Comment on *Monsanto Canada Inc. v. Schmeiser*

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I. Introduction

The Supreme Court of Canada has recently decided two cases dealing with patenting of life forms. In the celebrated case of *Harvard College v. Canada (Commissioner of Patents)*[1] ("*Harvard Mouse*") the Supreme Court of Canada considered the validity of a patent for a genetically modified mouse with heightened susceptibility to cancer which had been developed at Harvard University for use in cancer research. In a 5-4 decision the Court held that higher life forms such as mice, as well as plants and animals generally, are not patentable subject matter.[2] Less than two years later the Court decided *Monsanto Canada Inc. v. Schmeiser*,[3] the culmination of a patent infringement action brought by Monsanto against Percy Schmeiser, a Saskatchewan farmer who had intentionally grown Monsanto's genetically modified canola without a licence. Monsanto had used genetic engineering to insert a gene into canola which conferred resistance to certain herbicides.[4] This was just as the

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[1] [2002] 4 S.C.R. 45, 2002 SCC 76 [*Harvard Mouse*], rev'g [2000] 4 F.C. 528 (C.A.).

[2] *Ibid*. at para. 155.

[3] 2004 SCC 34 [*Schmeiser*], var'g [2003] 2 F.C. 165 (C.A.), aff'g (2001), 202 F.T.R. 78.

[4] In particular, the gene conferred resistance to glyphosate based herbicides, such as Monsanto's ROUNDUP; hence the canola composed of the patented cells is sold under the trade-mark ROUNDUP READY. The defendants were Percy Schmeiser himself and Schmeiser Enterprises Ltd., owned wholly by Schmeiser and his wife. For convenience I will refer to both collectively as "Schmeiser." It is not clear how the canola came onto Schmeiser's property. The evidence suggests that Schmeiser first noticed patches of herbicide resistant canola which may have originated from a passing seed truck when spraying Roundup to kill vegetation around his roadside ditches and power poles: see the trial decision, *supra* note 1, paras. 38-40. Nonetheless, no specific finding was made on this point at trial and nothing turns on it: *ibid.* at para. 119. It was found as a fact that after discovering the resistant seed Schmeiser intentionally selectively harvested it and

inventors at Harvard had done when they inserted a gene into a mouse which conferred susceptibility to cancer. The difference was that while Harvard claimed the mouse itself – "A transgenic non-human mammal [containing the specified gene]"[5] – Monsanto claimed only the genes and plant cells incorporating those genes – "A glyphosate-resistant plant cell [containing the specified gene]."[6] While the difference may seem to be one of form rather than substance, the consequences were dramatic. The Court in *Schmeiser* affirmed that the cells of plants and animals are patentable and in the result Schmeiser was held to have infringed Monsanto's patent by growing plants composed of the patented cells. In consequence it is now clear that a patent for the cells of a higher life form will give effectively the same protection as a patent for the higher life form itself.

The 5-4 division in *Schmeiser* was along essentially the same lines as in *Harvard Mouse*, but with a slight change in the composition of the Court.[7] *Harvard Mouse* has been reduced to little more than a trap for the unwary claims drafter, at least so far as higher life forms produced by genetic engineering are concerned.[8] But the difference in result reflected

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replanted it the following year: *ibid*. at para. 120.

[5] See claim 1; the complete claims are provided in the appendix to the decision of the Federal Court of Appeal, *supra* note 1 at 613. All the disallowed claims were of a similar form. The patent has since issued without the disallowed claims as Patent # 1,341,442.

[6] *Supra* note 3, Appendix, claim 22. There are some differences in the gene description between the two cases. The *Harvard Mouse* patent claimed any "activated oncogene sequence" which is permissible as the inventors were the first to introduce a cancer inducing gene into a mammal. The Monsanto patent claimed only a plant containing the specific gene which Monsanto itself had created. This gene was itself claimed in Claim 1 – "A chimeric plant gene which comprises [gene description]" and cells containing the gene were claimed in Claim 22. "A glyphosate resistant plant cell comprising a chimeric plant gene of Claim 1." Nothing turns on these differences so far as subject matter is concerned, as the variations are motivated by other aspects of patent law, such as the requirement that the invention must be new, and the claim must not exceed the bounds of what is actually invented.

[7] Three members of the Court – McLachlin C.J. and Major, Binnie JJ. – ruled in favour of the patentee in both *Harvard Mouse* (dissenting) and *Schmeiser* (in the majority), while three members – Iacobucci, Bastarache and LeBel JJ. – ruled consistently against the patentee. Two Justices who ruled against the patentee in *Harvard Mouse*, L'Heureux-Dubé and Gonthier JJ., have retired and their replacements favoured the patentee in *Schmeiser*. Of the Justices involved in both decisions, only Arbour J. ruled for the patentee in *Harvard Mouse* and against in *Schmeiser*.

[8] An apparently inadvertent result of the interplay between *Harvard Mouse* and *Schmeiser* is that traditionally hybridized plants remain effectively unpatentable, at least for the time being, because it is presently impractical to provide a cellular or genetic description of a new variety produced in this manner. This is in contrast to the situation in the United States where higher life forms are patentable *per se* and cellular or genetic

more than just the change in the Court and a formal difference in claims language. On the contrary, the result in *Schmeiser* addressed a fundamental flaw in the majority opinion in *Harvard Mouse*. In denying patent protection to a particular field of technology the decision was inconsistent with the scheme of the *Patent Act*, which seeks to promote innovation generally. The claim language in *Schmeiser* forced the Court to grapple directly with the conflict between *Harvard Mouse* and general patent principles. The majority in *Schmeiser* chose consistency with broad principles of patent law at the expense of practical consistency with the *Harvard Mouse* decision, while the dissent chose consistency with *Harvard Mouse* at the expense of patent principles. The result was a reaffirmation of sound patent principles and a vindication of the dissenting opinion in *Harvard Mouse*.

While this alone would have established *Schmeiser* as a landmark in patent law, the majority opinion also clarified two other areas of general patent law: it set the remedy of accounting of profits on a clear and principled foundation, and it significantly advanced the law related to infringement by patent "use." And as if all this were not enough, the decision provides important guidance, albeit in dicta, as to how the controversial "innocent bystander" problem will be treated.[9]

This Comment first addresses the aspect of *Schmeiser* dealing specifically with genetically modified life forms. Unsympathetic to the holding in *Harvard Mouse*, the majority in *Schmeiser* made no real effort to preserve it, and so was happy to apply standard principles in interpreting Monsanto's patent. The dissent in *Schmeiser* faced the much greater challenge of giving practical effect to the holding in *Harvard Mouse* by somehow integrating it into the body of patent doctrine. For this reason this Comment dwells more than is usual on the *Schmeiser* dissent. Changes in the composition of the Court between *Harvard Mouse* and *Schmeiser* tipped the balance from a technology specific approach to technology neutrality. Future changes might once again reverse that balance. The dissent's failed effort to incorporate *Harvard Mouse* into patent law teaches important lessons about the hidden perils of a technology specific approach to the *Patent Act*.

The Comment then turns to the more general issues of patent use and remedy, and, as importantly, the relationship between them. The majority in *Schmeiser* adopted a broad approach to defining patent "use", but a

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level claims are not required, so that traditionally hybridized varieties can be claimed at the plant level: see for example U.S. Patent Number 6,762,351 claiming "[a] potato tuber...of potato variety FL1867..."

[9] The problem arises when patented plants forms enter adventitiously onto the property of a farmer who is not initially aware of their presence: see below Part 4 "The Innocent Bystander."

narrow approach to remedy. This provides an excellent balance between allowing effective enforcement of patent rights without unduly burdening the user. This point is essential to the problem of the "innocent bystander" who finds patented plants have entered onto his land without his knowledge. The Court was very clear that the issue was not raised on the facts, as Schmeiser was an intentional user, but the principles which were established by the decision are nonetheless directly relevant. The broad definition of "use" indicates that an innocent bystander would be strictly considered an infringer, but the more stringent requirements at the remedial stage suggest that an innocent bystander has little or nothing to fear in the final result. The welcome conclusion is that the plight of the innocent bystander under existing law is not nearly so perilous as is sometimes supposed.

II. Patentable Subject Matter

A. Harvard College v. Canada (Commissioner of Patents)

The split in the Court in *Harvard Mouse* reflected a fundamental debate about the nature of the *Patent Act*. The most obvious way to characterize the division is pro- and anti-genetically modified organisms. But that is only the immediate manifestation of the more basic difference, which is whether there should be a presumption for or against patentability of new technology. This legal question is consequent on the policy question of whether technology specific regulation should come before patenting of new technology, or afterwards. The key argument of the majority in *Harvard Mouse* was that the legislature would want to address the contentious technology specific issues *before* encouraging the new technology with patent incentives: "The Act in its current form fails to address many of the unique concerns that are raised by the patenting of higher life forms, a factor which indicates that Parliament never intended the definition of "invention" to extend to this type of subject matter."[10] Thus the absence of technology specific regulation is in itself taken as strong evidence that the legislature did not intend to permit that technology to be patented.

The difficulty with this position is that it requires a court to make judgments beyond its competence. For example, the elements that the majority found particularly controversial with respect to patenting of higher life forms, such as the so-called innocent bystander problem and the lack of a farmer's privilege in the *Patent Act*, require considerations of matters of social policy which cannot be adequately addressed or

[10] *Harvard Mouse, supra* note 1 at para. 120. See to the same effect paras. 166, 167 and 183.

resolved in litigation.[11] A court cannot make any reasonable assessment of whether patenting is truly undesirable in a particular field of technology. In consequence, all it can do is adopt a negative stance which refuses to permit patenting of any new technology which appears controversial until Parliament has given express approval.[12] This attitude, which requires technology to move at the pace of law reform, is inimical to innovation.

For this reason, while the dissenters in *Harvard Mouse* agreed that patenting life forms raised complex issues, they did not think that this required *prior* regulation. On the contrary, "regulation necessarily follows, rather than precedes, the invention."[13] Parliament might believe technology specific legislation was needed with respect to higher life forms, or any other new technology; but on the other hand, it might not.[14] Moreover, history shows that while the legislature often regulates specific technologies, whether new ones such as nuclear power, or old ones such as firearms, it rarely chooses to modify the *Patent Act* to do so. Parliament normally addresses technology specific issues with technology specific statutes,[15] while the *Patent Act* is used for the technology neutral purpose of encouraging innovation across all fields of endeavour:

> Even a partial listing of the [biotechnology specific regulatory] possibilities demonstrates why it should occasion no surprise that such regulatory structures are not crammed into the *Patent Act*, which has always had the more modest and focussed objective of simply encouraging the disclosure of the fruit of human inventiveness in exchange for the statutory rewards.[16]

Arbour J. for the dissent in *Schmeiser* cited a number of examples intended to illustrate that subject matter restrictions on patentability are not uncommon, but the examples miss the mark. The problem with the prohibition on patenting higher life forms is that it is a *technology*

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[11] *Ibid*. at paras. 170-72.

[12] "Absent explicit legislative direction, the Court [page123] should not order the Commissioner to grant a patent on a higher life form." *Ibid*. at para. 155.

[13] *Ibid.* at para. 82. For an analysis of the innocent bystander problem which argues that no amendment to the *Patent Act* is necessary, see Norman Siebrasse, "The Innocent Bystander Problem in the Patenting of Higher Life Forms" (2004) 49:2 McGill L.J. 349.

[14] *Ibid.* at para. 114. See also para. 80 noting that there is no consensus as to which types of technology should be regulated.

[15] *Ibid*. at para. 83.

[16] *Ibid*. at para. 109. See similarly para. 81, "a court has no mandate to deny patentability because of the novelty or the potential social, economic or cultural impact of an invention, whether it be nuclear technology in the 1950s, biotechnology in the 1990s, or reproductive technology in the year 2002."

specific subject matter restriction which has been *judicially* created. Apart from *Harvard Mouse* itself, the examples cited by Arbour J. are either judicially created but technology neutral, or technology specific but legislatively created.[17] Neither of these types of restriction transgress the bounds of relative institutional competence in the way that the *Harvard Mouse* decision did.

The best established subject matter restriction is the judicially created rule that scientific principles, discoveries or abstract theorems cannot be patented *per se*.[18] On the other hand, concrete applications of such principles or discoveries are patentable. So, Einstein's discovery of the relationship between matter and energy, summarized in "$E=mc^2$" cannot be patented, though a nuclear reactor operating on that principle is patentable subject matter. The rule is "technology neutral" in that it applies whether the principle is one of chemistry, mathematics or civil engineering. The restriction is based on the general patent policy that the bounds of the claim must be clearly defined so that the public at large can know whether their conduct infringes. The scope of a scientific principle or abstract theorem is inherently uncertain, but once reduced to concrete form in a practical application, the bounds of the claim can be precisely delineated.[19] This rule of general application respects the boundaries of

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[17] The examples are cited *ibid*. at para. 133. *Schlumberger Canada Ltd. v. Commissioner of Patents*, [1982] 1 F.C. 845 (C.A.) and *Gale's Application*, [1991] R.P.C. 305 at 323 (C.A.) apply the rule against patenting of abstract theorems, discussed in the following paragraph. In *Gale's Application* the general rule was buttressed by s. 1(2)(c) of the U.K. *Patents Act*, 1977, which expressly excludes from patentability a program for a computer as such. The soundness of the application of the rule in these cases is questionable – compare *Re Alappat*, 33 F.3d 1526 (Fed. Cir. 1994) – but they are in any event expressly decided on the basis of that principle. *Re Application of Boussac*, CIPO, Decision No. 143, March 10, 1973, and *Re Application of Akzona*, CIPO, Decision No. 254, July 4, 1975 cite the rule against patenting professional skills, though both decisions held that the subject matter in question was patentable. *Re Application No. 995 for a Townhouse Building Design* (1979), 53 C.P.R. (2d) 211 (Pat. App. Bd.) is an application of the same rule, though in this case the decision rejected the patent on subject matter grounds. Again the result is questionable (see discussion below, note 20) but it is nonetheless an application of the general technology neutral rule. Curiously, Arbour J. cites *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (Fed. Cir. 1998) for the proposition that business systems and methods and professional skills and methods are not patentable, when this is the leading U.S. case establishing that business methods *are* patentable. *Tennessee Eastman Co. v. Commissioner of Patents*, [1974] S.C.R. 111, aff'g (1970), 62 C.P.R. 117 (Ex. Ct.) is based on what was then s. 41 of the *Patent Act*: see the discussion below at note 21.

[18] This principle is now codified s. 27(8) of the *Patent Act*, R.S.C. 1985, c. P-4, which provides that "[n]o patent shall be granted for any mere scientific principle or abstract theorem," but it emerged initially from judicial interpretation of the patentable subject matter: see for example *Betts v. Menzies* (1862), 11 ER 970, 984 (H.L.).

judicial competence, as it is the courts, rather than that of the legislature, which are best placed to decide whether a particular claim is so abstract that it would be impossible for a person to know whether it is being infringed. The same principle, that the bounds of a patent must be capable of being clearly ascertained, underpins the rule that subject matter that depends on artistic or professional skill is not patentable.[20]

On the other hand, technology specific subject matter restrictions have on occasion been created by express legislative provision. The prime example is the section of the *Act*, now repealed, which specified that substances intended for food or medicine could not be claimed as products *per se*, but only as products resulting from particular processes of manufacture.[21] This policy, which evidently turned on a legislative assessment that making medicines widely available was more important

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[19] See Norman Siebrasse, "A Property Rights Theory of the Limits of Copyright" (2001) 51 U.T.L.J. 1, Part F "Unpatentable Ideas" at 49.

[20] The leading Canadian case is *Lawson v. Com'r of Patents* (1970), 62 C.P.R. 101 (Ex. Ct.) which rejected a claim related to a method of subdividing land. *Lawson* has been cited in *Shell Oil v. Commissioner of Patents*, [1982] 2 S.C.R. 536, 555 as establishing that the exercise of professional skills is not patentable and this rule has been applied by the Patent Appeal Board in a number of decisions, but there are few, if any, other judicial decisions applying the rule to reject a claim. The decision of the Exchequer Court in *Tennessee Eastman Co. v. Commissioner of Patents*, *supra* note 17, does apply *Lawson* in rejecting the application, but the basis of the decision was varied on appeal to the Supreme Court: see the discussion below in footnote 22. Nor has this rule been codified. Consequently it is not as fully developed as the rule against patenting discoveries or scientific principles, and its application by the Patent Appeal Board and Commissioner of Patents has not been entirely consistent. The sound principle behind the rule suggests that while the ability to design aesthetically appealing housing should not be patentable, a particular well defined home design might be (so long as it satisfies other requirements, such as novelty). It must be said that the cases and decisions by the Commissioner of Patents do not uniformly support this view: see for example *Re Application No. 995 for a Townhouse Building Design*, *supra* note 17. *Re Application of Boussac*, *supra* note 17, on the other hand, is an excellent example of the rule that an "arrangement is not patentable if it produces only an aesthetic, intellectual or literary appeal" as the particular design for a pattern for fabric in question produced a well defined functional result and so *was* considered patentable subject matter. In any event, regardless of the vagaries of its application, the rule itself is technology neutral in that it is applicable to professional skills in any area of endeavour.

[21] Originally introduced in the *Patent Act* of 1923, S.C. 1923, c. 23, s. 17, it provided that "In the case of inventions relating to substances prepared or produced by chemical processes and intended for food or medicine, the specification shall not include claims for the substance itself, except when prepared or produced by the special methods or processes of manufacture particularly described and claimed or by their obvious chemical equivalents..." The word "special" was omitted in the *Patent Act, 1935*, S.C. 1935, c. 32, s. 40 and the provision was modified more substantially to apply only to "naturally occurring substances" produced by "microbiological processes" by S.C. 1985 (3rd Supp),

than ensuring their creation, depends on the broad issue of balance between incentives and restricting technology which is within the legislative competence.

The prohibition on patenting higher life forms created in *Harvard Mouse* falls into a third category of judicially created subject matter restrictions which apply only to a particular area of technology. This type of subject matter restriction is extremely rare, with *Harvard Mouse* being an almost unique example.[22] Judicially created subject matter restrictions must be based on the definition of "invention" in the *Patent Act* as meaning "any new and useful art, process, machine, manufacture or composition of matter" and any improvement thereon. The leading case prior to *Harvard Mouse* was the decision of the Supreme Court in *Shell Oil Co. v. Commissioner of Patents*.[23] Wilson J., for a unanimous Court, gave "invention" a broad interpretation. In the course of holding that a

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c. 33, s. 14 before being repealed by S.C. 1993, c. 2, s. 3 in favour of a detailed administrative regime relating to patented medicines: see the current *Act*, *supra* note 18, ss. 79-103.

[22] It was at one time common to restrict patentability on subject matter grounds in the U.K., particularly on the basis of the "vendible product" criterion enunciated in *Re Application for a Patent by G.E.C.* (1942), 60 R.P.C. 1 (Pat. App. Bd.). It is now recognized that there are substantial differences between the Canadian *Act* and British statute on which these decisions were based (*Tennessee Eastman Co. v. Commissioner of Patents*, *supra* note 17 at 120), and that this approach was unsound in principle as being "the confusion of the idea of the end with that of means" (per Cattanach J. in *Lawson v. Commissioner of Patents*, *supra* note 20 at 110, quoted with approval by Wilson J. in *Shell Oil*, *supra* note 20 at 555). The definition of patentable inventions in the U.S. *Act*, 35 U.S.C.A. § 101, is very similar to ours and has of course been given a very broad interpretation since the decision of the U.S. Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Arbour J. cited *Tennessee Eastman Co. v. Commissioner of Patents*, *supra* note 17, for the proposition that methods of medical treatment are not patentable, but, as explained in *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 at paras. 48-50, the decision was based on the provision of the *Act* discussed in the previous paragraph, which restricted claims for substances intended for medicine. It is true that at one time it held that methods of medical treatment were not patentable as not falling within the definition of patentable subject matter, but the rule now is that methods of medical treatment are not patentable only insofar as they are no more than an exercise of professional skill and judgment (see *Apotex Inc. v. Wellcome* and *Shell Oil* as cited therein). So, a surgeon's skill cannot be patented any more than a barrister's method of cross-examination (see *Lawson* at 111), but methods of treatment which are concrete and well defined, such as a more effective schedule for taking contraceptive pharmaceuticals, are patentable: see *Re Application of Akzona*, *supra* note 17. One of the few examples of a subject matter restriction specific to a particular area of endeavour is *Re Progressive Games, Inc. Patent Application No. 596,848* (1999), 3 C.P.R. (4th) 517 (F.C.T.D.) in which an application for a patent on a variant of five card stud poker was rejected on subject matter grounds. While the reasoning is not entirely clear, the case likely stands for the proposition that rules of a game are not patentable.

[23] *Supra* note 20.

practical application of the discovery of a new use for an old compound was patentable, she stated:

> What then is the "invention" under s. 2? I believe it is the application of this new knowledge to effect a desired result which has an undisputed commercial value and that it falls within the words "any new and useful art". I think the word "art" in the context of the definition must be given its general connotation of "learning" or "knowledge" as commonly used in expressions such as "the state of the art" or "the prior art".[24]

This approach does not take "art" as a narrowly defined category; instead it is taken as a reflection of the purposive definition of "invention" as "the application of this new knowledge to effect a desired result." This definition of invention is consonant with the goal of *Patent Act* as explained by the dissent in *Harvard Mouse*, namely "encouraging the disclosure of the fruit of human inventiveness in exchange for the statutory rewards."[25]

In contrast, the majority in *Harvard Mouse*, without reference to *Shell Oil*, chose to treat the listing of terms in the definition of invention as a series of pigeon holes:

> In drafting the *Patent Act*, Parliament chose to adopt an exhaustive definition that limits invention to any "art, process, machine, manufacture or composition of matter. . .By choosing to define invention in this way, Parliament signalled a clear intention to include certain subject matter as patentable and to exclude other subject matter as being outside the confines of the Act.[26]

This understanding of the intention of Parliament is at odds with that discerned by Wilson J. in *Shell Oil*, and the majority in *Harvard Mouse* conceded that "in their grammatical and ordinary sense" the key words "are somewhat imprecise and ambiguous"[27] and "can support a broad interpretation."[28] The primary basis for its striking conclusion that a mouse is not a "composition of matter" was therefore the policy arguments regarding the desirability of prior regulation of contentious technology.[29]

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[24] *Ibid*. at 549.
[25] *Supra* note 1 at para. 109.
[26] *Ibid.* at para. 158.
[27] *Ibid*. at para. 155.
[28] *Ibid*. at para. 120.
[29] *Ibid*.

B. Monsanto Canada Inc. v. Schmeiser

This brings us to the Court's decision in *Schmeiser*. Regulating higher life forms may well raise complex problems requiring legislative response. Or, as the dissent in *Harvard Mouse* pointed out, it may not. The question is ultimately one for the legislature, not the courts. But one complex issue which is within the purview of the courts is the problem of integrating a technology specific subject matter restriction into the technology neutral body of the *Patent Act*. This problem was at the fore in *Schmeiser*.

The most obvious difficulty in excluding higher life forms is where to draw the line between unpatentable higher life forms, such as plants and animals, and lower life forms, such as bacteria, yeast and moulds, which the majority in *Harvard Mouse* affirmed are patentable. The majority in *Harvard Mouse* acknowledged that some problems might arise, but was sanguine that evolving case-law would fashion a satisfactory demarcation.[30] And indeed this did not pose a particular difficulty in *Schmeiser.* It was accepted that higher plants such as canola are higher life forms, so that a claim for the plant itself would have been invalid under *Harvard Mouse*. But the claims at issue in *Schmeiser* were for the genes and modified plant cells containing those genes.[31] The majority and the dissent agreed that a genetically modified cell is patentable, thus affirming the dicta to this effect in *Harvard Mouse*.[32] Accordingly, all agreed that the genetically modified cells at issue were patentable subject matter.

The truly difficult problem, which had not been anticipated in *Harvard Mouse*, was not where to draw the line, but *how* to draw the line. The puzzle flows directly from the majority decision in *Harvard Mouse*. Higher life forms are not patentable, but their cells are; and since higher life forms are composed of cells, a patent on the cells of plant or animal would effectively give control over the plant or animal itself. An order for destruction of infringing plant cells, for example, would necessarily require destruction of the entire plant.

To resolve the contradiction, either the scope of cell and gene patents must be somehow restricted, or *Harvard Mouse* would be deprived of practical effect. The dissent in *Schmeiser* chose the former course.

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[30] See generally *Harvard Mouse*, *supra* note 1 at paras. 197-206.

[31] The key claims were claims 1 and 22, reproduced in note 6 above.

[32] The majority in *Harvard Mouse* had indicated quite clearly that a genetically modified egg *would* be patentable, even though the mouse which the egg becomes is not (*supra* note 1 at para. 162) and this was accepted by both the majority and the dissent in *Schmeiser* as holding that single cells generally, not just egg cells, are patentable: see *Schmeiser*, *supra* note 3 at paras. 21-24 (majority); paras. 115, 135-135 (dissent).

Arbour J. held that the claims did not extend to genes and cells in the form of mature plants: "The plant cell claim ends at the point where the isolated plant cell containing the chimeric gene is placed into the growth medium for regeneration."[33] The majority took the latter course and applied standard principles in interpreting the claims, holding that even though only the genes and modified cells were claimed, "we do not believe this fact requires reading a proviso into the claims that would provide patent protection to the genes and cells only when in an isolated laboratory form."[34]

The rationale underlying the dissent's narrow view of the scope of the claims was perfectly clear. Arbour J. felt strongly that the majority interpretation was inconsistent with the spirit of *Harvard Mouse*. As she pointed out, quite correctly, the practical effect of the lower court decision, affirmed by the majority, was to render *Harvard Mouse's* prohibition of patenting of higher life forms largely ineffectual.[35] As a result of the *Schmeiser* decision it is now clear law in Canada that while a claim to a higher life form *per se* is invalid, a patentee can gain equally effective protection by claiming the cells which make up that higher life form. "Such a result," the dissent argued, "is hard to reconcile with the majority decision in *Harvard College*."[36]

It may be that this result is difficult to reconcile with the spirit of *Harvard Mouse*, but it is equally difficult to reconcile the spirit of *Harvard Mouse*, as the dissent sees it, with the standard patent law framework. Arbour J. advanced three main arguments based on traditional patent law principles in an attempt to show that the scope of the cell patents should be interpreted restrictively. All three arguments illustrate, in different ways, the difficulty of integrating the technology specific exclusion of higher life forms into the technology neutral body of general patent law.

1. "What is not claimed is disclaimed."

The *Schmeiser* dissent's first substantive argument appealed to the principle that "what is not claimed is disclaimed." In the section with that heading Arbour J. stated a number of uncontroversial principles of patent

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[33] *Schmeiser*, *ibid*. at para. 130.

[34] *Ibid*. at para. 17.

[35] "Both lower court decisions 'allo[w] Monsanto to do indirectly what Canadian patent law has not allowed them to do directly: namely, to acquire patent protection over whole plants.'" *Ibid*. at para. 108. The prohibition on patenting higher life forms retains some effect, as traditionally hybridized plants remain unpatentable, at least until it becomes practical to describe them at the cellular level: see *supra* note 8.

[36] *Ibid*. at para. 109; and see similarly paras. 107, 108.

law, all to the effect that the claims limit the scope of the monopoly.[37] These general statements were not related to the facts at hand, except in the following conclusion:

> It is clear from the specification that Monsanto's patent claims do not extend to plants, seeds, and crops. It is also clear that the gene claim does not extend patent protection to the plant. The plant cell claim ends at the point where the isolated plant cell containing the chimeric gene is placed into the growth medium for regeneration.[38]

The dissent is apparently saying that it follows from the fact that if the claim does not specifically claim the plant *per se* that the claim cannot give effective control over the plant. This is quite wrong, as the majority's apt analogy illustrates:

> [T]he cells are somewhat analogous to Lego blocks: if an infringing use were alleged in building a structure with patented Lego blocks, it would be no bar to a finding of infringement that only the blocks were patented and not the entire structure.[39]

To elaborate, a toy truck is unpatentable because it is not novel, but the owner of a patent for Lego blocks could obtain an order for delivery up of a toy truck constructed from the blocks, not because the truck as a whole infringes, but because delivery up of the Lego blocks incidentally requires delivery up of the truck. The patentee would certainly get delivery up of the blocks if they were piled in a heap – the fact that they have been assembled into a truck neither adds to nor detracts from the patentee's remedy. The particular form is irrelevant. Thus while it is true that what is not claimed – a toy truck – is disclaimed, this does not imply that the patentee cannot get control over the defendant's toy truck if that truck happens to be constructed from patented blocks.

More broadly, while a patentee's monopoly extends *only* to what is described in the claims, it extends to *everything* which can be described in a way which falls within the scope of the claims. The dissent's view that the patentee is only entitled to a monopoly over embodiments of the invention which are particularly described in the claims (or perhaps in the specification as well) would be a radical rewriting of law which would undermine the entire patent system. It has long been established that the inventor is entitled to claim all embodiments of her inventive concept, not just those which she has particularly described. Otherwise, "the

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[37] *Ibid.* at paras. 123-124, "C. Purposive Construction of the Claims (2) What Is Not Claimed Is Disclaimed." The dissent began its analysis of scope with some anodyne comments regarding the need for fairness and predictability (para. 122) which made no substantive contribution to the analysis.

[38] *Ibid.* at para. 130.

[39] *Ibid.* at para. 42.

patent may be just as worthless as if it was invalid," as "[e]veryone will be free to use the invention in the unfenced area."[40] The principle that the claims may extend beyond the particular embodiments is illustrated most dramatically – and most commonly – when it is invoked against the patentee, to show that the claim is invalid because it covers some embodiment which itself is not useful or not novel. If that is proven, such an attack will be successful, notwithstanding that the non-useful embodiment was not particularly described or contemplated by the patentee.[41]

2. Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.

The dissent next turned to the principle that a patent is to be construed as it would be understood by a person skilled in the art. Arbour J. asserted that such a person "could not reasonably have expected that the exclusive rights for gene, cell, vector, and method claims extended exclusive rights over unpatentable plants and their offspring." As authority Arbour J. appealed to the decision of the U.K. Court of Appeal in *Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.*[42] and in particular that Court's remark that "third parties could reasonably expect that if they did not use a DNA sequence for insertion into a host cell, there would be no infringement."[43] The majority distinguished *Kirin Amgen* on the basis that it was decided in the context of the EU Directive on the legal protection of biotechnological inventions ("the Directive"), and the Directive, which, *inter alia*, restricts the patentability of human genes, has no parallel in Canada.[44] This does successfully distinguish *Kirin Amgen*, but it has the disturbing implication that the majority decision in *Schmeiser* is inconsistent with the Directive at a policy level. It also suggests that if comparable legislation were enacted in Canada, the *Schmeiser* decision might be implicitly overruled.

Neither inference is warranted, as *Kirin Amgen* is readily distinguishable on much stronger grounds. The Court of Appeal's remark

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[40] *Burton Parsons v. Hewlett-Packard*, [1976] 1 S.C.R. 555, 565.

[41] A striking example of this is *Minerals Separation North American Corporation v. Noranda Mines Ltd.* (1952), 69 R.P.C. 81 (P.C.) aff'g [1950] S.C.R. 36 which concerned an invention relating to the separation of minerals from ore. The process required the use of "xanthates" and this key term was interpreted to include cellulose xanthate, which would not work. The specification did not specifically claim cellulose xanthate, and all of the xanthates which were specifically claimed did work. Nonetheless, in the result, even though the invention was undoubtedly very meritorious and commercially valuable, the key claims were held to be invalid.

[42] [2003] R.P.C. 3 (C.A.).

[43] *Ibid.* at para. 60, quoted by Arbour J. in *Schmeiser*, *supra* note 1 at para. 127.

[44] *Schmeiser*, *ibid.* at para. 89.

in *Kirin Amgen* was not a statement about gene patents generally, it was simply an interpretation of the particular, narrowly claimed, patent at issue. The main claim in *Kirin Amgen* was for "A DNA sequence for use in securing expression in a...*host cell*...".[45] The key question was how "host cell" should be construed. The Court of Appeal, affirming the Patent Court on this point, held that as a matter of construction of the particular patent a "host cell" means a cell other than the cell in which the DNA is ordinarily found.[46] In the case of human erythropoietin,[47] the product at issue, a "host cell" therefore means any *non-human* cell, such as the bacterial cell which the patentee itself used. The defendants attempted to avoid the patent by expressing the DNA in a *human* cell, thus falling outside the literal scope of the claims as construed by the Court.[48] The question then was whether the patent was nonetheless violated because the defendant's activity fell within the principle of the patent.[49] The Court of Appeal held that the patent was not infringed even on this broader view. So, when the Court of Appeal said that "third parties could reasonably expect that if they did not use a DNA sequence for insertion into a host cell, there would be no infringement" it was not saying that as a general matter a gene patent could not be infringed unless the gene was inserted into a host cell. It was simply saying that given that the claim in question was literally for the DNA sequence expressed in a host cell, it would be unfair and unexpected to extend it to cover insert in a cell which was not a host cell. To cite this statement out of context for the broader proposition is a serious mischaracterization of the decision.

Arbour J. also emphasized the Court of Appeal's statement that "The patentee could not monopolise the gene *per se* as that existed in nature."[50] This statement is of doubtful authority, as it was dicta on a point which was not fully argued. The patentee had not attempted to broadly monopolize the DNA sequence and the Court of Appeal was merely speculating as to why it chose not to. Perhaps the patentee thought that such a patent would be more vulnerable, but a patent

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[45] Claim 1, reproduced *supra* note 42 at para. 21 [emphasis added].

[46] *Ibid.* at para. 42.

[47] Erythropoietin is a protein produced by certain kidney cells which increases production of red blood cells: *ibid.* at para. 9.

[48] *Ibid.* at para. 42.

[49] In U.K. law once it is concluded that there has been no literal infringement, it is necessary to determine whether there has been infringement in light of the principles of construction laid down in the Protocol on Interpretation of Article 69 of the European Patent Convention, and the so-called "Improver questions." See *Wheatley v. Drillsafe Ltd.*, [2001] R.P.C. 133 (C.A.); *Improver Corporation v. Remington Consumer Products Ltd.*, [1989] R.P.C. 69 (C.A.); *Catnic Components Ltd v. Hill and Smith Ltd.*, [1982] R.P.C. 183 (H.L.).

[50] *Kirin Amgen*, *supra* note 42 at para. 60, quoted by Arbour J. in *Schmeiser*, *supra* note 3 at para. 127.

applicant's caution does not establish the law. Indeed, this dictum from the Court of Appeal is inconsistent on its face with the Directive, which states expressly that while the simple discovery of a human gene is not patentable, "An element isolated from the human body...including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element."[51]

3. Scope and Validity

The dissent's final argument is that the claim to the genes and cells, while valid in itself, should be construed to extend only to the cells in isolated form, as they would exist in the laboratory, and not in the form of plants, seeds and crops.[52] The rationale was that the claims would be invalid if construed to extend to the cells in the form of plants, as this would amount to a claim to the plant itself. A narrow construction is required to avoid invalidity.

The interpretive principle that the claims should be construed narrowly if necessary to avoid a finding of invalidity is sound, but the premise that the claim would be invalid if it extended to cells in the form of plants is not. In this section Arbour J. relied primarily on the decision of Wilson J. for the unanimous Court in *Shell Oil Co. v. Commissioner of Patents*:[53]

> Wilson J., stated at p. 553, that "a claim for the compositions in these cases would, it seems to me, extend beyond the scope of the invention and violate s. 36". Section 36 provides that the specification needs to describe new subject matter in which exclusive property rights are claimed. Following Wilson J.'s reasoning, if any of Monsanto's patent claims had been construed to encompass plants, they would have been invalid.[54]

With due respect, this conclusion does not follow from Wilson J.'s reasoning. In the first place, the particular quotation relied on by Arbour J. is not about subject matter at all. The claims in question were invalid

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[51]EC, *Council Directive 98/44 of 6 July 1998 on the legal protection of biotechnological inventions*, [1998] O.J.L. 213/13 at art. 20. This is consistent with the position in *Shell Oil Co. v. Commissioner of Patents*, *supra* note 20 that while a discovery *per se* is not patentable, its practical embodiment is: see the discussion of *Shell Oil* in the text below. The primary goal of the Directive's prohibition on patenting of human genes is evidently to exclude the possibility that such a claim could result in the patentee having control over the individual person who carries the gene.

[52]*Supra* note 3 at para. 130.

[53]*Supra* note 20.

[54]*Schmeiser*, *supra* note 3 at para. 134.

for obviousness – lack of inventiveness – not lack of subject matter. The beginning of the sentence, not quoted by Arbour J., makes this clear: "[b]ecause those cases held that there was no further inventive step involved in mixing the compounds with inert carriers..."[55] It may be that Arbour J. simply misunderstood the holding in *Shell Oil*. At the time that case was decided there was no express statutory non-obviousness requirement,[56] and obviousness was considered fatal to patentability on the basis that an obvious device was not an "invention." It was not unusual at the time to say that an invalid patent "lacked subject matter" or "extended beyond the invention" even though in modern terminology we would say that the subject matter was unobjectionable and the defect was obviousness.[57]

More fundamentally, *Shell Oil* stands for a proposition essentially contrary to Arbour J.'s broader statement that "[i]f a claim encompasses subject matter that is precluded from patentability, it is invalid."[58] The true rule is that if a claim *claims* subject matter that is precluded from patentability, it is invalid. A claim that "encompasses" unpatentable subject matter in some broad sense is not invalid for that reason. This is not a semantic quibble, as *Shell Oil* illustrates. The basic invention in that case lay in the discovery that certain compounds were useful as plant growth regulators. As Wilson J. noted, "[a] disembodied idea is not *per se* patentable," so a claim for the discovery itself would have been invalid. "[b]ut," she continued, "it will be patentable if it has a method of practical application."[59] In the result, the claim in *Shell Oil* was valid, notwithstanding that all possible uses of the unpatentable discovery were encompassed. On this reasoning, the fact that Monsanto's gene and cell patent "encompasses" all practical uses of the unpatentable plant is no objection to the validity of the claim. This is consistent with the observation of the majority in *Schmeiser* that "[w]hether or not patent protection for the gene and the cell extends to activities involving the plant is not relevant to the patent's validity."[60]

Shell Oil is usefully contrasted with *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning*.[61] *Hoechst* concerned a patent for medicine. At the time patents for medicine were restricted by an express provision, then s. 41 (since

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[55] *Shell Oil*, *supra* note 20 at 553.

[56] Section 28.2 which defines the non-obviousness requirement in the present *Act* was only enacted in 1993 (*supra* note 21, s. 33).

[57] For a good illustration of this see *Slater Steel Industries Ltd. v. Lacal Industries*, [1972] S.C.R. 29.

[58] *Schmeiser*, *supra* note 3 at para. 134.

[59] *Shell Oil*, *supra* note 20 at 554.

[60] *Schmeiser*, *supra* note 3 at para. 24.

[61] [1964] S.C.R. 49 [*Hoechst*].

repealed) which specified that substances intended for medicine could not be claimed as products *per se*, but only as products resulting from particular processes of manufacture.[62] In other words, under that provision if someone had invented an entirely new drug which cured cancer, they would not be able to claim the drug itself, but only the drug produced by the specific product which they had used to manufacture it. If, once the composition of the drug was revealed by the patent, a competitor developed a different way of manufacturing the drug, the competitor would not infringe the patent notwithstanding that its drug was exactly the same as that invented by the patentee. This greatly reduced the protection for the inventor, as the composition of a new drug is normally the key invention, and there are often multiple routes by which it might be manufactured. In *Hoechst* the patentee had attempted to avoid obtain better protection by claiming a new medicinal substance mixed with an adjuvant (an inert carrier) as a product *per se*. The hope was evidently that this product would fall outside the bounds of section 41. Since the medicine in question would always be mixed with an adjuvant in practice, this would give essentially the same protection as a claim for the drug itself. For this very reason, the Supreme Court held this claim to be invalid: to allow the claim "would mean that all new medicines could be claimed free of the restrictions of Section 41 in the only practical form in which they may be used. This, of course, would defeat the whole purpose of the Section."[63] There is an obvious parallel with Monsanto's claims: permitting claiming of the cells rather than the plant *per se* means that all inventions related to higher life forms can now be claimed in the only practical form in which they may be used, thus defeating the holding in *Harvard Mouse*.

Despite the apparent contradiction, *Shell Oil* and *Hoechst* are readily reconciled. As Wilson J. explained in *Shell Oil*, *Hoechst* and related cases turned on s. 41, a statutory provision specifically directed at medicines. In consequence, "these cases did not establish a broad principle that compositions containing new compounds mixed with an inert carrier were not patentable."[64] The general principle, established in *Shell Oil* is that such compounds *are* patentable. The holding in *Hoechst* represented a departure from general principles which was necessary in order to uphold the technology specific legislative policy relating to substances intended for food or medicine set out in s. 41.

The comparison of *Shell Oil* and *Hoechst* teaches two important lessons. First, the judge-made, technology neutral subject matter restriction that scientific principles, discoveries or theorems cannot be

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[62] See note 21 above.

[63] *Hoechst*, *supra* note 61 at 55.

[64] *Shell Oil*, *supra* note 20 at 552.

patented *per se* and legislative technology specific subject matter restrictions such as that at issue in *Hoechst* are treated quite differently. The first type of restriction is based on the general patent policy that the bounds of the claim must be clearly defined so that the public at large can know whether their conduct infringes. The scope of a scientific principle or abstract theorem is inherently uncertain, but once reduced to concrete form in a practical application, the bounds of the claim can be precisely delineated. This is why it is irrelevant whether the claim "encompasses" all uses of the abstract principle. The principle may be applied in the context of specific technologies, but the principle itself is technology neutral. In contrast, technology specific provisions such as the restriction on patenting of medicines at issue in *Hoechst* depend on legislative decisions about the effect of patent law on particular sectors of the economy. The driving concerns are not internal to patent law, but rely on a broad array of social judgments. Once the legislature has expressed its judgment in express provisions of the *Patent Act*, the Court will endeavour to implement that specific policy by defining the bounds of the technology in question and reading the provision purposively to ensure that the intent is not evaded. But in so doing the Court will not pretend to be implementing general patent principles.

The dissent in *Schmeiser* failed entirely to distinguish subject matter restriction based on the general technology neutral principle from those based on technology specific legislation.[65] *Harvard Mouse* was an anomaly in patent law, a technology specific decision based on broad concerns about social policy, but one which was created by judges, not by the legislature. Perhaps because the exclusion was judge-made, Arbour J. attempted to fit it into the general patent law framework. But technology specific subject matter exclusions based on broad social concerns do not fit comfortably with general patent principles. This is the root cause of the failure of the dissent's arguments.

Conversely, the second lesson from *Shell Oil* and *Hoechst* is that technology specific restrictions require a departure from general patent principles. For this reason a more compelling argument for the dissent would have been to follow the example of the Court in *Hoechst* and forthrightly acknowledge that general patent principles would have to be abandoned within the biotechnology sphere if the effect of *Harvard Mouse* was to be preserved. The disadvantage of this approach, presumably, is that it would have revealed the majority decision in *Harvard Mouse* to be unprincipled judicial legislating.

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[65]On the contrary, Arbour J. expressly equated the two, *Schmeiser*, *supra* note 3 at para. 132: "Claims that would otherwise be valid may be limited by statutory provisions or by jurisprudence" citing *Shell Oil*, *supra* note 20, and *Hoechst*, *supra* note 61.

III. Use & Remedy

This grand debate over patentable subject matter and the nature of the *Patent Act* is crucially important to biotechnology and other emerging areas of innovation. The Court's holdings on patent "use" and remedy, while less glamorous, are of perhaps greater practical importance to patent law generally. Accordingly, we now turn to these topics.

But before examining what the majority did say regarding the law of patent use, we should be clear as to what the decision did *not* say. The dissent suggested that the majority adopted a "commercial use" test in which the test for use is "whether the alleged user has deprived the patentee of the commercial benefits flowing from his invention..."[66] Similarly, Professor Richard Gold has stated that the majority "reworked one of patent law's fundamental concepts" by replacing the traditional approach to patent "use" with a commercial exploitation test: "When does someone 'use' an invention? The court's answer is: when that someone is furthering a 'business interest' or is engaged in 'commercial exploitation' of the invention."[67]

It would indeed be a radical development and a matter for considerable concern if the Court had implemented such a test. But it did not. The majority did say that "if there is a commercial benefit to be derived from the invention, a contextual analysis of s. 42 indicates that it belongs to the patent holder."[68] However, this is not a 'test' as the word "indicates" implies and the immediately preceding sentence makes perfectly clear: "a defendant's commercial activities involving the patented object will be particularly *likely* to constitute an infringing use."[69]

In fact, the majority's statement of the test for determining use was

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[66]*Ibid.* at para. 152; see similarly paras. 145, 153.

[67]Richard Gold, "Monsanto's gain is everyone else's pain," *The Globe and Mail* (24 May 2004) at A17.

[68]*Schmeiser*, *supra* note 3 at para. 38; and see the summary *ibid.* at para. 58. The remark that "century-old patent law...holds that where a defendant's commercial or business activity involves a thing of which a patented part is a significant or important component, infringement is established," *ibid.* para. 78, is in a similar vein. However, the emphasis in this passage was on the point that incorporating a patented part into a whole does not excuse infringement.

[69]*Ibid.* at para. 38 [emphasis added]. Similarly, in the previous paragraph: "Where the defendant's impugned activities furthered its own commercial interests, we should therefore be particularly *alert to the possibility* that the defendant has committed an infringing use" [emphasis added]. Confirmation that the majority did not establish commercial activity as a sufficient test for infringement is the majority's express approval of *British United Shoe Machinery Co. v. Simon Collier Ltd.* (1910), 27 R.P.C. 567 (H.L.), in which possession in a commercial context was found not to constitute infringing use.

completely traditional: "[a]pplied to 'use', the question becomes: did the defendant's activity deprive the inventor in whole or in part, directly or indirectly, of full enjoyment of the monopoly conferred by law?"[70] Since it is long established law that the claims define the scope of the monopoly,[71] "the monopoly conferred by law" is simply the monopoly defined in the claim. Thus the test stated by the majority accords entirely with the dissent's statement that "[t]he test for determining "use" is...whether the alleged user has deprived the patentee of his monopoly over the use of the invention as construed in the claims."[72]

With that said, the majority did refer to "commercial" activities in a number of passages. This emphasis is puzzling. Nothing in the case turned on the point, as it was undisputed that Schmeiser's use was commercial. It is true enough, as the majority remarked, that infringement usually serves a business interest of the infringer.[73] But nothing much can be drawn from this fact. Litigated use of a patent usually involves a business interest because, as a practical matter, it is rarely worth litigating over non-commercial use. So, a person who imports a television which is subject to a patent in Canada is surely using the patented invention when he turns on the television at home in the evening, notwithstanding that his use is entirely for personal purposes. Affirming this general point, both the majority and the dissent expressly rejected the notion that commercial use is a necessary element of infringement.[74] The most likely explanation for the references is that the majority was leaving the door open to holding that the commercial nature of the use may be relevant to the so-called "experimental use" defence to infringement.[75] This point remains to be clarified.

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[70]*Schmeiser*, *ibid*. at para. 35 [emphasis removed], citing in para. 34 the parallel statement from Harold G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions*, 4th ed. (Toronto: Carswell, 1969) at 349.

[71]See for example *Whirlpool Corp. v. Camco Inc.*, [2000] 2 S.C.R. 1067 per Binnie J. for a unanimous Court.

[72]*Schmeiser*, *supra* note 3 at paras. 35, 152.

[73]*Ibid.* at para. 37.

[74]The majority stated that "[e]ven in the absence of commercial exploitation, the patent holder is entitled to protection," *ibid*. at para. 38, and the dissent similarly remarked that "[a]n inventor should be entitled to a remedy such as an injunction regardless of whether the infringing use has commercial applications," *ibid*. at para. 145.

[75]The Court's emphasis on commercial use began by quoting a passage from David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-marks* (Concord, Ont.: Irwin Law, 1997) at 151 to the effect that the "common thread' among infringing activities is that "the activity is usually for commercial purposes" cited *ibid*. at para. 36. In a part of the same passage not quoted by the Court, Professor Vaver made further remarks tying commercial use to a very broad interpretation of the experimental use exception. It should be noted that Professor Vaver's sweeping statements were unsupported by authority, and while the experimental use exception is very poorly defined, it is clear that non-

This brings us to the issue of what the majority *did* hold with respect to infringing use. The opinion on this point was perhaps not as transparent as on the issues of scope and remedy (discussed below), and a detailed exegesis is beyond the scope of the this Comment.[76] In broad strokes though, it is clear that "use" of an invention implies more than mere possession. The problem is to identify the "additional ingredient" which, combined with possession, constitutes infringing "use".[77] The majority answered this question by saying that "use" is utilization for, or with a view to, "production or advantage."[78]

That does not end matters, as Schmeiser's main argument raised a difficult question as to the exact nature of the necessary advantage. The gene patented by Monsanto confers resistance to certain herbicides. This facilitates weed control as herbicide can be sprayed to kill weeds without harming the canola itself even after the crop has emerged and is actively growing. Unmodified canola would be killed by this treatment, so other less effective weed control techniques must be used. Even though it was established that he had knowingly planted the patented canola seed, it was never established that Schmeiser sprayed the patented canola with herbicide in order to control weeds. Schmeiser argued that because he never took commercial advantage of the "special utility" that invention offered, namely resistance to Roundup herbicide, he should not be held to have "used" Monsanto's invention. Thus the question is whether the advantage necessary to establish use must be an advantage derived from the special properties of the patent, or whether any general benefit, such as that from growing the patented seed as an ordinary crop, will suffice. The majority held that Schmeiser had "used" the invention notwithstanding that there was no evidence that he had ever taken advantage of its special properties.[79] This makes it reasonably clear that

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commercial use is at most one element of the defence, and is neither necessary nor sufficient on its own: see *Dableh v. Ontario Hydro*, [1996] 3 F.C. 751 (C.A.), in which the experimental use defence was successful in a commercial context, and see David Gilat, *Experimental Use and Patents*, IIC Studies Vol. 16 1995, (Weinheim: VCH Verlag, 1995) for a thorough multi-jurisdictional review.

[76]For a detailed discussion see Norman Siebrasse, "Patent Use, Intent and Remedy in Light of *Monsanto v. Schmeiser*" (draft article, on file with the author).

[77]*Schmeiser*, *supra* note 3 at para. 55, citing Wilberforce L.J. in *Pfizer Corp. v. Ministry of Health*, [1965] A.C. 512, 572 (H.L.).

[78]*Ibid.* at para. 69.

[79]"Saving and planting seed, then harvesting and selling the resultant plants containing the patented cells and genes appears, on a common sense view, to constitute "utilization" of the patented material for production and advantage, within the meaning of s. 42," *ibid.* at para. 69; see also para. 72 to the effect that cultivation alone is sufficient to establish use. The majority also quoted, with apparent approval, the judge's remark that "whether or not that crop was sprayed with Roundup ... [was] not important" (*ibid.* at para. 82). The majority expressly accepted that it had not been established that Schmeiser

only a general advantage is required to establish use.[80] That is, the only advantage Schmeiser gained from his possession of the patented canola was the advantage he would have gained from any canola, patented or unpatented, namely the value of a normal crop grown with standard methods.

This definition of use is broad, as it does not require any causal link between a finding of infringement and a benefit derived from the invention. But this breadth at the substantive level is balanced by precision at the remedial level.

At trial Monsanto had elected an accounting of profits and had been awarded all of Schmeiser's profit from the sale of his crop. This was affirmed by the Court of Appeal. This holding was the sole point on which the Supreme Court reversed the decision of the trial court and the Court of Appeal. The Supreme Court held that there must be a causal link between the use of the invention and the profits awarded. The correct approach is to use the "differential profit" approach in which the amount awarded is the difference between the defendant's actual profit and the profit he would have made had he used the best non-infringing alternative.[81] This difference, which is equivalent to the "special advantage" gained by the defendant by the use of the patented invention, is the amount of profit causally attributable to the infringement. Since, as we have noted, there was no evidence that Schmeiser had even taken advantage of the patented canola's herbicide resistant properties, the Court held that Monsanto was entitled to nothing on their claim of account.[82] As the Court pointed out, this holding was mandated by the basic principle of non-punitive remedies, that the losses made good must be caused by the wrong.[83]

This holding has clarified the previously confused Canadian law on this point.[84] And the clarification was achieved in the best possible way, by placing the law relating to accounting of profits on a firm and

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had sprayed with Roundup herbicide to reduce weeds and this was central to the remedial aspect of the decision: see *ibid*. at para. 104. The dissenting view on this point is not entirely clear, since Arbour J.'s discussion of "use" was largely dependent on her narrow interpretation of the scope of the cell claims.

[80]There was some equivocation, particularly with respect to the problem of the "innocent bystander." See Siebrasse, "Patent Use, Intent and Remedy in Light of *Monsanto v. Schmeiser*," *supra* note 76 for a detailed analysis.

[81]*Schmeiser*, *supra* note 3 at para. 102, citing Norman Siebrasse, "A Remedial Benefit-Based Approach to the Innocent-User Problem in the Patenting of Higher Life Forms" (2004) 20 C.I.P.R. 79.

[82]*Ibid*. at para. 105, and see generally Section D "Remedies" of the decision.

[83]*Ibid*. at para. 101.

[84]For a discussion of prior Canadian law, see Siebrasse, "A Remedial Benefit-Based Approach," *supra* note 81, esp. Part 2.2.2 "Current Law: Canada" at 85-88.

principled foundation which is consistent with the general body of remedial law. It should be recognized that in consequence U.K. law is now at odds with Canadian law on this point, and the relevant U.K. case-law can no longer be considered good authority in Canada.[85] The Canadian position is consistent with the U.S. position, where the law related to an accounting of profits is well developed. Since the *Schmeiser* decision only established the basic principles, reference should be made to U.S. case-law as fine points arise in the future.[86]

More generally, we should recognize that the same argument which Schmeiser lost on the issue of "use" was successful on the issue of remedy. No causal link is required between the special properties of the patent and the use in order to establish infringement, but a causal link is required to establish an entitlement to an account of profits at the remedial level. The holding on infringement might seem unduly broad when considered in isolation, but when taken as a whole the majority opinion combines a broad definition of infringement at the substantive level with a narrower holding at the remedial level. The great advantage of such an approach is that it allows the remedy to be tailored more precisely to the facts. In particular, intent has never been relevant to infringement,[87] but it has always been relevant to injunctive relief, in the sense that an injunction restrains future intentional acts.[88] Thus Schmeiser, an intentional non-benefiting defendant, was not liable to account for profits, but he was made subject to an injunction, based on

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[85]See *Terrell on the Law of Patents*, 15th ed. by Simon Thorley et. al. (London: Sweet & Maxwell, 2000) at para. 13.47, stating expressly that the differential profit approach is not to be used in U.K. law. In particular *Celanese International Corp. v. BP Chemicals Ltd.* (1999), 6 R.P.C. 203 (Pat. Ct.), cited by Terrell as authority, and *United Horse-Shoe and Nail v. Stewart* (1888), 13 L.R. App. Cas. 401 (H.L.) can no longer be considered good law in Canada on this point. The majority in *Schmeiser* did cite *Celanese* with approval at para. 101 for the proposition that "the inventor is only entitled to that portion of the infringer's profit which is causally attributable to the invention," but this correct statement of principle was misapplied in *Celanese* which, as a whole, is inconsistent with *Schmeiser* in both reasoning and result: see the discussion of *Celanese* in Siebrasse, "A Remedial Benefit-Based Approach," *ibid.,* Part 2.4 "Cost-Based Apportionment" at 103-106, and see the discussion of *United Horse-Shoe*, *ibid.* in Part 2.3.2.1 "Rejection of 'But For' Causation" at 93-96.

[86]For example, one difficult issue is how to allocate fixed and variable costs in fixing profits related to the use of an invention. Note that an accounting of profits has not been available in U.S. patent law since 1946, but the remedy was quite well developed in patent law before that time and it remains available in related areas such as trade secrets and copyright, where an accounting of profits is still permitted: see Siebrasse, "A Remedial Benefit-Based Approach," *ibid.*, Part 2.2.1 "Current Law: United States" at 84-85.

[87]This well established point was affirmed in *Schmeiser*, *supra* note 3 by both the majority (para. 49) and the dissent (para. 157).

the intentional nature of his use. Had the definition of infringing "use" itself required a showing of a causal link between the invention and the benefit, injunctive relief would have been much more difficult to obtain.

IV. The Innocent Bystander

The importance of intention at the remedial level brings us to the issue of the innocent bystander. Schmeiser used the patented invention intentionally, and accordingly, the Court emphasized that it was not concerned with the so-called "innocent bystander" problem, which would arise if patented plants entered adventitiously onto the property of a farmer who was unaware of the presence of those plants.[89] However, the majority felt entirely comfortable in applying "established principles of patent law"[90] in the context of patents related to higher life forms, and in particular it expressed a disinclination to judicially amend the *Patent Act* in order to deal with innocent bystanders.[91] The clear implication is that the principles applicable to an innocent bystander will be the established principles of patent law as developed in the *Schmeiser* decision.

In view of this it is worthwhile to sketch the implication of *Schmeiser* for the innocent bystander. The Court unanimously affirmed the traditional view that intent is not relevant to patent infringement. From this it follows that an innocent bystander who was otherwise in Schmeiser's position would be an infringing user. However, the patentee would not have any remedies at all. As in Schmeiser's case, the farmer would not be liable for an accounting of profits. An injunction to restrain intentional future infringing acts, such as was granted against Schmeiser, would not be appropriate; a court would never make an innocent user liable to the quasi-criminal sanctions for contempt for an act which the user could not have prevented.[92] The question of damages (as opposed to an accounting of profits) and ancillary orders such as delivery up or

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[88]The patentee need not show that the defendant knew that the use was an infringement in order to obtain an injunction, but the injunction itself will restrain specified future intentional acts. See for example the injunction granted at trial and affirmed by the Supreme Court in *Schmeiser*, *supra* note 3 at para. 106, which enjoined Schmeiser from "planting or growing seeds which they know or ought to know contain genes or cells as claimed in claims 1, 2, 5, 6, 22, 23, 27, 28 and 45 of the patent"(Court of Appeal, *supra* note 3 at para. 74).

[89]*Schmeiser*, *ibid.* at paras. 2, 95.

[90]*Ibid.* at para. 3.

[91]*Ibid.* at paras. 93-95.

[92]See Robert J. Sharpe, *Injunctions and Specific Performance*, 3rd ed. (Toronto: Canada Law Book, 2000), §6.190; and see the injunction granted to Monsanto in *Schmeiser*, *supra* note 88 above.

destruction, are less clear, but even here a strong argument may be made that intent is relevant at the remedial level, so that these remedies would not be available against an innocent bystander.[93] In other words, the innocent farmer who did not benefit from the patent would be technically an infringer, but the patentee could not obtain any remedy. The situation would be different again in the case of a innocent bystander who did receive some benefit from the patent, notwithstanding he did not know of the nature of the crop (for example if the patented canola gave an especially high yield in normal conditions). In such a case the patentee would not be entitled to intent based remedies, but it would be entitled to some monetary remedy based on the special advantage gained by the farmer.

Given that the most sympathetic figure in the innocent bystander debate is the innocent non-benefiting farmer, it is important to recognize that under existing law such a farmer is not liable to any penalty for infringement. The sole effect of a legislatively introducing a substantive innocent bystander exception would be to allow the innocent *benefiting* farmer to retain the special benefits conferred by the use of the invention. I have discussed the merits of such a proposal at length elsewhere.[94] Suffice it to say at this point that the case for relieving the benefiting farmer from liability are not as compelling as in the case of the non-benefiting farmer.

V. Conclusion

In addressing the issues of patent "use" and remedy the majority decision in *Schmeiser* advanced the law of use, clarified the law of remedies, and in so doing struck a reasonable balance between the interests of the patentee and those of the user of the invention. This alone would have established *Schmeiser* as a sound and significant decision. But the greater long term importance of the decision was that it laid to rest the anomalous attempt by the majority in *Harvard Mouse* to rewrite the *Patent Act* in response to perceived controversy. Had the dissenters in *Schmeiser* prevailed in their attempt to force patent law to fit *Harvard Mouse*, the damage to patent principles would have reverberated far beyond the realm of patents related to life forms. The majority decision in *Schmeiser* marks a determination to ensure that patent law remains a body of coherent principles which can provide legal stability in the face of technological change. The dissent in *Schmeiser* should be remembered as a warning to future judges who would seek to do otherwise.

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[93]Siebrasse, "A Remedial Benefit-Based Approach," *supra* note 81, Part 3.1 "Relationship between Damages and an Accounting of Profits" at 112-15.

[94]Siebrasse, "The Innocent Bystander Problem," *supra* note 13.