meant that the invention lacked "utility" or that it had not been adequately disclosed in the specifications. If a person skilled in the art was not able to reproduce the oncomouse, then how could the oncomouse invention be said to be useful or adequately disclosed? But what did it mean to be able to "reproduce the oncomouse"? Binnie J. for the minority pointed out that "the utility of the invention had nothing to do with the length of the mouse's whiskers. Its value, in terms of the patent, appears to reside wholly in the oncogene."[79] This, with respect, must have been the crux of the matter. The "invention" that was in issue was that which was set out in the patent claims and specifications. The claimants were not patenting mice or mammals *per se:* instead, the product claims were limited to mammals described by reference to artificially inserted activated oncogenes and/or promotor sequences. The claimants would only have to demonstrate control over the length of the oncomouse's whiskers if that was an essential component of the *claimed* invention.[80] Once the scope of the invention is properly confined to the oncomouse as set out in the patent claims, the laws of nature objection naturally took on less importance and relevance. The inventive step in the pathway that led to the oncomice appeared to reside in the construction of an activated oncogene sequence and the splicing of that gene into a suitable plasmid as a vector to carry the oncogene into the fertilized mouse egg in an attempt to incorporate that oncogene into the mouse's genome. This, clearly, was technical intervention by man. Indeed, Binnie J. points out that even the majority accepted that the fertilized genetically modified egg was patentable.[81] Thereafter, nature took over and was responsible for the development of that egg into a mouse, with its hair length, eye colour, tail length and so forth all under control of natural Mendelian laws of genetics and inheritance. The oncomouse would not have been born but for the laws

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[79] See *Harvard College* (S.C.), *supra* note 26 at para. 84.

[80] As Binnie J. says, "researchers who wish to use a wild mouse can catch one in the parking lot. Harvard would have no complaint. . .": *ibid.* at para. 97.

[81] *Ibid.* at para. 85, referring to Bastarache J. at para. 162.

of nature, but equally, but for the technical intervention of man, the mouse that was born would not have had that activated oncogene in each and every one of its cells. As Binnie J. poignantly pointed out: "the laws of nature are an essential part of the working of many and probably most patented inventions. . .An inventor whose invention harnesses the forces of nature is no less an inventor."[82] Once the essential feature (from the perspective of the patent claims) of the oncomouse is identified as the activated oncogene and/or promotor sequence, the laws of nature objection "naturally" fell away.[83]

Second, it might be said that the claims were "bad" as extending beyond that which had been disclosed. In some ways, this argument seems to lie behind the assertions of unjust enrichment, *de minimis* and the laws of nature. The technical intervention by man was limited to the activated oncogene sequence, the creation of the plasmid vector and the microinjection process. The finished mammal, as born after the normal period of gestation, owed more to nature than anything else. Where the argument breaks down, however, is that the product patent claims that were filed, as already noted, reflected the technical intervention that had been made. An activated oncogene sequence is not itself a mouse: but equally, the claims were not directed towards mice *per se*. If the fertilized genetically altered oncomouse egg was accepted to be an invention (and not a mere discovery following the laws of nature), how could the oncomouse that resulted be any less of an invention? Thus, Binnie J. for the minority concludes that "[t]he Harvard researchers did not merely "uncover" a naturally occurring oncomouse. The complexity of gene splicing did not "follow" the laws of nature, but was a human intervention of a high order. They engineered that

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[82] *Ibid*. at para. 87. Indeed, can you ever have an invention which works contrary to the laws of nature? In Europe, *The Guidelines for Examination in the European Patent Office*, European Patent Office, Munich, Germany, 2000, states at C.IV 4 (in the context of the European Patent Convention 1973 requirement of industrial application) that "articles or processes alleged to operate in a manner clearly contrary to well-established physical laws, *eg* a perpetual motion machine" would not be capable of industrial application.

[83] Another way in which the objection was put was described by Binnie J. as "the *de minimis*" objection. All that the inventors had done was to be responsible for one gene out of the 30,000 or so genes in the mouse genome. But, as Binnie J. retorts, a mutation in a single gene (which in turn may be due to a single change in the nucleotide base sequence) can result in catastrophic effects such as Tay-Sach's disease. Put another way, invention and inventive step are qualitative and the size of the invention should rightly be regarded as irrelevant. Similarly, an unjust enrichment argument based on the impropriety of granting a patent over something that occurs naturally in the wild when only gene is engineered was rightly rejected. A patent over the process was insufficient since "it would be easy for free riders to circumvent the protection sought to be given to the inventor by the Patent Act simply be acquiring an oncomouse and breeding it to as many wild mice as desired and selling the offspring (probably half of which will be oncomice) to the public." See *Harvard College* (S.C.), *supra* note 26 at para. 98.

part of its genetic code that appears responsible for its commercial value."[84] This is also why Binnie J. stressed that the product patent claims did not extend to wild mice (or indeed any wild animal). To this, it might also be added that if a third party "made" or bred a mouse that looked just like one of the founder oncomice—same hair colour, whisker length, tail length and so forth but without any activated oncogene sequence introduced at an embryonic stage—there would be no infringement. The essential part of the invention would not have been taken.

Turning to the language of the Patent Act, the minority agreed that if the product claims were sustainable, it would have to be as "compositions of matter" and "manufacture".[85] As to compositions of matter, the minority followed closely the reasoning of the majority in *Chakrabarty* case.[86] The expression was "open-ended" and "the statutory subject matter had to be framed broadly because by definition the Patent Act had to contemplate the unforeseeable."[87] Further, the minority pointed out that "the definition is not expressly confined to inanimate matter, and the appellant Commissioner agrees that composition of organic and certain living matter can be patented."[88] If "lower life forms" could be regarded as compositions of matter, why not "higher life forms" too? The minority disagreed that a line had to be drawn and concluded that the distinction between higher and lower life forms "in its application to section 2 [was] the invention of the Patent Office."[89] To be fair, the point could have been taken that any definition of

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84 *Ibid*. at para. 30.

85 *Ibid*. at para. 42. In fact the minority only found in favour of the oncomouse being a form of composition of matter. See para. 57 of the minority judgment.

86 447 U.S. 303 (1980).

87 See *Harvard College* (S.C.), *supra* note 26 at para. 43. By implication, the minority did not accept that *ejusdem generis* reasoning could apply given the purpose of the Patent Act.

88 See *Harvard College* (S.C.), *supra* note 26 at para. 43. In Canada, see *Continental Soya Co. v. J. R. Short Milling Co.* [1942] S.C.R. 187 (enzyme products regarded as living matter held patentable); *Laboratoire Pentagone Ltee v. Parke Davis & Co.* [1968] S.C.R. 307 (engineered microorganisms) and *Re Application of Abitibi* (1982) 62 C.P.R. (2d) 81 (mixed fungal yeast culture system).

89 *Ibid*. Binnie J. noted at para. 31 that in the *Abitibi* decision, the Patent Appeal Board (in *dicta*) opined: "[I]f an inventor creates a new and unobvious insect (*i.e.* a higher life form) which did not exist before (and thus is not a product of nature) and can recreate it uniformly and at will, and it is useful (for example to destroy the spruce bud worm), then it is every bit as much a new tool of man as a micro-organism . . ." Other cases relied on as indicating that living material from higher life forms were patentable included *Re Application for Patent of Connaught Laboratories* (1982) 82 C.P.R. (2d) 32 where cell lines derived from higher life forms were held patentable. Granted cells line are different from the higher life form from where the cell lines are cultured—nevertheless, the minority felt that patents over such cell lines demonstrate just how difficult the distinction between lower and higher life form proved in practice. The minority also referred to the fact that the Patent Commissioner had granted patents for higher plant life forms: *Round Up Ready Canola*, a genetically modified

"higher life form" was bound to be contentious and more likely to obfuscate than to inform. But this in itself might be said to beg the question as to whether the line was one which Parliament intended to be drawn in the Patent Act in the first place. If the oncomouse was not composition of matter because it was a higher life form, what was that something else that made such a difference? To answer this, the observation of Binnie J. that "the Court's mandate is to approach this issue as a matter . . . of law, not murine metaphysics" bears repeating.[90] What might have been some approaches to the line drawing exercise? Some of these were considered by Binnie J. and are briefly summarised below. Is the line to be drawn between higher "intelligent" life forms and less intelligent life forms;[91] more complex life forms and less complex life forms;[92] single celled organisms and multicellular organisms;[93] prokaryotic as against eukaryotic life forms[94] or the ability to self replicate against inability to self replicate?[95] Binnie J. was of

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plant, that was before the Canadian courts in *Monsanto Canada Inc v. Schmeiser* [2002] F.C.J. No. 1209.

90 See *Harvard College* (S.C.), *supra* note 26 at para. 45.

91 *Ibid*. at para. 46, where Binnie J. retorts that the Commissioner offered no definition of what was meant by "intelligent life form".

92 *Ibid*. at para. 47. Binnie J.'s view was that the Patent Act did not draw any distinction based on complexity of the alleged invention. Indeed, it might be added that from a philosophical point of view, complexity does not mean more intelligent. There is intelligent virtue in simplicity!

93 *Ibid*. at para. 49 where Binnie J. notes that this distinction, based not on sentient versus non-sentient beings, was suggested as the common usage of the terms by the C.B.A.C. report. But note again that the C.B.A.C. in its Report (June 2002) recommended that higher life forms (plants and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. See also *Re Application of Abitibi* (1982) 62 C.P.R. (2d) 81 that patents be extended to life forms which are produced en masse as chemical compounds with uniform properties and characteristics.

94 *Ibid*. at para. 50. Prokaryotic life forms do not have a nucleus in their cells. Eukaryotic organisms, on the other hand, do. Eukaryotic organisms might in this way be said to be more "advanced." The real point, however, is not so much whether the organism has a cell nucleus, but whether the cells are able to live on their own. A micro-organism comprises a single cell or cell cluster that is able to live on its own as an entity in its own right. Animal or plant cells cannot exist on their own in nature "and can only be successful in either a specialized environment such as a culture system (typically created by man in the laboratory) or as part of a multicellular organism such as simple plants or oysters . . ." Binnie J. at para. 50 quoting Rudolph, *A Study of Issues Relating to Patentability of Biotechnological Subject Matter* (Ottawa: Industry Canada, 1997).

95 Binnie J. notes that this was a factor picked on by Bastarache J. for the majority. But, as Binnie J. points out, self-replication is a fundamental characteristic of many lower life forms including genetically engineered bacteria. *Ibid*. at para. 51. Query also what is meant by "self-replication"? All living things including the simplest virus or single cell bacterium desire to replicate so as to ensure the survival of its genes. See Dawkins, *The Selfish Gene* (Oxford: Oxford University Press, 1976). Perhaps, the point is that the simplest of life forms such as viruses cannot replicate independently on their own, needing to invade other cells so as to take over the DNA replication and protein synthesis mechanism of that other organism

the view that all of the proposed dividing lines were policy driven and were not supported by the current Patent Act.[96]

As discussed already, the Patent Commissioner and the majority had placed considerable weight on the negative inference to be drawn from the enactment of special legislation to protect new plant varieties. Since the Canadian Plant Breeders' Rights Act was passed in 1990, the inference was that plant varieties were not intended by Parliament to be patentable subject matter. Further, since plants were but one type of higher life form, it followed that other higher life forms including animals were not intended to be patented. Binnie J. robustly rejected this argument, noting that there was nothing in the Plant Breeders' Rights Act which expressly excluded patentability and, further, that the exclusive rights conferred by the Patent Act were more extensive than those granted by the Plant Breeders Rights' Act. In any case, as the majority also recognised, it was likely that the Plant Breeders Rights' Act was passed in Canada, not so much out of recognition that higher life forms are not patentable subject matter, but rather because of recognition that plant varieties deserved some form of protection despite the fact that they often did not meet the technical criteria of the Patent Act.[97]

VI. Position of Genetically Engineered Life Forms in Singapore

This section deals briefly with the position of genetically engineered higher life forms under the Singapore's patent law. Singapore's current Patents Act,[98] which is modeled on the English Patents Act of

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so as to ensure its own genetic survival. In this way, viruses may be thought of as parasites that operate at the cellular level. Even if this is a distinction, it is submitted that it is not a good one for the Patent Act since it would effectively draw the line at genetically engineered viruses and the like. Even self-replicating bacteria such as those that featured in *Chakrabarty* might be caught on the wrong side of the patent divide. See *Harvard College* (S.C.), *supra* note 26 at para. 51. Indeed, if the line is to be pitched so "low" it may be better simply to exclude patents for any living matter. Binnie J. at para. 52 noted that this was in fact the view of Brennan J. (for the minority) in the *Chakrabarty* case.

96 Whilst Binnie J. accepted that a dividing line had to be drawn between higher life forms and human beings, he was of the view that such a line was not extraneous to the Patent Act. Section 40 of the Patent Act provided that if the Commissioner was satisfied that an applicant was not entitled to a patent by law, the application must not be granted. Both common law, *Somerset v. Stewart* (1772) 98 E.R. 499 and statute, section 7 of the Canadian Charter of Rights and Freedoms prohibited the commodification of human beings.

97 See *Harvard College* (S.C.), *supra* note 26 at para. 61.

98 Cap. 221, 2002 Rev. Ed. Sing. The Patents Act was passed in October 1994 and, with the exception of Part XIX, came into force on 23 February 1995. The Act was amended by the Patents (Amendment) Act 1995 (No. 40 of 1995, Sing.) which came into force on 1 January 1996. It was amended again by the Intellectual Property Office of Singapore Act 2001 and the Patents (Amendment) Act 2001. The latter was mainly concerned with new provisions on the patent agents.

1977,[99] was passed in 1994 after the Patents Bill had been referred to a Select Committee of Parliament. As originally enacted, the statutory provisions on patentability followed closely the scheme of the English Act. Section 13(1) defined patentable invention as an invention that was new, involved an inventive step and which was capable of industrial application.[100] The Singapore Act did not, like its English counterpart, set out any general definition of what constituted an invention in law. Instead, a non-exhaustive list of things to be excluded from the definition of invention "as such" was set out in section 13(2). This list covered: a discovery, scientific theory or mathematical method; a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever; a scheme, rule or method for performing a mental act, playing a game or doing business, or a program for a computer and finally methods of presenting information.[101] A power was also given to the Minister in section 13(5) to vary the list of excluded things for the purpose of maintaining the list in conformity with developments in science and technology. In addition, section 13(3) set out a public policy based provision excluding patentability for "an invention the publication or exploitation of which would be generally expected to encourage offensive, immoral or anti-social behaviour."[102]

One point of difference between the Singapore provisions on patentability and the English provisions, is that Singapore did not enact any express provision barring the patenting of varieties of plants or animals and essentially biological processes for their production.[103] Why were the English

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[99] See the Explanatory Statement to the Patent Bill 1994 which states that the "Bill seeks to establish a new law of patents and to enable Singapore to give effect to certain patent treaties. The Bill is based on the United Kingdom Patents Act 1977 with the necessary modifications."

[100] This is equivalent to section 1(1) of the Patents Act 1977 (U.K.). Note that the English Patents Act 1977 was passed largely to ensure that U.K. patent law complied with the U.K.'s obligations under the European Patent Convention 1973. Section 1(1) of the U.K. Act follows Article 52(1) of the E.P.C. 1973.

[101] Section 13(2) is equivalent to section 1(2) of the English Act and Article 52(2) of the E.P.C. 1973.

[102] This provision is similar to the one found in section 1(3) of the English Act. Note that the latter provision has since been amended in U.K. to read: "A patent shall not be granted for an invention the commercial exploitation of which would be contrary to public policy or morality." The U.K. provision was amended to make it closer to Article 53(a) of the E.P.C. which provides that patents were not to be granted to inventions the publication or exploitation of which would be contrary to "*ordre public*" or morality.

[103] In the U.K., see section 1(3)(b) which stated that "[a] patent shall not be granted ... (b) for any variety of animal or plant or any essentially biological process for the production of animals or plants, not being a micro-biological process of the product of such a process." This has since been amended to read "patents shall not be granted in respect of ... (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision does not apply to microbiological processes or the products thereof." The re-wording of the bar in U.K. appears to be designed to ensure that the bar follows more closely the wording of the similar bar in Article 53(b) E.P.C. 1973.

provisions on this not copied into the Singapore Act, given that the Singapore Act was intended to be based on the English Patents Act 1977? The Singapore Parliament was clearly conscious of the fact that there was no express bar on animal or plant varieties.[104] The answer, which may well have an important impact on the interpretation of the Patents Act in its application to life forms, can be found in the Report of the Select Committee on the Patents Bill. The Select Committee, after noting the existence of English provisions on non-patentability of animal and plant varieties, stated:

> The Committee recommends no change to the existing provisions. In the UK, plant varieties were excluded because UK is party to the Plant Varieties Convention (UPOV), and they have given effect to UPOV under the Plant Varieties and Seeds Act 1964. Singapore, however, is not a member of UPOV. In addition, the Committee feels that it is desirable to encourage the development of new plant varieties. Patenting of new plant varieties would therefore allow protection for the products of horticultural and agricultural research. With regard to animal varieties (non-human species), the general justification for patenting new life forms is that it provides an incentive for people to invest and innovate. Since the biotechnology industry relies on the patent system as an incentive mechanism, patenting is essential to maintain the creation of benefits flowing from biotechnology research. For human beings and the related biological processes, the Committee is of the view that such inventions can be excluded by invoking Clause 13(5) which empowers the Minister . . . to vary the provisions in sub-clause (2) for the purposes of maintaining them in conformity with developments in science and technology. Clause 13(2) declares the list of things which would not be inventions under the Bill.[105]

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[104] See the representation of Ng Siew Kuan to the Select Committee on the Patent Bill where the point is made that since Singapore was not going to have a provision equivalent to section 1(3)(b) of the Patents Act 1977 that the "Patents Bill does not appear to contain any specific bar to the patentability of living organisms *per se*." See Report of the Select Committee on the Patents Bill [Bill No. 4/94/A], Parl. 5 of 1994 at A4.

[105] Report of the Select Committee on the Patents Bill, Parl. 5 of 1994 at vi. See also the exchange at B4 where the Select Committee stated: "Our biotechnology industry has shown to be one where patent systems do act as an important inducement for innovation as well as investment. Therefore, since the biotechnology industry does rely on a patent system as an important incentive mechanism, surely patenting is essential to maintain the system of benefits flowing from such biotechnological research. It may include benefits for human health, animal health, protection of the natural environment, and so on. I understand that in Australia and New Zealand, they are granting patents for new life forms without assessing the social, ethical or ecological impact on such patents. Also in Europe . . . they are discussing a proposed EC directive . . . which if approved would envisage patenting of such life forms . . ." Similar points were also made at B18 and B19 of the Select Committee Report.

Thus, Singapore did not want to exclude the possibility of patents for new plant varieties (always assuming that the general criteria for patentability were met) as she had not, unlike the United Kingdom, introduced any special legislation to protect new plant varieties (whether produced by traditional cross breeding techniques or otherwise). Similarly, Parliament was clearly cognizant in 1994 of the exciting opportunities presented by developments in biotechnology and the possibilities of engineered life forms. No distinction was drawn between lower and higher life forms. Indeed, the Select Committee was already aware of the possibility of biotechnology techniques being applied to human beings and preferred to deal with this through amendments to the list of things declared to be not inventions "as such".[106]

In 1996, shortly after the new Patents Act had come into force in Singapore, the Act was subjected to a number of important amendments.[107] Of particular importance to the issue at hand was the repeal in 1996 of sections 13(2) and (5) which dealt with things deemed not to be inventions as such for the purposes of the Patents Act. As pointed out elsewhere, this meant that Singapore no longer had any express statutory guidance on the question of what constituted an invention under the Act.[108] There was now no general definition nor any list of things deemed to be excluded as such. The absence of any statutory definition could hardly mean that the concept of "invention" was no longer a controlling principle in patent law. Clearly, section 13 still demands that, before the criteria of patentability arises (novelty, inventiveness and industrial application), the thing in question be an

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[106] Note that the fact there is no specific exclusion from patentability for "essentially biological processes" for the production of animals or plants does not mean that these are patentable under Singapore law. Aside from problems with novelty and lack of inventive step, essentially biological processes may well be regarded as "mere discoveries" and not as inventions. See Guidelines for Examination in the European Patent Office, C-IV at 3.4 that under the E.P.C., "the question whether a process is essentially biological is one of degree depending on the extent to which there is technical intervention by man in the process ... To take some examples, a method of crossing, inter-breeding, or selectively breeding, say horses involving merely selecting for breeding and bringing together those animals having certain characteristics would be essentially biological and therefore unpatentable ..." It appears that a similar approach is taken in Canada where even though there is no express bar against patenting essentially biological processes, these are regarded as not patentable on the basis that they are not on general principles to be regarded as inventions. See *Harvard College* (S.C.), *supra* note 26 at para. 28 and 189. See also *Pioneer Hi-Bred Limited v. Commissioner of Patents* [1989] 1 S.C.R. 1623 at 1634: "the courts have regarded creations following the laws of nature as being discoveries the existence of which man has simply uncovered without thereby being able to claim he has invented them ..."

[107] The Explanatory Statement to the Patent (Amendment) Bill 1995 states that the Bill sought "to amend the Patents Act so as to bring the Act into conformity with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs)."

[108] See generally the discussion in Wei, "Inventions, Genes and Napoleonic Victories" (1997) 9 S.Ac.L.J. 1, Part 1 [Wei, "Inventions"].

invention.[109] A parliamentary draughtsman faced with a concept as tricky as "invention" might adopt a number of approaches to its definition. In the first place, the term might be defined by reference to some general principle. Alternatively, the term may be defined in the negative by setting out some general principle as to what is not an invention. If these approaches are unattractive, it may be possible to avoid any express general definition and to offer guidance by setting out an extended (but ultimately non-exhaustive) list of what is not an invention. If the list is comprehensive enough, the general question of what is an invention may become largely academic (although there may still be ambiguity in the scope of the things that are expressly excluded). Finally, there is always the alternative of avoiding any definition at all and to leave it to the courts to determine the scope of the word on a case by case basis bearing in mind the overall goals and policy behind the legislation.[110] Under the Patent Act of Canada, section 2, as noted already, defines invention by reference to five broad categories of subject matter: new and useful art, process, machine, manufacture or composition of matter. Given the broad objectives of patent legislation, it was not perhaps too surprising to find, in the *Oncomouse* case, that the categories raised almost as many questions as they answered. Indeed, some might ask whether the scope of the categories could ever be pinned down without reference to the general policy behind patent protection. Thus, in Australia, the High Court in *National Research and Development Corporation v. Commissioner of Patents*[111] took the view that any attempt to set out a precise definition of "manufacture" was bound to be problematic and that the inquiry into the expression was not so much an inquiry into the meaning of a word but the scope and breadth of the concept which the law has developed by its consideration of the text and purpose of the statute.[112]

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[109] See *Genetech Incs. Patent* [1989] R.P.C. 147 at 263 *per* Lord Mustill that whilst the question of invention may overlap with other objections, it is a separate question that ought to be separately investigated. Contrast Lord Hoffmann in *Biogen Inc. v. Medeva plc.* [1995] R.P.C. 25 that in most cases under the U.K. Patents Act, it would be enough to simply address the issue of novelty, inventiveness, industrial utility and the exclusions. There would be very few things that satisfied these four limbs and which would still not be an invention. Be that as it may, Singapore no longer has a list of things excluded as such from the definition of invention. It follows that the Patent Office and the courts in Singapore must place greater emphasis on the threshold question of whether the thing described in the patent claims is in fact an invention as a matter of law.

[110] See generally the discussion in Wei, "Inventions", *supra* note 108 at 13–19.

[111] [1960] A.L.R. 114.

[112] Under the Australian Patent Act 1990, patentable invention is defined in terms of "manner of manufacture." See also *CCOM Pty Ltd v. Jiejing Pty Ltd.* (1994) 122 A.L.R. 417, where the principle was whether there was a mode or manner of achieving an end result which is artificially created state of affairs of utility in the field of economic endeavor. For more detailed discussion, see Wei, *An Introduction to Genetic Engineering, supra* note 23 at paras. 4.5–4.8.

Will the courts in Singapore adopt a broad flexible approach to the question of invention in the light of the overall policy objectives of the Patents Act? And, more to the point, will that approach be broad enough to encompass genetically engineered life forms irrespective of whether it is a higher or lower life form?[113] The answer is very likely to be affirmative even if the general approach of the majority of the Supreme Court of Canada is followed in Singapore. It will be recalled that a key reason as to why the *Oncomouse* product claims failed before the Canadian Supreme Court was that the majority, whilst accepting that the expression "composition of matter" was broad, took the view that the concept was not unlimited and did not necessarily cover every thing under the sun that was new, inventive and useful. It did not accept that Parliament intended the expression to cover higher life forms as the detailing of the Act was felt to be not well-suited to protect higher life forms. Further, there were the strong inferences to be drawn from the enactment of the Plant Breeder's Rights Act. The Singapore position is clearly different. First, Singapore has not introduced any special legislation to protect new varieties of plants. Instead, as is apparent from the report of the Select Committee on the Patents Bill, the intention was that new plant varieties that met the requirements of the new Patents Act were to be treated as patentable subject matter. Second, Parliament in Singapore was cognizant of the interface between biotechnology and patent law at the time when the Patents Bill was enacted. Indeed, the intention was that the patent system should support and encourage the development of that industry. Third, it is also apparent that Parliament in Singapore intended a broad and flexible approach to be taken to the application of the patent regime. After all, the Minister for Law, Professor S. Jayakumar stated at the third reading of the Patent Bill in October 1994 that:

> The Committee's approach was to maintain a balanced patent protection scheme. In other words, to provide adequate protection and returns to patentable inventions and, at the same time, give due recognition to consumer and industry interests in having wider access to inventive products and services. *The Select Committee took into account the fast-changing technology and the need for a patents regime which is responsive to technological change*. Outdated legislation, of course, impedes economic growth. This is especially so as our economy is becoming increasingly service-orientated, where the creation, transmission and processing of information, especially in the field of R&D and product development, is assuming greater importance. Modern patent legislation would also

[113] Note that viruses have been patented in Singapore. See *Genelabs Diagnostics Pte Ltd v. Institut Pasteur & Anor* [2001] 1 S.L.R. 121 which concerned the isolation of the HIV-2 virus. For comment, see Kwek, *The Biotechnology Era: Ramifications of Genelabs Diagnostics v Institut Pasteur*, 13 S.Ac.L.J. 89.

> attract investments, particularly in the field of science and technology . . . The Bill . . . will meet our objective of promoting Singapore as a regional and international centre for research and development . . .[114]

Fourth, there is the fact that Singapore, by repealing section 13(2) and (5), appears to have adopted an approach to the issue of invention that is not dissimilar to that taken in Australia. In Australia, it is clear that "invention" is regarded as a concept that is very much driven by policy considerations to encourage economic and industrial growth.[115] In Singapore, the list of things deemed not to be inventions as such was removed to ensure compliance with the TRIPs Accord. Associate Professor Ho Peng Kee, then Parliamentary Secretary to the Minister of Law, explained at the second reading of the Patents (Amendment) Bill 1995 that:

> Section 13(2) is a short and non-exhaustive listing of subjects which are considered non-patentable, *e.g.*, a discovery or mathematical model. The deletion of section 13(2) is intended to conform to Article 27(3) of TRIPS which does not provide for such a listing . . . Sir, this deletion will not limit our flexibility in rejecting any subject matter which is non-patentable under section 13(1). The existing provisions are sufficient to enable Singapore to keep up with advances and changes in science and technology.[116]

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[114] Singapore Hansard, 31 October 1994, Third Reading of the Patents Bill [emphasis added]. See also section 9A (1)of the Interpretation Act (Cap. 1, 2002 Rev. Ed. Sing.) which states that "in the interpretation of a provision of written law, an interpretation that would promote the purpose or object underlying the written law (whether that purpose or object is expressly stated in the written law or not) shall be preferred to an interpretation that would not promote that purpose or object." Section 9A(2) also permits the use of extrinsic material, *inter alia*, to help ascertain the meaning of a provision which is unclear or ambiguous. Section 9A(3) defines extrinsic material as including "(a) all matters not forming part of the written law that are set out in the document containing the text of the written law as printed by the Government printer; (b) any explanatory statement relating to the Bill containing the provision; (c) the speech made in Parliament by a Minister on the occasion of the moving by that Minister of a motion that the Bill containing the provision be read a second time in Parliament; (d) any relevant material in any official record of debates in Parliament; (e) any treaty or other international agreement that is referred to in written law; and (f) any document that is declared by the written law to be a relevant document for the purposes of this section."

[115] Indeed, the majority in *Harvard College* (S.C.), *supra* note 26 at para. 185 accepted that "there is no doubt that two of the central objects of the Act are to 'advance research and to encourage broader economic activity'."

[116] Singapore Hansard, 1 November 1995, Second Reading of the Patents (Amendment) Bill. Note that the reference to Article 27(3) is likely to have been intended as a reference to Article 27(1). The latter provides: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application." Para. 2 sets out an *ordre public* bar (in Singapore a broadly equivalent provision can be found

The repeal of section 13(2) does not of course mean that discoveries and natural laws of nature are now patentable. These are likely to remain unpatentable on the basis that they are not inventions under section 13(1). The repeal means that the Singapore Patent Office (The Intellectual Property Office of Singapore) and the courts now bear the brunt of the responsibility for determining the scope of invention, always bearing in mind changes and developments that have taken place in science and technology.

Fifth, whilst the majority of the Canadian Supreme Court in *Oncomouse* case had some reservations about drawing the line between human beings and other types of higher life forms for the purpose of determining the application of invention to life forms, the Singapore Parliament does not appear to share in those reservations. After all, the Report of the Select Committee on the Patent Bill comments that so far as inventions involving human beings and the related biological processes were concerned, these could be excluded by the Minister using his powers under section 13(5) to amend the list of excluded items set out in section 13(2). These two statutory provisions have of course since been repealed, but it is still open for the courts to hold that "human being inventions" are not patentable under section 13(3) simply because such inventions are likely to encourage offensive, immoral or anti-social behaviour.

Given that the Singapore courts are more likely than not to accept that genetically engineered life forms (whether lower or higher) can constitute invention under the Patents Act, it should be stressed that this does not mean that all of such inventions will in fact be patentable. To be patentable, the invention must satisfy the usual requirements of novelty, inventiveness and be capable of industrial application.[117] In an area of technology as fast moving as biotechnology and the life sciences, information can rapidly enter the

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in section 13(3)). Para. 3 permits two exclusions from patentability. Firstly, methods of treatment of humans and animals. In Singapore, there is a provision on this in section 16(2). Second, Members may also exclude patentability for plants and animals other than micro-organisms, and essentially biological processes for production of plants and animals other than non-biological and microbiological processes. Note that if Members decide not to allow patents for plant varieties, they are bound under Para. 3 to introduce some *sui generis* system for the protection of plant varieties. Canada, of course, has such a system in its Plant Breeders' Rights Act 1990.

[117] Tricky issues can arise over the meaning of industrial application and its relationship to invention, novelty and utility. In the United Kingdom, commentators have argued that inutility and industrial application are not the same concepts. See C.I.P.A. Guide to the Patents Act 5th ed. at para.4.03. See also generally the guidelines on industrial applicability set out in the Guidelines for Examination in the European Patent Office, June 2000. The question of industrial applicability can be especially acute in the area of gene sequences and the like, especially if no specific use has been found for the gene sequence. This is a topic that deserves an article in its own right and for comprehensive discussion, the reader is referred to Ng-Loy Wee Loon, *Patenting of Genes—A Closer Look at the Concepts of Utility and Industrial Applicability*, IIC Volume 33 No. 4/2002 at 393.

public domain and render "old" or "obvious" what was "new" and highly "inventive" only months in the past. The procurement of early priority dates to protect innovation from the ever expanding state of art is perhaps at its most critical in fast moving technological areas. Then again, problems may also arise with the scope of the patent claims and the sufficiency of specifications. The *Oncomouse* litigation demonstrates the importance to the inventor of obtaining broad product claims. Process claims, whilst valuable in their own right may be more susceptible to invention around or other means of avoidance. But, whilst claims directed towards the product *per se* are attractive to the inventor, the law has to be vigilant to ensure that the inventor has not claimed more than he has actually invented and that the specifications set out a disclosure that supports the width of the claims.[118] Take for example an inventor who has developed a particular technique for splicing a gene into the genome of the rice plant such that the genetically modified plant acquires resistance to fungal attack. The inventor will naturally seek patent protection for the process as well as the new genetically engineered rice plant. He will not want to limit the process claims to rice plants and will prefer to extend it to all plants and indeed, possibly, to all life forms. He may also desire protection for the genetically engineered rice plant *per se* so that even if another inventor develops a new technique for insertion of the gene, the first inventor still retains control via the patent over the genetically engineered rice plant *per se*. Further, the first inventor may naturally want to patent any genetically modified plant (or life form) which has the gene spliced into its genome so as to confer the trait of fungal resistance. Whilst these may all be capable of constituting inventions, the law will need to examine the specifications carefully to see that the claims are in fact supported. If, for example, a skilled reader, following the teaching of the specifications, is unable to make the invention work in respect of other plants, problems of insufficiency of disclosure and the scope of invention will arise.

Still yet another problem that may be exacerbated by broad product claims is that such claims may open the door wider to *ordre public* type or morality based objections in those jurisdictions which allow such objections to the grant of a patent. In Canada, the current Patent Act does not have such a provision and accordingly the patentability of the *Oncomouse* product claims was not subjected to such arguments. But, in Singapore, the United Kingdom and the member states of the European Patent Convention 1973, the

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[118] Section 25(5) of the Singapore Patents Act requires that claims shall define the matter for which the applicant seeks protection; be clear and concise; be supported by the description; and relate to one invention or to a group of inventions as being so linked as to form a single inventive concept. Section 24(4) requires that specifications shall disclose the invention in a manner which is clear and complete for the invention to be performed by a person skilled in the art.

position is different. As noted already, in the United Kingdom and Europe, patents are not to be granted if the publication or exploitation of the invention is against *ordre public* or morality. A similar provision can be found in Singapore's patent legislation. What, then, have patent offices and the courts made of this provision? This is a large and controversial question which goes beyond the scope of this article. Briefly, in Europe, the equivalent proceedings over the *Oncomouse* invention did not center on the issue of whether the claims disclosed an invention. Instead the fight was over whether the *oncomouse* was an "animal variety" and hence caught by the exclusion in Article 53(b) of the European Patent Convention. Once this had been resolved in favour of the claimant,[119] the focus of the battle shifted to *ordre public* and morality dressed up in the form of animal welfare, animal suffering, environmental damage and other similar arguments. These arguments, whilst hotly contested, were rejected by the Examination Division of the European Patent Office. In doing so, the Examination Division noted that patent law did not confer a positive right on the patentee to exploit the invention since the legislator could always subject the use of the invention to regulatory control. Further, the Examination Division was of the view that exceptions to patentability were to be narrowly construed and that all new technologies were normally afflicted with risks. In deciding whether *ordre public* or morality objections applied, a balancing approach had to be taken to the possible detrimental effects and risks and the merits and advantages that the invention offered. On this basis, the Examination Division concluded that the benefits of the invention (development of cancer treatments and so forth) outweighed the risks and dangers (such as animal suffering and risk to the environment through accidental escape of oncomice). The *Oncomouse* saga in Europe did not, however, end with the decision of the Examination Division since opposition proceedings continued. Indeed, in November of 2001, it was reported that the European Patent Office opposition division whilst upholding the oncomouse claims, decided to limit it to "transgenic rodents containing an additional cancer gene".[120] The reasons for the cutback on the claims is not immediately apparent. One possibility (though unlikely) might have been that claims directed towards "non-human onco-mammals" went beyond the teaching set out in the specifications. Still yet another reason, which seems far more probable, is that different and possibly more cogent *ordre public*/morality arguments might arise in the case

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[119] See the discussion in Wei, *An Introduction to Genetic Engineering, supra* note 23 at para. 4.26. Since the claims were not limited to rodents, the Examination Division of the European Patent Office was satisfied that the claim was not caught by the bar against animal varieties. See *Harvard Oncomouse Patent* [1990] E.P.O.R. 501; [1991] E.P.O.R. 525.

[120] See E.P.O. Press releases, 7 November 2001, online <http://www.european-patent. . .e.org/news/pressrel/ch_2001_11_05_e.htm>. It may be that this decision will be subject to a further appeal.

of other forms of onco-mammals. After all, the Examination Division itself had stated in 1991 that its analysis of the balance of advantages and disadvantages applied solely to the case at hand and "that other cases of transgenic animals are conceivable for which a different conclusion might be reached in applying Article 53(a) EPC".[121]

Whilst the courts in Singapore have yet to have an opportunity to examine the scope and application of the "morality" provisions set out in section 13(3), it is probable that an approach similar to that taken by the European Patent Office will be followed. The question of immorality, offensiveness and the anti-social nature of any invention will have to be balanced against the benefits that are said to accompany the invention in issue. As in Europe, it is probable that section 13(3) will be construed strictly and applied only where there is clear evidence supporting the basis upon which the objections are made. In the case of "morality" type objections, this is likely to mean that the courts will, at the very least, require clear proof that a substantial and representative portion of the population in Singapore share in the moral objection. In the case of environmental danger and other similar arguments that might come in under the category of "anti-social" behaviour, these risks will have to be established at least on a balance of probabilities and

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[121] *Harvard Oncomouse* [1991] E.P.O.R. 525 at 528. But see *Leland Stanford/Modified Animal* [2002] E.P.O.R. 16. This case concerned an immuno-compromised mouse that had been implanted with human hematopoietic tissue. The head note explains that the production technique involved the use of cells and tissues from aborted foetuses or children below the age of three years to create an "animal-human" chimera. The wording of the patent claim in issue was complex but for present purposes it is enough to point out that the claim, which was upheld in its amended form, extended to any "chimeric non-human mammalian host" comprising certain stated elements. The medical benefits of the invention were not in issue; instead, the case was fought on issues of novelty, inventive step, sufficiency of disclosure, methods of treatment and *ordre public*/morality. On the latter, the opposition division carried out the balancing act test and noted that the claimed invention provided the only animal model for HIV-1 infection and could be used to test potential anti-AIDS therapies before human trials were undertaken. Other benefits included the promise of a supply of human cells and organs for transplant in the future. The opposition division dismissed the "hypothetical potential risks" associated with xenotransplantation. In order for risks to be taken into account, they had to be conclusively documented hazards and not just "possibilities" Further, the opposition division noted at 23 that xenotransplantation was already subject to regulatory control and that it agreed with the patentee that "as long as a claimed invention has a legitimate use, it cannot be the role of the E.P.O. to act as a moral censor and invoke the provisions of Article 53(a) E.P.C. to refuse on ethical grounds to grant a patent on legal research and directed to an invention indisputably associated with medical benefits. The technology underlying the present invention is undoubtedly controversial and the subject of intensive discussion in the media and among members of the public. However, there is at present no consensus in European society about the desirability or otherwise of this technology, and public opinion is still being formed on this and related matters. It would be presumptuous for the E.P.O. to interfere in this public debate . . ." For a summary of genetic engineering and mice, see Reiss and Straughan, *Improving Nature? The Science and Ethics of Genetic Engineering* (Cambridge: Cambridge University Press, 1996) especially at 169–71.

not on the basis of speculation and rumor. If the balance that is achieved by this light touch approach seems skewed in favour of patentability, perhaps some justification can be found in the fact that a decision to refuse a patent under section 13(3) is unlikely on its own to lead to an abandonment of the technology in question. All that a refusal to grant means is that the erstwhile patentee will be unable to sue third parties for patent infringement. The erstwhile patentee may have lost the patent reward for the invention, but the reality is that the invention has already been made and will still be available for exploitation by the inventor or indeed by anyone else. What is needed is a system for regulatory control over the licensing, use and exploitation of such potentially hazardous or abhorrent technologies. No patentee will be free from such regulatory control simply by virtue of being a patentee. Using the patent system to "police" technology goes well beyond the objective and indeed competence of the patent system. Environmental, public health and safety issues require constant monitoring and governmental licences for use need to be constantly fine-tuned in the light of new knowledge and experience of the scope of the actual hazards and dangers. The reluctance of the European Patent Office to act on speculative evidence of possible dangers should not be taken as a sign that those dangers are being trivialized. Instead, it is an acknowledgement that the risks need to be properly evaluated by competent authorities, not just on a one-off basis, but under some system that would provide for constant monitoring and supervision.

VII. Conclusion

The conclusion of the *Oncomouse* litigation in Canada is likely to see the debate over the patentability of life forms in Canada move to the Canadian Parliament. Indeed, the issue of patenting of higher life forms in Canada has already been subject to considerable discussion by the Canadian Biotechnology Advisory Committee. In the C.B.A.C. report to the Government of Canada,[122] the issue of patenting of life forms was addressed in the context of the role of the patent system to advance the public good. Specifically, the C.B.A.C. agreed with the views of Justice Jackson of the United States Supreme Court that

> . . . [t]he primary purpose of our patent system is not reward of the individual but the advancement of the art and sciences. Its inducement is directed to disclosure of advances of knowledge which will be beneficial to society; it is not a certificate of merit but an incentive to disclosure.[123]

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[122] June 2002.

[123] *Sinclair & Carroll Co. Inc. v. Interchemical Corporation* 325 U.S. 327 at 330–31.

A study of the recommendations of the C.B.A.C. will go beyond the scope of this article; nevertheless, a brief summary of its key recommendations may be helpful in pointing to changes that may be forthcoming in Canada. Whilst the C.B.A.C. recommended that patents should not "be granted on human bodies at any stage of development", it did conclude that higher life forms (plants and non-human animals) that meet the criteria of novelty, non-obviousness and utility be recognized as patentable. As noted earlier in this article, the concerns raised in the *Oncomouse* litigation over the scope of protection and the position of farmers, innocent bystanders and researchers were also addressed. The C.B.A.C. has recommended that farmers be permitted to "save and sow seeds from patented plants or to breed patented animals, as long as these progeny are not sold as commercial propagating material or in a manner that undermines the commercial value to its creator of a genetically engineered animal." It has also recommended that innocent bystanders be protected from claims of patent infringement with respect to "adventitious spreading of patented seed or patented genetic material or the insemination of an animal by a patented animal." To safeguard the interests of researchers, the C.B.A.C. also recommended an exception covering use of a patented invention privately and for non-commercial purposes or for the purposes of study to investigate the properties of the invention and to improve upon it or create a new product or process.

Moving further afield, important recommendations were also made in respect of other issues touching on the use of intellectual property law to protect biotechnology. These included recommendations: that Canada participates in international negotiations to address the issue of liability and redress for the adventitious spreading of patented seed or genetic material or the insemination of an animal by a patented animal; that the Federal Government develops policies to encourage the sharing of the benefits of research involving genetic material;[124] that Canada supports the efforts of the World Intellectual Property Organization to determine whether a form of intellectual property could be developed to protect traditional knowledge and that the Canadian Intellectual Property Office should provide guidance

[124] In particular, it was recommended that the benefits of medical and pharmaceutical research based on human genetic material be shared with groups or communities who provided the material. Another important aspect of this recommendation was that Canada should participate in on going process of the Convention of Biological Diversity and to address outstanding issues with respect to the voluntary Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization. Canada should encourage and facilitate compliance with the Bonn Guidelines and also sign and ratify the International Treaty on Plant Genetic Resources for Food and Agriculture. Canada should also encourage and facilitate benefit sharing arrangements between users of genetic resources and traditional and local communities within Canada.

on assessing as prior art, traditional knowledge that has been made public through oral as well as written or published transmission.[125]

The C.B.A.C.'s recommendations ultimately seek a fair balance between patentees, the public at large and the needs and interests of countries and communities that are repositories of much of the world's genetic resources. Difficult though it may be to reach a consensus (especially as to the sharing of the benefits of inventions derived from third party genetic resources) over the details of the balance, a balance which may need constant refinement, this must be the right approach if an acceptable face is to be put on patent law for developed and developing countries alike.

Singapore also has actively embarked on developing her interest in biotechnology and the life sciences. This article has concluded that genetically engineered higher life forms are likely to be regarded as capable of constituting an invention and patentable subject matter under Singapore' patent laws. The history behind Singapore's Patents Act is different from Canada's and the close, almost forensic examination of the language of the Patent Act, that took up so much of the legal analysis in the Canadian *Oncomouse* litigation, is unlikely to arise in Singapore. What then are some of the lessons that the *Oncomouse* litigation in Canada and elsewhere holds for Singapore? In the first place, the cases demonstrate that in the light of rapidly advancing science and technology, that a broad approach to the question of invention (patentable subject matter) is needed if the patent system is to continue to function as an inducement towards "disclosures of advances of knowledge which will be beneficial to society." Second, that many of the objections raised to the patenting of life forms are concerned more with the scope of the rights conferred and the need for special exceptions given the nature of biotechnology based inventions. The Canadian litigation identified three such concerns: farmers' privileges,[126] innocent bystanders and research interests. Singapore, like Canada and other countries, would do well to consider whether special exceptions are needed in these areas both

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[125] Other recommendations touched on improving the administration of the patent system through the issuance of interpretative guidelines on biological inventions, improvement of service standards and reporting, working towards further international harmonization of patent policies and the introduction of a patent opposition procedure.

[126] Farmers' privileges may be less of a concern in Singapore, given her very small agricultural and animal husbandry base of activities. Nevertheless, the issue is important to the international community. The term "farmers' privileges" appears to be capable of covering a broad spectrum of matters. These range from the right of farmers to save and sow farm-saved seed all the way through to protection of traditional knowledge relevant to plant genetic resources for food and agriculture. See Adcock, "Farmers' Right of Privilege?" [2001/2] 3 B.S.L.R. 90, citing the definition set out in the International Treaty on Plant Genetic Resources for Food and Agriculture. Adcock concludes at 93 that "[f]armers' rights are not an intellectual property right, but they need to be viewed as an important counterbalance to the rights conferred to breeders in the formal sector under plant variety protection or patents."

in terms of available defences and in the remedies that might be made available (or cut back).[127] Third, the *Oncomouse* litigation demonstrates well the range of "morality" based arguments that can be marshaled in a general attack on certain aspects of biotechnology. Many of these arguments are concerned with controlling or preventing the use of certain biotechnology inventions whether by the patentee, his licensee or anybody else. Withholding the grant of a patent in such cases simply takes away some of the incentive to develop the technology. Given that is the only consequence, it is perhaps not surprising that the European Patent Office approach is to limit *ordre public* and morality objections to demonstrably abhorrent inventions. What the *Oncomouse* case reveals is the urgent need for a system, external to the Patents Act, for the licensing and control of the use of the technology. In Singapore, aside from existing regulatory mechanisms for pharmaceuticals and so forth,[128] important new initiatives are well under way. A number of committees already exist charged with the duty to determine ethical and other guidelines in the area of biotechnology and the life sciences. These include the Genetic Modification Advisory Committee (GMAC), the National Medical Ethics Committee and the Bioethics Advisory Committee (BAC).[129] What is needed now is for the regulatory controls to be put in

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[127] In Singapore, section 66(2)(a) of the Patents Act already sets out a defence covering acts "done privately and for purposes which are not commercial". There is a further defence, touched on earlier, in section 66(2)(b) covering anything "done for experimental purposes relating to the subject-matter of the invention". Will these be sufficient to protect innocent bystanders and research interests? This is open to debate. Certainly, as defensive provisions which avoid liability for what would otherwise be an interference with a property right, the courts may well adopt a restrictive interpretation. Singapore does have a provision in section 69 which precludes the recovery of damages and account of profits where the defendant proves that he was not aware and had no reasonable grounds for supposing that the patent existed. This provision, however, does not cover the scenario of "innocent infringement" that the C.B.A.C. had in mind, namely, the reproduction of animals and plants on their own accord and without the knowledge and control of the defendant. Note that in the Copyright Act (Cap. 63, 1999 Rev. Ed. Sing.) there is a provision in section 119 that prevents the award of damages where the defendant was not aware and had no reasonable grounds for suspecting, that the act constituted copyright infringement. Might a similar provision be considered for the Patents Act? Even more radical would be a true defensive provision to negate liability where innocent infringement occurs. Even if such a defence was limited to inventions capable of reproducing, such as plants, seeds and animals, the defence would be controversial as patent infringement is traditionally a strict liability action.

[128] Medicines Act (Cap. 176, 1985 Rev. Ed. Sing.) and the Health Science Authority and the Agri-Food and Veterinary Authority. See Wei, *An Introduction to Genetic Engineering, supra* note 23 at Chapter 5.

[129] A summary of the work of these committees can be found in Wei, *An Introduction to Genetic Engineering, supra* note 23 at 283–7. Some recent developments include the release by the G.M.A.C. of guidelines governing the release of agriculture-related genetically modified organisms. The B.A.C. has also already released two important reports on especially controversial areas of life sciences. The first is the report on "Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning", June 2002 whilst the

place, as soon as possible, so as to implement the various proposals that might have been accepted by the Government.[130]

The *Oncomouse* has rightly earned its place in legal history for it has raised issues from technical black letter law all the way through to tricky questions over the meaning of life, ethics, animal rights and the impact of genetic engineering on the environment. If nothing else, the *Oncomouse* litigation should provide added impetus for an effective system of regulatory control to be put in place in Singapore and elsewhere.[131] It also continues and deepens the debate on what changes are needed to patent law to ensure an adequate balancing of patent rights and obligations and the interests of society in general.

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second is the report on "Human Tissue Research", November 2002. The B.A.C. is generally charged with the duty to examine ethical, legal and social issues arising from research on human biology and behaviour and its applications and to develop and recommend policies to the Ministerial Committee for Life Sciences. The range of matters covered by these reports is extensive and goes well beyond the scope of this article. The reports deserve full treatment and analysis in their own right. The reports do not, however, make any direct recommendation for changes to patent law and concentrate on regulation of the use and development of the technology.

130 The first B.A.C. report on stem cell research and cloning whilst concentrating on the ethical issues, social norms and philosophical perspectives, acknowledged that "there are detailed legal and regulatory issues that arise from the positions adopted on the ethical issues" but that these would not be exhaustively covered in the report. Nevertheless, the B.A.C. recognised that it "is crucial to set up a comprehensive legislative and regulatory framework to control human stem cell research". To this end, a key proposal was the setting up of a regulatory body to licence, control and monitor human stem cell research in Singapore. The B.A.C. supported vesting the regulatory body with power to impose sanctions, including criminal sanctions, on those who failed to comply with the laws or regulations. Similarly, in its second report on human tissue research, the B.A.C. recommended that there should be statutory regulation and supervision of tissue banking and that a statutory authority should be given supervisory and licensing jurisdiction to carry this out and that the authority should be given sufficient powers of direction, enforcement and supervision, so as to enable it to effectively supervise and give ethical and legal direction for the conduct of research tissue banking in Singapore. An effective system for regulating (including sanction powers) and licensing life science technology is far more likely to achieve success in dealing with the social, ethical and philosophical issues that surround the technology, rather than over-reliance on discretion in patent legislation to deny patents to morally abhorrent inventions.

131 For an interesting discussion of the need for regulation, see Francis Fukuyama, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (United States: Profile Books, 2002). Professor Fukuyama argues at 10 that the response to the power of biotechnology should be obvious—to use the power of the state to regulate it—and that if this is "beyond the power of any individual nation-state to regulate, it needs to be regulated on an international basis." Professor Fukuyama argues that aside from discussion at the "relatively abstract level" over the ethics of procedures such as cloning and stem cell research, there is need for "more practical guidance so that technology remains man's servant rather than his master."