

CASE LAW ANALYSIS

Monsanto v Schmeiser: A Landmark Decision concerning Farmer Liability and Transgenic Contamination

Biotechnology—Genetically modified crop resistant to brand pesticide—Farmer grows crop without licence—Does patent on transgenic cells extend to seeds and crop itself?—Is there an infringement of patent despite lack of knowledge by farmer of presence of gene in seeds?—Farmer does not use brand pesticide on crop—Remedy for patent holder where user takes no advantage of benefits of patent

Monsanto Canada Inc v Schmeiser

[2004] 1 SCR 902; 2004 SCC 34; Supreme Court of Canada

The Judgment

The judgment of McLachlin CJ and Major, Binnie, Deschamps and Fish JJ was delivered by:

THE CHIEF JUSTICE AND FISH J:

Introduction

- 1 This case concerns a large scale, commercial farming operation that grew canola containing a patented cell and gene without obtaining licence or permission. The main issue is whether it thereby breached the *Patent Act*, RSC 1985, c P-4. We believe that it did.
- 2 In reaching this conclusion, we emphasise from the outset that we are not concerned here with the innocent discovery by farmers of ‘blow-by’ patented plants on their land or in their cultivated fields. Nor are we concerned with the scope of the respondents’ patent or the wisdom and social utility of the genetic modification of genes and cells—a practice authorised by Parliament under the *Patent Act* and its regulations.
- 3 Our sole concern is with the application of established principles of patent law to the essentially undisputed facts of this case.

The Salient Facts

- 4 Percy Schmeiser has farmed in Saskatchewan for more than 50 years. In 1996 he assigned his farming business to a corporation in which he and his wife are the sole shareholders and directors. He and his corporation grow wheat, peas, and a large amount of canola.
- 5 In the 1990s, many farmers, including five farmers in Mr Schmeiser's area, switched to Roundup Ready Canola, a canola variety containing genetically modified genes and cells that have been patented by Monsanto. Canola containing the patented genes and cells is resistant to a herbicide, Roundup, which kills all other plants, making it easier to control weeds. This eliminates the need for tillage and other herbicides. It also avoids seeding delays to accommodate early weed spraying. Monsanto licenses farmers to use Roundup Ready Canola, at a cost of \$15 per acre.
- 6 Schmeiser never purchased Roundup Ready Canola nor did he obtain a licence to plant it. Yet, in 1998, tests revealed that 95 to 98 percent of his 1,000 acres of canola crop was made up of Roundup Ready plants. The origin of the plants is unclear. They may have been derived from Roundup Ready seed that blew onto or near Schmeiser's land, and was then collected from plants that survived after Schmeiser sprayed Roundup herbicide around the power poles and in the ditches along the roadway bordering four of his fields. The fact that these plants survived the spraying indicated that they contained the patented gene and cell. The trial judge found that 'none of the suggested sources [proposed by Schmeiser] could reasonably explain the concentration or extent of Roundup Ready canola of a commercial quality' ultimately present in Schmeiser's crop (*Monsanto Canada Inc v Schmeiser* (2001), 202 FTR 78, at para 118).
- 7 The issues on this appeal are whether Schmeiser infringed Monsanto's patent, and if so, what remedies Monsanto may claim.

*Analysis***A. The Patent: Its Scope and Validity**

- 11 Monsanto requires a farmer who wishes to grow Roundup Ready Canola to enter into a licensing arrangement called a Technology Use Agreement (TUA). The licensed farmers must attend a Grower Enrollment Meeting at which Monsanto describes the technology and its licensing terms. By signing the TUA, the farmer becomes entitled to purchase Roundup Ready Canola from an authorised seed agent. They must, however, undertake to use the seed for planting a single crop and to sell that crop for consumption to a commercial purchaser authorised by Monsanto. The licensed farmers may not sell or give the seed to any third party, or save seed for replanting or inventory.
- 12 The TUA gives Monsanto the right to inspect the fields of the contracting farmer and to take samples to verify compliance with the TUA. The farmer must also pay a licensing fee for each acre planted with Roundup Ready Canola. In 1998, the licensing fee was \$15 per acre.
- 13 A Roundup Ready Canola plant cannot be distinguished from other canola plants except by a chemical test that detects the presence of the Monsanto gene, or by spraying the plant with Roundup. A canola plant that survives being sprayed with Roundup is Roundup Ready Canola.
- 14 The trial judge found the patent to be valid. He found that it did not offend the *Plant Breeders' Rights Act*, SC 1990, c 20, and held that the difficulty of distinguishing canola plants containing the patented gene and cell from those without it did not preclude patenting the gene. The trial judge also rejected the argument that the gene and cell are unpatentable because they can be replicated without human intervention or control.

- 18 Purposive construction of patent claims requires that they be interpreted in light of the whole of the disclosure, including the specifications: *Whirlpool Corp v Camco Inc* [2000] 2 SCR 67, 2000 SCC 67; *Consolboard Inc v MacMillan Bloedel (Sask) Ltd* [1981] 1 SCR 504.
- 19 A purposive construction therefore recognises that the invention will be practised in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory. It is difficult to imagine a more likely or more evident purpose for patenting ‘a method of genetically transforming plant cells which causes *the cells and plants* regenerated therefrom to become resistant to glyphosate’ (trial judgment, para 20 (emphasis added)).
- 20 More particularly, the patented claims are for:
 - (1) A *chimeric gene*: this is a gene that does not exist in nature and is constructed from different species.
 - (2) An *expression vector*: this is a DNA molecule into which another DNA segment has been integrated so as to be useful as a research tool.
 - (3) A *plant transformation vector*: used to permanently insert a chimeric gene into a plant’s own DNA.
 - (4) Various species of *plant cells* into which the chimeric gene has been inserted.
 - (5) A *method of regenerating a glyphosate-resistant plant*. Once the cell is stimulated to grow into a plant, all of the differentiated cells in the plant will contain the chimeric gene, which will be passed on to offspring of the plant.
- 21 The appellant Schmeiser argues that the subject matter claimed in the patent is unpatentable. While acknowledging that Monsanto claims protection only over a gene and a cell, Schmeiser contends that the result of extending such protection is to restrict use of a plant and a seed. This result, the argument goes, ought to render the subject matter unpatentable, following the reasoning of the majority of this Court in *Harvard College v Canada (Commissioner of Patents)* [2002] 4 SCR 45, 2002 SCC 76 (*‘Harvard Mouse’*). In that case, plants and seeds were found to be unpatentable ‘higher life forms’.
- 22 This case is different from *Harvard Mouse*, where the patent refused was for a mammal. The Patent Commissioner, moreover, had allowed other claims, which were not at issue before the Court in that case, notably a plasmid and a somatic cell culture. The claims at issue in this case, for a gene and a cell, are somewhat analogous, suggesting that to find a gene and a cell to be patentable is in fact consistent with both the majority and the minority holdings in *Harvard Mouse*.
- 23 Further, all members of the Court in *Harvard Mouse* noted in obiter that a fertilised, genetically altered oncomouse egg would be patentable subject matter, regardless of its ultimate anticipated development into a mouse (at para 3, per Binnie J for the minority; at para 162, per Bastarache J for the majority).
- 24 Whether or not patent protection for the gene and the cell extends to activities involving the plant is not relevant to the patent’s validity. It relates only to the factual circumstances in which infringement will be found to have taken place, as we shall explain below. Monsanto’s patent has already been issued, and the onus is thus on Schmeiser to show that the Commissioner erred in allowing the patent: *Apotex Inc v Wellcome Foundation Ltd* [2002] 4 SCR 153, 2002 SCC 77, at paras 42–4. He has failed to discharge that onus. We therefore conclude that the patent is valid.

B. Did Schmeiser ‘Make’ or ‘Construct’ the Patented Gene and Cell, Thus Infringing the Patent?

- 26 We are not inclined to the view that Schmeiser ‘made’ the cell within the meaning of section 42 of the *Patent Act*. Neither Schmeiser nor his corporation created or constructed

the gene, the expression vector, a plant transformation vector, or plant cells into which the chimeric gene has been inserted.

- 27 It is unnecessary, however, to express a decided opinion on this point, since we have in any event concluded that Schmeiser infringed section 42 by ‘using’ the patented cell and gene.

C. Did Schmeiser ‘Use’ the Patented Gene or Cell, Thus Infringing the Patent?

(1) *The Law on ‘Use’*

- 28 The central question on this appeal is whether Schmeiser, by collecting, saving and planting seeds containing Monsanto’s patented gene and cell, ‘used’ that gene and cell.
- 31 Determining the meaning of ‘use’ under section 42 is essentially a matter of statutory construction. (...)
- 32 Three well-established rules or practices of statutory interpretation assist us further. First, the inquiry into the meaning of ‘use’ under the *Patent Act* must be *purposive*, grounded in an understanding of the reasons for which patent protection is accorded. Second, the inquiry must be *contextual*, giving consideration to the other words of the provision. Finally, the inquiry must be attentive to the wisdom of the *case law*. We will discuss each of these aids to interpretation briefly, and then apply them to the facts of this case.
- 33 We return first to the rule of purposive construction. Identifying whether there has been infringement by use, like construing the claim, must be approached by the route of purposive construction (...).
- 35 The guiding principle is that patent law ought to provide the inventor with ‘protection for that which he has actually in good faith invented’: *Free World Trust*, supra at para 43. Applied 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?*
- 39 We turn now to the case law, the third aid to interpretation. Here we derive guidance from what courts in the past have considered to be use. As we shall see, precedent confirms the approach proposed above and it is of assistance as well in resolving some of the more specific questions raised by this case.
- 40 First, case law provides guidance as to whether patent protection extends to situations where the patented invention is contained within something else used by the defendant. This is relevant to the appellants’ submission that growing *plants* did not amount to ‘using’ their patented *genes* and *cells*.
- 43 Infringement through use is thus possible even where the patented invention is part of, or composes, a broader unpatented structure or process. This is, as Professor Vaver states, an expansive rule. It is, however, firmly rooted in the principle that the main purpose of patent protection is to prevent others from depriving the inventor, even in part and even indirectly, of the monopoly that the law intends to be theirs: only the inventor is entitled, by virtue of the patent and as a matter of law, to the *full* enjoyment of the monopoly conferred.
- 45 In determining whether the defendant ‘used’ the patented invention, one compares the object of the patent with what the defendant did and asks whether the defendant’s actions involved that object.
- 46 In fact, the patented invention need not be deployed precisely for its intended purpose in order for its object to be involved in the defendant’s activity. (...) The common thread is that the defendants employed the invention to their advantage, depriving the inventor of the full enjoyment of the monopoly.
- 49 The general rule is that the defendant’s intention is irrelevant to a finding of infringement. (...) And the governing principle is whether the defendant, by his actions, activities

or conduct, appropriated the patented invention, thus depriving the inventor, in whole or part, directly or indirectly, of the full enjoyment of the monopoly the patent grants.

- 50 However, intention becomes relevant where the defence invoked is possession without use. Where the alleged use consists of exploitation of the invention's 'stand-by' utility, as discussed above, it is relevant whether the defendant intended to exploit the invention should the need arise.
- 56 Thus, a defendant in possession of a patented invention in commercial circumstances may rebut the presumption of use by bringing credible evidence that the invention was neither used, nor intended to be used, even by exploiting its stand-by utility.
- 57 The court does not inquire into whether the patented invention in fact assisted the defendant or increased its profits. (...) The defendant's benefit or profit from the activity may be relevant at the stage of remedy, but not in determining infringement.
- 58 These propositions may be seen to emerge from the foregoing discussion of 'use' under the *Patent Act*:
 - 1 'Use' or '*exploiter*', in their ordinary dictionary meaning, denote utilisation with a view to production or advantage.
 - 2 The basic principle in determining whether the defendant has 'used' a patented invention is whether the inventor has been deprived, in whole or in part, directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.
 - 3 If there is a commercial benefit to be derived from the invention, it belongs to the patent holder.
 - 4 It is no bar to a finding of infringement that the patented object or process is a part of or composes a broader unpatented structure or process, provided the patented invention is significant or important to the defendant's activities that involve the unpatented structure.
 - 5 Possession of a patented object or an object incorporating a patented feature may constitute 'use' of the object's stand-by or insurance utility and thus constitute infringement.
 - 6 Possession, at least in commercial circumstances, raises a rebuttable presumption of 'use'.
 - 7 While intention is generally irrelevant to determining whether there has been 'use' and hence infringement, the absence of intention to employ or gain any advantage from the invention may be relevant to rebutting the presumption of use raised by possession.

(2) *Application of the Law*

- 59 The trial judge's findings of fact are based, essentially, on the following uncontested history.
- 61 In the spring of 1997, Mr Schmeiser planted the seeds saved on field number 1. The crop grew. He sprayed a three-acre patch near the road with Roundup and found that approximately 60 percent of the plants survived. This indicates that the plants contained Monsanto's patented gene and cell.
- 62 In the fall of 1997, Mr Schmeiser harvested the Roundup Ready Canola from the three-acre patch he had sprayed with Roundup. He did not sell it. He instead kept it separate, and stored it over the winter in the back of a pick-up truck covered with a tarp.
- 63 A Monsanto investigator took samples of canola from the public road allowances bordering on two of Mr Schmeiser's fields in 1997, all of which were confirmed to contain Roundup Ready Canola. In March 1998, Monsanto visited Mr Schmeiser and put him on notice of its belief that he had grown Roundup Ready Canola without a licence. Mr Schmeiser nevertheless took the harvest he had saved in the pick-up truck to a seed treatment plant and had it treated for use as seed. Once treated, it could be put to no

other use. Mr Schmeiser planted the treated seed in nine fields, covering approximately 1,000 acres in all.

64 Numerous samples were taken, some under court order and some not, from the canola plants grown from this seed. Moreover, the seed treatment plant, unbeknownst to Mr Schmeiser, kept some of the seed he had brought there for treatment in the spring of 1998, and turned it over to Monsanto. A series of independent tests by different experts confirmed that the canola Mr Schmeiser planted and grew in 1998 was 95 to 98 percent Roundup resistant. Only a grow-out test by Mr Schmeiser in his yard in 1999 and by Mr Freisen on samples supplied by Mr Schmeiser did not support this result.

66 The remaining question was how such a pure concentration of Roundup Ready Canola came to grow on the appellants' land in 1998. The trial judge rejected the suggestion that it was the product of seed blown or inadvertently carried onto the appellants' land (at para 118):

It may be that some Roundup Ready seed was carried to Mr Schmeiser's field without his knowledge. Some such seed might have survived the winter to germinate in the spring of 1998. However, I am persuaded by evidence of Dr. Keith Downey... that none of the suggested sources could reasonably explain the concentration or extent of Roundup Ready canola of a commercial quality evident from the results of tests on Schmeiser's crop.

67 He concluded, at para 120:

I find that in 1998 Mr Schmeiser planted canola seed saved from his 1997 crop in his field number 2 which he knew or ought to have known was Roundup tolerant, and that seed was the primary source for seeding and for the defendants' crops in all nine fields of canola in 1998.

68 In summary, it is clear on the findings of the trial judge that the appellants saved, planted, harvested and sold the crop from plants containing the gene and plant cell patented by Monsanto. The issue is whether this conduct amounted to 'use' of Monsanto's invention—the glyphosate-resistant gene and cell.

69 The preliminary question is whether this conduct falls within the meaning of 'use' or 'exploiter'. We earlier concluded that these words, taken together, connote utilisation with a view to production or advantage. 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 'utilisation' of the patented material for production and advantage, within the meaning of section 42.

70 We turn next to whether the other considerations relevant to 'use' support this preliminary conclusion.

71 In this regard, the first and fundamental question is whether Monsanto was deprived in whole or in part, directly or indirectly, of the full enjoyment of the monopoly that the patent confers. And the answer is 'yes'.

72 Monsanto's patent gives it a monopoly over the patented gene and cell. The patent's object is production of a plant which is resistant to Roundup herbicide. Monsanto's monopoly enabled it to charge a licensing fee of \$15 per acre to farmers wishing to grow canola plants with the patented genes and cells. The appellants cultivated 1030 acres of plants with these patented properties without paying Monsanto for the right to do so. By cultivating a plant containing the patented gene and composed of the patented cells without licence, the appellants thus deprived Monsanto of the full enjoyment of its monopoly.

73 The complementary question is whether the appellants employed or possessed the patented invention in the context of their commercial or business interests. The initial answer must again be 'yes'.

- 74 One of the appellants' businesses was growing canola. It used seeds containing the patented qualities in that business. Subject to the appellants' argument discussed below that they did not use the patented invention itself (whether because they used only the plant or because they did not spray with Roundup), the appellants' involvement with the disputed canola is clearly commercial in nature.
- 75 The answers to the two questions of principle that lie at the heart of 'use' under the *Patent Act* both thus suggest that the trial judge and the Court of Appeal were correct in finding that the appellants 'used' the protected invention and hence infringed Monsanto's patent. It is helpful as well, however, to consider the insights gained from the case law discussed above and their impact on arguments raised against this conclusion.
- 76 First, it is suggested that because Monsanto's claims are for genes and cells rather than for plants, it follows that infringement by use will only occur where a defendant uses the genes or cells in their isolated, laboratory form. This argument appears not to have been advanced in any detail at trial or on appeal, but is the position taken by our colleague, Arbour J.
- 77 It is uncontested that Monsanto's patented claim is only for the gene and cell that it developed. This, however, is the beginning and not the end of the inquiry. The more difficult question—and the nub of this case—is whether, by cultivating plants *containing the cell and gene*, the appellants used the patented components of those plants. The position taken by Arbour J assumes that this inquiry is redundant and that the only way a patent may be infringed is to use the patented invention in isolation.
- 78 This position flies in the face of century-old patent law, which 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. It is no defence to say that the thing actually used was not patented, but only one of its components.
- 79 Professor Vaver, *supra*, observes that this is an 'expansive doctrine'. This is so because otherwise the inventor would be deprived of the full enjoyment of the monopoly that the law of patent confers on him or her. It is rare that patented components or processes are used in isolation; without this principle, an infringer could use the invention to his advantage, and take shelter in the excuse that he or she was not using the invention in isolation.
- 80 Provided the patented invention is a significant aspect of the defendant's activity, the defendant will be held to have 'used' the invention and violated the patent. If Mr Schmeiser's activities with Roundup Ready Canola plants amounted to use interfering with Monsanto's full enjoyment of their monopoly on the gene and cell, those activities infringed the patent. Infringement does not require use of the gene or cell in isolation.
- 81 Second, Mr Schmeiser argued at trial that he should not be held to have 'used' Monsanto's invention because he never took commercial advantage of the special utility that invention offered—resistance to Roundup herbicide. He testified that he never used Roundup herbicide as an aid to cultivation. (That he used it in 1996 in his initial gathering of the Roundup Ready seed is clear.)
- 82 The trial judge dismissed this argument. He pointed out, at para 122, that it 'is the taking of the essence of the invention . . . that constitutes infringement', and that by growing and selling the Roundup Ready crop Mr Schmeiser took that invention. Consequently, in the judge's view, 'whether or not that crop was sprayed with Roundup . . . [was] not important' (para 123).
- 83 Perhaps the appellants' failure to spray with Roundup herbicide is a way of attempting to rebut the presumption of use that flows from possession. However, the appellants have failed to rebut the presumption.
- 84 Their argument fails to account for the stand-by or insurance utility of the properties of the patented genes and cells. Whether or not a farmer sprays with Roundup herbicide,

cultivating canola containing the patented genes and cells provides stand-by utility. The farmer benefits from that advantage from the outset: if there is reason to spray in the future, the farmer may proceed to do so.

- 86 Further, the appellants did not provide sufficient evidence to rebut the presumption of use. It may well be that defendant farmers could rebut the presumption by showing that they never intended to cultivate plants containing the patented genes and cells. They might perhaps prove that the continued presence of the patented gene on their land was accidental and unwelcome, for example, by showing that they acted quickly to arrange for its removal, and that its concentration was consistent with that to be expected from unsolicited 'blow-by' canola. Knowledge of infringement is never a necessary component of infringement. However, a defendant's conduct on becoming aware of the presence of the patented invention may assist in rebutting the presumption of use arising from possession.
- 87 However, the appellants in this case actively cultivated canola containing the patented invention as part of their business operations. Mr Schmeiser complained that the original plants came onto his land without his intervention. However, he did not at all explain why he sprayed Roundup to isolate the Roundup Ready plants he found on his land; why he then harvested the plants and segregated the seeds, saved them, and kept them for seed; why he next planted them; and why, through this husbandry, he ended up with 1030 acres of Roundup Ready Canola which would otherwise have cost him \$15,000. In these circumstances, the presumption of use flowing from possession stands un rebutted.
- 88 Third, as in their submissions on validity, the appellants seek to rely on the decision of the majority of this Court in *Harvard Mouse*. They contend that the patent should be given a narrow scope for infringement purposes, since the plants reproduce through the laws of nature rather than through human intervention. Thus, they argue, propagation of Roundup Ready Canola without a licence cannot be a 'use' by them because plants are living things that grow by themselves.
- 90 The appellants' argument also ignores the role human beings play in agricultural propagation. Farming is a commercial enterprise in which farmers sow and cultivate the plants which prove most efficient and profitable. Plant science has been with us since long before Mendel. Human beings since time immemorial have striven to produce more efficient plants. Huge investments of energy and money have been poured into the quest for better seeds and better plants. One way in which that investment is protected is through the *Patent Act* giving investors a monopoly when they create a novel and useful invention in the realm of plant science, such as genetically modified genes and cells.
- 91 Finally, many inventions make use of natural processes in order to work. For example, many valid patents have referred to various yeasts, which would have no practical utility at all without 'natural forces'. See *Re: Application of Abitibi Co* (1982), 62 CPR (2d) 81 (Pat App Bd), in which the inventive step consisted of acclimatising a known species of yeast from domestic sewage to a new environment, where it would then through its natural operation act to purify waste from pulp plants.
- 92 The issue is not the perhaps adventitious arrival of Roundup Ready on Mr Schmeiser's land in 1998. What is at stake in this case is *sowing* and *cultivation*, which necessarily involves deliberate and careful activity on the part of the farmer. The appellants suggest that when a farmer such as Mr Schmeiser actively cultivates a crop with particular properties through activities such as testing, isolating, treating, and planting the desired seed and tending the crops until harvest, the result is a crop which has merely 'grown itself'. Such a suggestion denies the realities of modern agriculture.
- 93 Inventions in the field of agriculture may give rise to concerns not raised in other fields—moral concerns about whether it is right to manipulate genes in order to obtain

better weed control or higher yields. It is open to Parliament to consider these concerns and amend the *Patent Act* should it find them persuasive.

- 94 Our task, however, is to interpret and apply the *Patent Act* as it stands, in accordance with settled principles. Under the present Act, an invention in the domain of agriculture is as deserving of protection as an invention in the domain of mechanical science. Where Parliament has not seen fit to distinguish between inventions concerning plants and other inventions, neither should the courts.
- 95 Invoking the concepts of implied licence and waiver, the appellants argue that this Court should grant an exemption from infringement to ‘innocent bystanders’. The simple answer to this contention is that on the facts found by the trial judge, Mr Schmeiser was not an innocent bystander; rather, he actively cultivated Roundup Ready Canola. Had he been a mere ‘innocent bystander’, he could have refuted the presumption of use arising from his possession of the patented gene and cell. More broadly, to the extent this submission rests on policy arguments about the particular dangers of biotechnology inventions, these, as discussed, find no support in the *Patent Act* as it stands today. Again, if Parliament wishes to respond legislatively to biotechnology inventions concerning plants, it is free to do so. Thus far it has not chosen to do so.
- 96 The appellants argue, finally, that Monsanto’s activities tread on the ancient common law property rights of farmers to keep that which comes onto their land. Just as a farmer owns the progeny of a ‘stray bull’ which wanders onto his land, so Mr Schmeiser argues he owns the progeny of the Roundup Ready Canola that came onto his field. However, the issue is not property rights, but patent protection. Ownership is no defence to a breach of the *Patent Act*.
- 97 We conclude that the trial judge and Court of Appeal were correct in concluding that the appellants ‘used’ Monsanto’s patented gene and cell and hence infringed the *Patent Act*.

D. Remedy

- 100 The *Patent Act* permits two alternative types of remedy: damages and an accounting of profits. Damages represent the inventor’s loss, which may include the patent holder’s lost profits from sales or lost royalty payments. An accounting of profits, by contrast, is measured by the profits made by the infringer, rather than the amount lost by the inventor. Here, damages are not available, in view of Monsanto’s election to seek an accounting of profits.
- 101 It is settled law that the inventor is only entitled to that portion of the infringer’s profit which is causally attributable to the invention (...).
- 102 The preferred means of calculating an accounting of profits is what has been termed the value-based or ‘differential profit’ approach, where profits are allocated according to the value contributed to the defendant’s wares by the patent (...). A comparison is to be made between the defendant’s profit attributable to the invention and his profit had he used the best non-infringing option (...).
- 103 The difficulty with the trial judge’s award is that it does not identify any causal connection between the profits the appellants were found to have earned through growing Roundup Ready Canola and the invention. On the facts found, the appellants made no profits *as a result of the invention*.
- 104 Their profits were precisely what they would have been had they planted and harvested ordinary canola. They sold the Roundup Ready Canola they grew in 1998 for feed, and thus obtained no premium for the fact that it was Roundup Ready Canola. Nor did they gain any agricultural advantage from the herbicide resistant nature of the canola, since no finding was made that they sprayed with Roundup herbicide to reduce weeds. The appellants’ profits arose solely from qualities of their crop that cannot be attributed to the invention.

105 On this evidence, the appellants earned no profit from the invention and Monsanto is entitled to nothing on their claim of account.

Conclusion

106 We would allow the appeal in part, setting aside the award for account of profit. In all other respects we would confirm the order of the trial judge. In view of this mixed result, we would order that each party bear its own costs throughout.

The reasons of Iacobucci, Bastarache, Arbour and LeBell were delivered by:

ARBOUR J (DISSENTING IN PART):

Introduction

- 107 This case was decided in the courts below without the benefit of this Court's decision in *Harvard College v Canada (Commissioner of Patents)* [2002] 4 SCR 45, 2002 SCC 76. The heart of the issue is whether the Federal Court of Appeal's decision can stand in light of our decision in that case.
- 108 More specifically, the trial judge interpreted the scope of the Monsanto patent without the benefit of the holding in *Harvard College* that higher life forms, including plants, are not patentable. 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' (E.R. Gold and W.A. Adams, 'The *Monsanto* Decision: The Edge or the Wedge' (2001), 19 *Nat Biotechnol* 587).
- 109 Such a result is hard to reconcile with the majority decision in *Harvard College*. It would also invalidate the Patent Office's long-standing policy of not granting exclusive rights, expressed in a patent grant, over higher life forms, that was upheld in *Harvard College*. Patent Office, *Manual of Patent Office Practice* (1998 '*Patent Office Manual*'), at para 16.05.
- 110 The two central issues here, the scope of Monsanto's patent and whether agricultural production of Roundup Ready Canola constitutes an infringing use, are determined by a purposive construction of the patent claims and the proper application of the majority decision in *Harvard College*. Monsanto is on the horns of a dilemma; a narrow construction of its claims renders the claims valid but not infringed, the broader construction renders the claims invalid: *Gillette Safety Razor Co v Anglo-American Trading Co* (1913), 30 RPC 465 (HL), at p 481.
- 111 In light of *Harvard College*, I conclude that the patent claims here cannot be interpreted to extend patent protection over whole plants and that there was no infringing use. I need not review, and take no issue with the factual overview of the case provided in my colleagues' reasons.

Analysis

A. The Decision in *Harvard College*

- 112 The issue in *Harvard College*, *supra*, was whether a mouse that was genetically modified to make it susceptible to cancer was the valid subject matter for a patent claim. The majority found that higher life forms were not 'compositions of matter'. Plants were clearly included in the category of higher life forms: e.g. *Harvard College*, at para 199. Accordingly, plants do not fit within the definition of an 'invention': *Patent Act*, RSC 1985, c P-4, section 2.

- 113 The majority approved the line drawn by the Patent Office between unpatentable higher life forms, patentable lower life forms, and patentable processes for engineering transgenic higher life forms in the laboratory: *Harvard College*, at para 199. That line is described in the *Patent Office Manual*, supra, at para 16.05;
- Higher life forms are not patentable subject matter. However, a process for producing a higher life form may be patentable provided the process requires significant technical intervention by man and is not essentially a natural biological process which occurs according to the laws of nature...
- 114 The line was clearly enunciated in *Re Application of Abitibi Co* (1982), 62 CPR (2d) 81 (Pat App Bd), at p 89; patents apply to:
- all micro-organisms, yeasts, moulds, fungi, bacteria, actinomycetes, unicellular algae, cell lines, viruses or protozoa; in fact to all new life forms which are produced *en masse* as chemical compounds are prepared, and are formed in such large numbers that any measurable quantity will possess uniform properties and characteristics.
- 115 Thus, in *Harvard College*, claims for a genetically modified plasmid and the process claims to genetically modify a mouse so that it became susceptible to cancer were found to be valid. Claims for the mouse itself were found to be invalid by the Patent Commissioner and that finding was upheld by this Court. No other claims were at issue in *Harvard College*; transgenic mammalian eggs (single cells) were not claimed, although the majority suggested in *obiter* that such a claim may be the valid subject matter of a patent claim: *Harvard College*, at para 162.

B. The Patent Claims

- 116 Monsanto's Canadian Patent No. 1,313,830 is entitled 'Glyphosate-Resistant Plants' (see Appendix). The use is evident on the face of the claims, namely glyphosate resistance that a person skilled in the art would understand to mean the conferring of resistance to a glyphosate herbicide, such as 'Roundup'.
- 117 The patent contained a series of hierarchical claims. The method claims are separate. The claims in the patent may be split into five general categories:
- (1) the chimeric gene, claims 1–7, that does not exist in nature and is constructed, through human intervention, of three components;
 - (2) the cloning or expression vector, claims 8–14 (a vector is a DNA molecule into which another DNA segment has been integrated);
 - (3) the plant transformation vector, claims 15–21, 52;
 - (4) the glyphosate-resistant plant cell containing the chimeric gene, claims 22–8 and claims 43–51; and
 - (5) the method for constructing (1)–(4) and, in the laboratory, regenerating a plant from the plant cell containing the chimeric gene, claims 29–42.
- 118 All of the differentiated cells in the regenerated plant contain the chimeric gene, which will be passed to offspring of the plants through natural reproduction. However, as recognised by my colleagues, there is no claim for the regenerated plant or its progeny.

C. Purposive Construction of the Claims

- 119 The first and pivotal step in an infringement action is the purposive construction of the patent claims: *Whirlpool Corp v Camco Inc* [2000] 2 SCR 1067, 2000 SCC 67, at para 43. The claims construction will set the scope of the patent claims, which, in turn, resolves the two issues in this case: validity and infringing use. However, Monsanto's patent

claims cannot be construed with an eye to either infringement or the appellants' defence to infringement, invalidity: *Whirlpool*.

- 120 Purposive construction delineates the scope of the invention. It identifies what the inventor considered to be the essential elements of the invention: *Whirlpool*, supra, at para 45.
- 121 My colleagues emphasise the commercial value of the exclusive rights to the patentee as the primary consideration in distilling the 'essential elements' of the patent claims. However, commercial interests are not the only considerations. There are three further themes to purposive construction of patent claims. I will address each of these in turn.

(1) *Fairness and Predictability*

- 122 Fairness to the public is a recurring theme in jurisprudence on claims construction because of the severe economic consequences of patent infringement: *Consolboard Inc v MacMillan Bloedel (Sask) Ltd* [1981] 1 SCR 504; *Pioneer Hi-Bred Ltd v Canada (Commissioner of Patents)* [1989] 1 SCR 1623; *Free World Trust v Électro Santé Inc* [2000] 2 SCR 1024, 2000 SCC 66, at para 41. The scope of the patent protection should be both 'fair' and 'reasonably predictable': *Whirlpool*, supra, at para 49; *Consolboard*, supra, at pp 520–1. 'Predictability is achieved by tying the patentee to its claims; fairness is achieved by interpreting those claims in an informed and purposive way': *Free World Trust*, supra, at para 43.

(2) *What is not Claimed is Disclaimed*

- 123 The classic rule is 'what is not claimed is considered disclaimed': *Whirlpool*, supra, at para 42. The inventor may not get exclusive rights to an invention that was not part of the public disclosure of the invention. The public must be able to predict the activities that will infringe on the exclusive rights granted to the patentee: *Free World Trust*, supra, at para 41.
- 124 So long as the claims are interpreted fairly and knowledgeably, if the patentee has limited the claims, then the public is entitled to rely on that limitation: *Free World Trust*, supra, at para 51. An inventor cannot enlarge the scope of the grant of exclusive rights beyond that which has been specified: *Western Electric v Baldwin International Radio of Canada* [1934] SCR 570. However, the full specification may be looked at to discern the scope of the claims: *Whirlpool*, supra, at para 49; *Free World Trust*, supra; *Western Electric*, supra, at p 573; Lindley LJ in *Needham v Johnson and Co* (1884), 1 RPC 49 (HCA), at p 58. The claims are invalid if they are broader than the disclosures: *Amfac Foods Inc v Irving Pulp & Paper Ltd* (1984), 80 CPR (2d) 59 (FCTD), at p 80, citing a long list of authority; *B.V.D. Co v Canadian Celanese Ltd* [1936] SCR 221.

(3) *The Person Skilled in the Art*

- 125 Patent claims must be interpreted from the point of view of the hypothetical worker skilled in the art, who has been described by Binnie J as a:
 hypothetical person possessing the ordinary skill and knowledge of the particular art to which the invention relates, and a mind willing to understand a specification that is addressed to him. This hypothetical person has sometimes been equated with the 'reasonable man' used as a standard in negligence cases. He is assumed to be a man who is going to try to achieve success and not one who is looking for difficulties or seeking failure. (*Free World Trust*, supra, at para 44, quoting from H.G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th edn 1969), at p 184.)
- 126 A reasonable person skilled in the art, however, must also be taken to know the state of the law as it relates to the subject matter of his or her invention. For example, in *Lubrizol*

Corp v Imperial Oil Ltd (1992), 98 DLR (4th) 1 (FCA), at p 18, Mahoney JA accepted that drafters of patents were able to express their claims with ‘extreme precision’ in order for their claims to stand up to any challenge on validity, that is, they were taken to understand patent law so as to draft claims that accorded with statutory requirements.

- 127 This interpretation is fair and predictable because the public must equally be entitled to rely on this Court’s jurisprudence in determining the scope of patent claims: *Kirin Amgen Inc v Hoechst Marion Roussel Ltd* [2002] EWJ 3792 (QL), [2002] EWCA Civ 1096, at para 60. In *Kirin Amgen*, the English Court of Appeal considered the testimony of opposing experts (persons skilled in the art) and narrowed a patent claim over a naturally occurring DNA sequence (EPO gene) so that it excluded that DNA sequence in its natural and therefore unpatentable form. In doing so, the court stated at para 60:

The patentee could not monopolise the gene per se as that existed in nature. The patentee therefore monopolised the DNA sequence encoding for DNA when isolated and in that respect was suitable for use to express EPO in a host cell. As of 1984 such a monopoly would have seemed to give fair protection. To seek to monopolise use of the sequence when not isolated by inserting a construct into a human cell would provide a monopoly not properly supported by the description in the specification. *We also believe 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.* [Emphasis added.]

- 128 In conclusion, a person skilled in the art, upon filing of Monsanto’s patent, 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.

(4) *Conclusion on the Scope of Monsanto’s Claims*

- 129 Accordingly, a purposive construction that limits this claim to its ‘essential elements’, considering both the plain language of the claim and the specifications, leads me to the conclusion that the gene patent claims and the plant cell claims should not be construed to grant exclusive rights over the plant and all of its offspring.
- 130 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. Once the cell begins to multiply and differentiate into plant tissues, resulting in the growth of a plant, a claim should be made for the whole plant. However, the whole plant cannot be patented. Similarly, the method claim ends at the point of the regeneration of the transgenic founder plant but does not extend to methods for propagating that plant. It certainly does not extend to the offspring of the regenerated plant.
- 131 In effect, the patent claims grant Monsanto a monopoly over the chimeric gene and the cell into which it is inserted and the method for doing so. Therefore, no other biotechnology company can use the chimeric gene to create a glyphosate-resistant plant cell that can then be regenerated into a glyphosate-resistant plant.

D. Validity

(1) *The Law on Validity*

- 132 Claims that would otherwise be valid may be limited by statutory provisions or by jurisprudence: *Commissioner of Patents v Farbwerke Hoechst Aktiengesellschaft Vormals Meister*

- Lucius & Bruning* [1964] SCR 49; *Shell Oil Co v Commissioner of Patents* [1982] 2 SCR 536. As stated in Farbwerke, at p 57, '[t]here is no inherent common law right to a patent. An inventor gets his patent according to the terms of the Patent Act, no more and no less. If the patent for which he is applying comes within the provisions of section 41(1) [an exemption] of the Act, then he must comply with that section'.
- 133 Subject matters that are specifically precluded by statute from patent protection are natural phenomena, laws of nature, and scientific principles: section 27(8). Other subject matter has been excluded by judicial interpretation of section 2 definitions of 'invention' and 'process' and section 27(8). For example, the following have been excluded: computer programs if the discovery involved is a method of calculation (*Schlumberger Canada Ltd v Commissioner of Patents* [1982] 1 FC 845 (CA)); methods of medical treatment (*Tennessee Eastman Co v Commissioner of Patents* [1974] SCR 111); higher life forms (*Harvard College*, supra); business systems and methods and professional skills and methods (*State Street Bank & Trust Co v Signature Financial Group Inc*, 149 F3d 1368 (Fed Cir 1998)); printed matter producing only an artistic intellectual or literary result (*Re Application of Boussac*, CIPO, Commissioner's Decision 143, 10 March 1973); mere human conduct or mental steps, or instructions (*Re Application of Ijzerman*, CIPO, Commissioner's Decision 254, 4 July 1975; *Gale's Application* [1991] RPC 305 (Pat Ct), at p 323); and architectural plans (*Application 995 for a Townhouse Building Design (Re)* (1979), 53 CPR (2d) 211 (Pat App Bd)). These examples demonstrate that it is not unusual for courts and the Patent Office to interpret provisions of the Patent Act so as to exclude subject matter from patentability.
- 134 If a claim encompasses subject matter that is precluded from patentability, it is invalid. However, a claim may be interpreted taking into account the exemption. In *Shell Oil*, supra, 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 section 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.

(2) *Validity of Monsanto's Claims*

- 135 Applying the purposive construction of Monsanto's product claims, that they do not extend patent protection to plants, all of Monsanto's product claims are valid.
- 136 Monsanto's process claims are likewise valid. The method claims for making transgenic glyphosate-resistant plant cells should be valid because an invention may be a 'process': *Tennessee Eastman*, supra. A process claim may be valid even where the subject matter it manufactures is not patentable, for example, because it is obvious: *F. Hoffmann-Laroche & Co v Commissioner of Patents* [1955] SCR 414; or it constitutes unpatentable subject matter: *Harvard College*, supra.
- 137 The second part of the method—the regeneration of the plant cell into a plant—may, however, seem more problematic. However, since this process involves substantial human intervention and does not follow the 'laws of nature' as would natural asexual or sexual reproduction, I conclude that this part of the process would likewise be patentable. The Patent Commissioner in *Harvard College* found that the process of creating a transgenic cell culture that had the intermediate step of 'allowing said embryo to develop into an adult animal' was patentable as a process claim. This conclusion is consistent with the policy of the Patent Office: *Patent Office Manual*, supra, at para 16.05, and with Article 27(3)(b) of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ('TRIPS'), 1869 UNTS 299 (being Annex 1C of the *Marrakesh Agreement establishing the World Trade Organisation*, 1867 UNTS 3).

E. Summary and Conclusion on Construction and Validity of the Claims

- 138 In short, properly construed, Monsanto's claims both for products and processes are valid. Neither extends patent protection to the plant itself, a higher life form incapable of patent protection. In order to avoid the claim extending to the whole plant, the plant cell claim cannot extend past the point where the genetically modified cell begins to multiply and differentiate into plant tissues, at which point the claim would be for every cell in the plant, i.e. for the plant itself.
- 139 Therefore, Monsanto's valid claims are solely for genetically modified chimeric genes and cells in the laboratory prior to regeneration—and for the attendant process for making the genetically modified plant.

F. Infringement

- 140 'Infringement' is not defined in the *Patent Act*. To determine what constitutes infringement, recourse must be had to the common law, the statutory provisions that define the grant of rights to the inventor and the recourse to remedies, and, most importantly, the scope of the exclusive rights claimed in the patent: Fox, *supra*, at p 349. Infringement, in short, is 'any act that interferes with the full enjoyment of the monopoly granted to the patentee', if done without the consent of the patentee: Fox, *supra*, at p 349.
- 141 The issue at this stage is whether the appellants used the invention so as to interfere with the exclusive rights of the patentee, keeping in mind that the scope of Monsanto's patent does not extend to plants. The public is entitled to rely on the reasonable expectation that unpatentable subject matter falls outside the scope of patent protection and its use does not constitute an infringement: *Kirin Amgen*, *supra*, at para 60.
- 142 I will assume, as found by the courts below, that the appellants planted seeds containing Monsanto's patented gene and cell. I agree with my colleagues that the appellants did not make or construct the gene or cell contained in the canola crop and did not use Monsanto's patented process.

(1) *Statutory Interpretation of 'Use' in Section 42 of the Patent Act*

- 143 The relevant statutory provision is section 42 of the *Patent Act* where:
- 42 Every patent granted under this Act shall contain the title or name of the invention, with a reference to the specification, and shall, subject to this Act, grant to the patentee and the patentee's legal representatives for the term of the patent, from the granting of the patent, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication in respect thereof before any court of competent jurisdiction.
- 144 I will use the same three principles of statutory interpretation as did my colleagues to construe the meaning of 'use' in section 42 of the *Patent Act*. These are a purposive interpretation of the word 'use', a contextual analysis given the surrounding words in the provision, and the case law.
- 145 A purposive construction of 'use' suggests that 'use' is limited by the subject matter of the invention, and that any acts for a purpose whether foreseen or not by the inventor may constitute an infringing use. The problem with defining 'use' in the manner of my colleagues as commercial use is that the inventor is not obliged to describe the utility of the invention, the inventor must merely describe the invention so as to produce it: *Consolboard*, *supra*. Utility need not include commercial utility, contrary to my colleagues' opinion. That is determined by the market place: D. Vaver, *Intellectual Property Law: Copyright, Patents, Trademarks* (1997), at p 120. An inventor should be entitled to a remedy

such as an injunction regardless of whether the infringing use has commercial applications: *Adair v Young* (1879), 12 Ch D 13 (CA).

- 146 Dickson J (as he then was) in *Consolboard*, supra, cited with approval, at p 526, the following passage, per Thorson P in *The King v American Optical Co* (1950), 11 Fox Pat C 62 (Ex Ct), at p 85:

If an inventor has adequately defined his invention he is entitled to its benefit even if he does not fully appreciate or realise the advantages that flow from it or cannot give the scientific reasons for them. It is sufficient if the specification correctly and fully describes the invention and its operation or use as contemplated by the inventor, so that the public, meaning thereby persons skilled in the art, may be able, with only the specification, to use the invention as successfully as the inventor could himself.

- 147 Although *Consolboard*, supra, rejected a need to either claim a utility, or set out the ‘useful’ characteristics of the invention in the disclosure, it did not necessarily eliminate any relationship between infringement and the specification. In *Pioneer Hi-Bred*, supra, at p 1637, Lamer J (as he then was) held that ‘[s]ection 36(1) was enacted so competitors could know the limits within which they should avoid infringing the subject of the invention and be aware of their freedom of maneuver when they work in an area related to that of the patentee’.

- 148 This reasoning is essential to a more balanced interpretation of section 42. A contextual analysis of that section links the verbs ‘use’, ‘sell’, and ‘make’ to the noun ‘invention’. The definition of ‘use’ in any given circumstances must therefore be limited by the subject matter of the invention. This approach has been followed to interpret ‘use’ in the context of section 58, now section 56, of the *Patent Act*. Section 56 grants an exemption from infringement for persons who have acquired patentable subject matter prior to the grant of a patent:

- 56 (1) Every person who, before the claim date of a claim in a patent has purchased, constructed or acquired the subject matter defined by the claim, has the *right to use* and sell to others the *specific article, machine, manufacture or composition of matter patented* [i.e. the invention] and so purchased, constructed or acquired without being liable to the patentee or the legal representatives of the patentee for so doing. [Emphasis added.]

- 149 In *Libbey-Owens-Ford Glass Co v Ford Motor Co of Canada* (1969), 1 Ex CR 529, at p 553, in reasoning approved by this Court: *Libbey-Owens-Ford Glass Co v Ford Motor Co of Canada* [1970] SCR 833, and followed in *Merck & Co v Apotex Inc* (1994), 59 CPR (3d) 133 (FCTD), the trial judge stated that ‘the proper approach to the interpretation of section 58 [now section 56] is to first read its wording, coupled with that of section 2(d) [the definition of invention], in an effort to ascertain its meaning therefrom’.

- 150 Further, the Federal Court of Appeal in *Merck & Co v Apotex Inc* [1995] 2 FC 723, at p 745, stated:

It is the intention of the inventor, as inscribed in the patent, which protects the appellant under section 56, given that the law is not one based on form but on the scope of the whole invention ...

...

This conclusion will, I believe, be strengthened in the subsequent consideration of the composition and use claims of the patent, which will reveal even more clearly the interrelatedness of the whole patent.

- 151 Therefore ‘use’ and ‘invention’ must be read conjunctively and the scope of ‘use’ must be bounded by the scope of the claims.

- 152 The test for determining ‘use’ is not whether the alleged user has deprived the patentee of the commercial benefits flowing from his invention, but whether the alleged user has

deprived the patentee of his monopoly over the use of the invention as construed in the claims.

- 153 Applied here, the question is whether the appellants used Monsanto's genetically modified cells and genes as they existed in the laboratory prior to differentiation and propagation—or the process of genetic alteration. The question is not whether the appellants deprived Monsanto of some or all the commercial benefits of their invention.

(2) *The Law on Use*

- 154 With respect, in my view, the case law does not support my colleagues' interpretation of use. Much of the jurisprudence on 'use' and various analogies are unhelpful because of the unique properties of biological materials, especially higher life forms that can self-replicate and spread. The fact that self-replicating materials are difficult to place within the confines of the *Patent Act* was acknowledged by the Federal Court of Appeal, at para 57: 'it seems to me arguable that the patented Monsanto gene falls into a novel category. It is a patented invention found within a living plant that may, without human intervention, produce progeny containing the same invention'.
- 155 It is well established that the use or sale of unpatented subject matter may still infringe a patent where the unpatented subject matter is made employing a patented *process*: *Saccharin Corp v Anglo-Continental Chemical Works Ltd* (1900), 17 RPC 307 (HCJ); *F. Hoffmann-Laroche*, supra, at p 415; *Wellcome Foundation Ltd v Apotex Inc* (1991), 39 CPR (3d) 289 (FCTD); *American Cyanamid Co v Charles E. Frosst & Co* (1965), 29 Fox Pat C 153 (Ex Ct). This proposition does not assist the respondent, however. The appellants have not infringed the *process* claim because they have not used the claimed method to produce their canola crop.
- 156 The real question is whether a patented *product* (the gene or cell) extends patent protection to the unpatentable object into which it is incorporated. The respondents and the intervener, BIOTEC Canada, further contend that '[i]t is trite law that an unpatentable composition of matter can be an infringement by virtue of it incorporating *patented material* (joint factum of BIOTEC Canada and the Canadian Seed Trade Association, at para 39 (emphasis added)), but, like my colleagues, provided no authority on this point. In any event, there is no genuinely useful analogy between growing a plant in which every cell and every cell of all its progeny are remotely traceable to the genetically modified cell and contain the chimeric gene and putting a zipper in a garment, or tires on a car or constructing with Lego blocks. The analogies are particularly weak when it is considered that the plant can subsequently grow, reproduce, and spread with no further human intervention.
- 157 One option that was urged on us by the appellants was to incorporate a knowledge element into the definition of 'use'. Such a solution would be broadly applicable to other types of patents and lend uncertainty to a settled issue in Canadian patent law that intention is irrelevant to infringement: *Terrell on the Law of Patents* (15th edn 2000), at para 8.10; *Hughes and Woodley on Patents* (1984), at §26; *British United Shoe Machinery Co v Gimson Shoe Machinery Co* (1928), 45 RPC 290 (CA), at p 308; *Computalog Ltd v Comtech Logging Ltd* (1992), 44 CPR (3d) 77 (FCA), at p 88; *Illinois Tool Works Inc v Cobra Anchors Co* (2002), 221 FTR 161, 2002 FCT 829. Lord Hoffmann in *Merrell Dow Pharmaceuticals Inc v H.N. Norton & Co* [1996] RPC 76 (HL), at p 92, pointed out that since liability is absolute, the alleged infringer's state of mind is irrelevant. '[I]t is and always has been the law in relation to direct infringement that the knowledge or intention of the infringer is irrelevant' (*Terrell on the Law of Patents*, supra, at para 8.08).
- 158 Most people are not aware of the contents of patents but are effectively deemed to have knowledge. What matters is what the person does. If the person's acts interfere with the

exclusive rights granted by the patent, then there is infringement: *Pfizer Corp v Ministry of Health* [1965] AC 512 (HL). A case such as *British United Shoe Machinery Co v Simon Collier Ltd* (1910), 27 RPC 567 (HL), that may suggest the contrary is unusual and restricted to its facts: *Pfizer*, supra, or goes to remedy and not infringement: *Terrell on the Law of Patents*, supra, at para 8.09. As pointed out by my colleagues, the presumption of use may only be rebutted in the very rare circumstances, such as in *British United Shoe Machinery Co v Simon Collier Ltd*, supra, where neither the product nor its stand-by value was used.

- 159 A truly innocent infringer may be able to rebut the presumption of use. However, that would likely prove difficult once the innocent infringer became aware that the genetically modified crop was present—or was likely to be present—on his or her land and continued to practice traditional farming methods, such as saving seed. The complexities and nuances of innocent bystander protection in the context of agricultural biotechnology should be expressly considered by Parliament because it can only be inadequately accommodated by the law on use.

(3) Conclusion on Infringement

- 160 In the result, the lower courts erred not only in construing the claims to extend to plants and seed, but in construing ‘use’ to include the use of subject matter disclaimed by the patentee, namely the plant. The appellants as users were entitled to rely on the reasonable expectation that plants, as unpatentable subject matter, fall outside the scope of patent protection. Accordingly, the cultivation of plants containing the patented gene and cell does not constitute an infringement. The plants containing the patented gene can have no stand-by value or utility as my colleagues allege. To conclude otherwise would, in effect, confer patent protection on the plant.
- 161 Uses that would constitute an infringement include using the chimeric gene in its isolated form to create an expression or cloning vector or a transformation vector and using the transformation vector to create a transgenic plant cell. The use claimed for the plant cell extends to the isolated plant cell in a laboratory culture used to regenerate a ‘founder plant’ but not to its offspring.
- 162 There is no claim for a ‘glyphosate-resistant’ plant and all its offspring. Therefore saving, planting, or selling seed from glyphosate-resistant plants does not constitute an infringing use.
- 163 Obviously, as was done here, Monsanto can still license the sale of seeds that it produces from its patented invention and can impose contractual obligations on the licensee. Licensing allows the patent owner to impose conditions on the use of the plant, such as a prohibition on saving seeds, with the concomitant ability to sue the farmer for breach of contract if the farmer violates any of the terms of the licence.

G. The Conclusion Is Consistent With Canada’s International Obligations Under the Agreement on Trade-Related Aspects of Intellectual Property Rights

- 164 In *Harvard College*, supra, both the majority and the minority called for Parliament’s intervention on the issue of patenting higher life forms. As things stand, my conclusion on the scope of Monsanto’s patent claims that is determinative of both validity and infringing use is not contrary to Article 27(1) of *TRIPS* whereby Canada has agreed to make patents available for any invention without discrimination as to the field of technology.

- 165 The Canadian Biotechnology Advisory Committee, in *Patenting of Higher Life Forms and Related Issues* (June 2002), suggests that the contrary may, in fact, be the case. The use of biologically replicating organisms as a ‘vehicle’ for genetic patents may overcompensate the patentee both in relation to what was invented, and to other areas of invention. The Canadian Biotechnology Advisory Committee explains the point as follows (at p 12):

Because higher life forms can reproduce by themselves, the grant of a patent over a plant, seed or non-human animal covers not only the particular plant, seed or animal sold, but also all its progeny containing the patented invention for all generations until the expiry of the patent term (20 years from the priority date). In addition, much of the value of the higher life form, particularly with respect to animals, derives from the natural characteristics of the original organism and has nothing to do with the invention. In light of these unique characteristics of biological inventions, granting the patent holder exclusive rights that extend not only to the particular organism embodying the invention but also to all subsequent progeny of that organism represents a significant increase in the scope of rights offered to patent holders. It also represents a greater transfer of economic interests from the agricultural community to the biotechnology industry than exists in other fields of science.

- 166 My conclusion does not violate, and indeed is supported by Article 27(3)(b) of *TRIPS*, that states:

Article 27

...

3 Members may also exclude from patentability:

...

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof...

- 167 Allowing gene and cell claims to extend patent protection to plants would render this provision of *TRIPS* meaningless. To find that possession of plants, as the embodiment of a gene or cell claim, constitute a ‘use’ of that claim would have the same effect as patenting the plant. Therefore, my conclusion on both the scope of the claims and the scope of use is consistent with Canada’s international obligations under *TRIPS*.
- 168 Canada has a *sui generis* system of protection for plants. The *Plant Breeders’ Rights Act*, SC 1990, c 20, represents a nuanced statutory regime that takes into consideration the rights of both the developers of new plant varieties and users. There is nothing in the *Plant Breeders’ Rights Act* that would exclude genetically modified new plant varieties, such as Roundup Ready Canola, from its purview.
- 169 While the ‘rights available under the *Plant Breeders’ Rights Act* fall well short of those conferred by patent, both in comprehensiveness and in duration’ (*Harvard College*, supra, at para 61), they may be all that Monsanto is entitled to. Indeed, Professor Vaver, supra, at p 128, recognises that patents should not necessarily be available when other, more tailored intellectual property protection exists. Monsanto has since had the opportunity to come within its protection even though the Act was not in force when Monsanto was granted its patent.
- 170 In light of my conclusion on the issue of infringement, it is unnecessary for me to consider the other issues on appeal.

Disposition

- 171 I would allow the appeal with costs to the appellants throughout.

Analysis by Philippe Cullet, Law Department, School of Oriental and African Studies, University of London

In recent times, the introduction of genetically modified organisms and in particular transgenic seeds has been controversial in many parts of the world. Most countries that seek to introduce transgenic seeds into the environment today accept the need for some form of biosafety regulation. The same consensus does not yet exist with regard to the need for a specific liability and redress regime. Further, there has been comparatively little work done on the link between intellectual property rights, biosafety and liability.

The recent decision of the Canadian Supreme Court in *Monsanto Canada Inc v Schmeiser* is a landmark case. It has significant implications for Canada but more broadly imposes carefully reconsidering the overall regulatory framework which should underlie the introduction of transgenic seeds into the environment. There are two main dimensions of the case that are of interest in international perspective. Firstly, the decision proposes liability principles in the field of biosafety whose implementation elsewhere would seriously weaken attempts to strengthen international and national biosafety regulatory frameworks. Secondly, the case provides a clear illustration that biosafety regulation and patent law cannot be dissociated. Further, it also indicates that patent liability and environmental liability must be considered together if the former is not to trump the latter.

Monsanto v Schmeiser

The background to this case is the development by Monsanto of a transgenic variety of canola which is resistant to the application of Roundup Ready, a herbicide that kills most plants. Before this case, the understanding was that the transgenic construction—but not the transgenic plant—was protected under the Canadian Patent Act. Mr Schmeiser is a farmer from Saskatchewan who has been growing canola for many years. In the 1990s a number of his neighbours decided to use the Monsanto canola variety on their fields. Mr Schmeiser seems to have decided not to introduce the transgenic variety. However, Mr Schmeiser was found in possession of Roundup Ready Canola even though he had never purchased it. The source of the introduction of transgenic seeds on Mr Schmeiser's land has not been established conclusively by the courts. As stated by the Supreme Court, '[t]he origin of the plants is unclear'.¹ The judges found that they may have been derived from Roundup Ready seed that blew onto or near Schmeiser's land while at the same time indicating that none of the proposed sources of contamination could explain the overall very high concentration of transgenic seeds in the samples taken from Mr Schmeiser's fields.

Following the discovery of transgenic seeds on Mr Schmeiser's fields, Monsanto brought an action for infringement of their patent on Roundup Ready Canola. More specifically, Monsanto asserted that Mr Schmeiser had used, reproduced and created genes, cells, plants and seeds containing the genes and cells claimed in Monsanto's patent without authorisation. The Supreme Court found that the patent

¹ *Monsanto Canada Inc v Schmeiser*, Supreme Court of Canada, Judgment of 21 May 2004, 2004 SCC 34 at §6 [hereafter *Monsanto v Schmeiser*].

had been violated but that Mr Schmeiser did not owe anything to Monsanto. The reasons given for this judgment and the broader analysis provided by the judges is extremely instructive.

Firstly, the judges decided that this case was exclusively a case concerning the infringement of a patent held by Monsanto.²

Secondly, the judges set out to determine whether the Monsanto patent was valid. The main question was whether the patent on transgenic cells also extended to the plants. The issue of whether the patentability of a component of a broader unpatented structure imposes on the user of the latter to respect the patent has been considered at length in patent cases over time. In general, it is often accepted that if the patented component is significant to the activities carried out with the unpatented structure, the user has to respect the rights of the patent holder. The added problem in the case of a plant is that in countries like Canada plants themselves are not patentable.³ As a result, the question that arises is whether the patentability of a gene inserted in a seed makes the plant itself protectable. The judges asserted that since the patented invention was going to be used in plants regenerated from the patented cells, the plant itself could not be overlooked in determining whether the Monsanto patent had been infringed.⁴

Thirdly, the judges considered whether Mr Schmeiser should be deemed to have used the patented gene or cell and thereby infringed the patent. In the context of patent protection, the issue is first whether using the seeds for regeneration in subsequent years constitutes a 'use' of the patented gene. Patent law practice often accepts that infringement of a patent can occur even where the patented invention is part of a broader unpatented structure. An expansive interpretation of this principle leads to the conclusion that even if the inventor is deprived indirectly of some of the benefits of her/his invention, that constitutes an infringement of the full enjoyment of the monopoly conferred by the patent.⁵

The question that arises subsequently is whether the mere fact of possessing the patented gene implies use. In principle, it is recognised that possession without use or intention to use is not an infringement. The presumption would be that possession is not an infringement as long as possession happens in non-commercial circumstances.⁶ In the case of transgenic seeds found on private or common lands that are not commercially exploited, this would imply that there is no scope for infringement. In the case of a commercial farm, the presumption would be that use is intended unless it can be proved that the user was never planning to use the invention.⁷ In this specific case, this implies that even if Mr Schmeiser had not taken advantage of the special utility offered by the invention, he would have had to demonstrate that he had never intended to spray his crop with Roundup Ready even if there had been an unexpected need to do so.

² *Monsanto v Schmeiser*, supra n 1 at §3.

³ *Harvard College v Canada (Commissioner of Patents)*, 5 December 2002, Supreme Court of Canada [2002] 4 SCR 45, 2002 SCC 76.

⁴ *Monsanto v Schmeiser*, supra n 1 at §24.

⁵ *Monsanto v Schmeiser*, supra n 1 at §43.

⁶ However, this does not imply that the patent holder is deprived of protection where there is no commercial exploitation.

⁷ *Monsanto v Schmeiser*, supra n 1 at §56.

In the *Schmeiser* case, the judges decided that even though Mr Schmeiser never sprayed his crops with Roundup Ready, it could not be ruled out that he might not have done so had the need arisen. This was based on the finding that Mr Schmeiser 'knew or ought to have known' that the seeds he planted in 1998 were Roundup Ready tolerant. This led the Court to determine that Monsanto had been deprived at least in part of the enjoyment of the patent, on the basis that even if the invention was not used directly by Mr Schmeiser, possession gave him a chance to sell it to other farmers unwilling to pay the licence fee.⁸ In other words, even though it is possible that Mr Schmeiser may not have known that his crop was Roundup Ready tolerant, he is held to have used the invention.

The judges addressed one last argument concerning the relationship between real property rights and intellectual property rights. Mr Schmeiser argued that once the patented seeds had made their way to his fields, he should be held to own the seeds in the same way that landowners own the progeny of animals reproducing on their land. The trial judge addressed this issue directly and came to the conclusion that while the farmer may own the seeds spilled onto his land or seeds having germinated from pollen carried to his fields from elsewhere by insects, birds or the wind, this does not give him the right to use the patented gene or the seed containing the patented gene or cell.⁹ The Supreme Court judges merely noted that the issue in the *Schmeiser* case was one of patent protection and that ownership would be no defence to a breach of the Patent Act.

Having determined that Mr Schmeiser had infringed the Monsanto patent, the Supreme Court found that Mr Schmeiser did not owe Monsanto anything because he had not benefited from the use of the patent. This conclusion was arrived at because Monsanto decided to elect for a type of remedy—accounting of profits—which is measured by looking at the profits made by the infringer rather than the amount lost by the inventor.¹⁰ Since Mr Schmeiser had not used Roundup Ready on his crop, he had not take advantage of the herbicide resistant nature of the transgenic canola and had therefore gained nothing.

Monsanto v Schmeiser in Broader Perspective

The Supreme Court judgement is a decision nearly exclusively grounded in patent law. In the narrow context in which the judges decided to consider this case, they reached the conclusion that patent rights prevail over real property rights and that Mr Schmeiser should be deemed to have infringed the invention even if he had not actually used and taken advantage of it. Having established these principles, the Court then determined that Mr Schmeiser owed nothing to Monsanto because he had not gained economically from the use of the invention.

The judgment raises questions from the point of view of patent law. Besides patent issues, the judgment raises other questions since it fails to address other important issues related to the introduction of transgenic seeds into the environment. Thus, it

⁸ *Monsanto v Schmeiser*, supra n 1 at §71.

⁹ *Monsanto v Schmeiser*, 29 March 2001, 2001 FCT 256 at §92.

¹⁰ *Monsanto v Schmeiser*, supra n 1 at §100.

neither considers questions related to biosafety, nor questions related to the environmental liability of the company commercialising the transgenic seeds, nor questions related to farmers' rights or privileges.

Patent Protection

The findings of the Canadian Supreme Court on patent law are potentially wide-ranging. The principle established by the Court is that Mr Schmeiser is deemed to have infringed the patent whether or not he knew that the Monsanto patented gene was present in his seeds. This is an odd result because it cannot be assumed that individual farmers have the capacity to test their seeds for the presence of patented genes. In the case of Roundup Ready Canola, for instance, this would seem to imply that farmers growing non-transgenic canola in an area where transgenic canola is also grown would be under an obligation to either have their seeds tested in a laboratory or to spray Roundup Ready on their crop which would have the effect of killing the crop if it is found not to be transgenic canola.

Whether or not Mr Schmeiser knew that there were transgenic seeds on his land, broader issues arise. As noted above, in Canada plants are in principle not patentable. Further, both countries also have a special regime for the protection of plant varieties which introduces an alternative intellectual property rights protection known as plant breeders' rights. It is noteworthy that there used to be a strict distinction between inventions which were the product of human inventiveness and products of nature such as plants which were possibly selected by human beings but not controlled by them. In fact, this distinction helps to understand the rationale for the development of plant breeders' rights which were developed partly as a compromise between proponents of intellectual property protection for plants and proponents of the patent system who felt that the introduction of plants in the patent system would have negative impacts on the whole patent system by bringing in protectable subject matter where the human contribution was small. In recent decades, in parallel with the development of genetic engineering, patents on life forms have progressively been accepted as confirmed by the TRIPS Agreement which imposes life patents in all WTO member states. However, even if life patents are now allowed, countries neither have to provide patentability for plants nor for plant varieties.¹¹ There are good reasons for maintaining this distinction. Firstly, should the Monsanto patent automatically extend to the plant of which it is a part, this would blur the distinction between patents on transgenic cells or genes and patents on plants.¹² Secondly, the fact that certain plants can self-replicate and spread in the environment strengthens the rationale for maintaining the prohibition on plant patents.

Biosafety and Liability

As indicated above, the judgement does not consider issues besides patent protection. While patent protection is one of the main legal incentives for the development

¹¹ See Article 27(3)(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakech, 15 April 1994, 33 ILM 1197 (1994).

¹² Cf *Novartis/Transgenic Plant*, Case G01/98, European Patent Office (Enlarged Bd App), Decision of 20 December 1999 [2000] EPO Reports 303 where the patenting prohibition for plant varieties was discussed.

of genetic engineering in the private sector, biosafety regulation is the main instrument through which the environmental and health impacts of genetically modified organisms are examined. Most countries of the world, even most of those that have not ratified the Biosafety Protocol to the Biodiversity Convention like Canada, have biosafety regulations at the national level.¹³

One of the main reasons why biosafety should be considered in a case like this is that it brings up different but complementary aspects to the dispute. The patent dispute looked exclusively at the question of whether Mr Schmeiser had infringed a patent. The biosafety dispute would have also looked at the issue of whether Monsanto should be deemed responsible for introducing into the environment a transgenic construct which has the potential to self-replicate.¹⁴

Seen from this broader perspective, the dispute between Mr Schmeiser and Monsanto becomes a question of the respective liability of Mr Schmeiser concerning the patent infringement versus Monsanto's liability for the contamination of his property. This raises problems which were not addressed by the court.

Firstly, there is a need for clarity concerning the responsibility of the different entities and individuals involved in the introduction of genetically modified seeds into the environment. One of the good solutions is the one adopted by Switzerland in its Gene Technology Act which clearly indicates that the entity which has been given the authorisation to introduce a genetically modified organism into the environment is solely liable for damage that is a result of the modification of the genetic material.¹⁵ Should a different solution prevail, the legal framework should at the very least clearly demarcate the responsibility of the entity marketing the transgenic organism and the responsibility of other users. In the Schmeiser case where the farmer is deemed to have infringed the patent even if his fields were in fact contaminated, this would seem to absolve the entity marketing the seeds from any liability and shift the burden to the users. On the basis of the Schmeiser decision, the principle established would appear to be that the only legal relationship that farmers have with Monsanto is with regard to patent protection. In a situation where their fields are contaminated, they would only be able to sue their neighbours for the contamination. This would be an unwelcome situation against which countries which have not yet given themselves a clear liability framework should protect themselves.

Secondly, the issue of a balance of liabilities raises the question of the control that farmers have or can have over the land they own or use. Different farmers may take different decisions concerning the kind of agriculture they want to undertake and some decide to pursue organic agriculture. Since the definition of organic agriculture implies that there should be no genetically modified plants, contamination by genetically modified seeds would immediately disqualify the organic farmer from selling his/her crop as organic and would lead to a loss of earning since organic products fetch in general a higher price than non-organic ones. The question which is raised here is that of co-existence, an issue which has been extensively discussed in

¹³ See e.g. Canadian Regulatory Directive Dir94-08: Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits.

¹⁴ This goes beyond and is not related to the decision allowing Monsanto to commercialise Roundup Ready Canola.

¹⁵ Article 30 of the Swiss Federal Law relating to Non-Human Gene Technology, 21 March 2003, *Recueil systématique* 814.91.

scientific and policy debates.¹⁶ Unless there is a clear decision to forgo organic agriculture, contamination of organic crops should be compensated by the entity causing the contamination. The entity which benefits from the commercialisation of the transgenic seed should be the one shouldering the costs related to the contamination of the environment.

Thirdly, this also raises the issue of farmers' rights. The situation can be divided between the rights of farmers who purchase transgenic seeds and other farmers. In the case of farmers who purchase, for instance, Roundup Ready Canola from Monsanto, they have to sign as part of the transaction a Technology Use Agreement which contractually restricts the rights they have over the seeds they purchase. These agreements have, for instance, been challenged in some cases in the United States but the courts have found that even if they deprive farmers of some statutory rights this does not invalidate the contract which they voluntarily sign as part of the purchase agreement with the company.¹⁷ While the situation of farmers who are bound by a Technology Use Agreement seems clear at least in North America, these contractual provisions should not, in principle, affect the rights of other farmers. Farmers who do not purchase these seeds should, in principle, have the rights they customarily enjoy as part of the 'farmer privilege' enjoyed under the plant breeders' rights system. These farmers should theoretically have the right to save and use seeds that they have grown even if they have been pollinated by transgenic pollen. The Schmeiser case, however, seems to indicate that unless a farmer had no inkling of the potential presence of transgenic seeds, s/he would be liable. In practice, this means that the onus of proof is on the farmers. This also implies that if farmers grow non-transgenic crops in an area where transgenic crops are grown, there could be a presumption that they 'ought to know' of the possible presence of protected transgenic seeds on their fields.

Implications of *Monsanto v Schmeiser*

The Schmeiser case is a landmark decision. On the one hand, it may be seen as providing a warning to other farmers in Canada that they have to watch their fields for the presence of transgenic seeds. It also indicates that patent protection seems to prevail today over the rights that landowners have and that issues concerning biosafety, co-existence and liability are of low importance. On the other hand, the finding that the patent holder can in principle assert its rights on all transgenic seeds used in a commercial context whatever their origin may make the link between environmental contamination and the patent holder easier to establish.

In comparative perspective, the Schmeiser case can be seen in two different ways. On the one hand, the case may remain an isolated decision and its impacts may stop at Canadian borders. This will be the case if all other countries adopt strict biosafety frameworks which, like the Swiss Law, make it clear that the entity marketing the genetically modified organism is solely liable for all consequences arising from its introduction into the environment. On the other hand, there remain at present a

¹⁶ See e.g. Agriculture and Environment Biotechnology Commission, *GM Crops: Coexistence and Liability* (London: Biotechnology Commission, 2003).

¹⁷ See e.g. *Monsanto v McFarling*, United States Court of Appeals, Federal Circuit, 23 August 2002, 302 F3d 1291.

number of countries where the legal framework is not necessarily specific enough to ensure that similar cases will never occur in the future. The above analysis indicates that the Schmeiser decision is unhelpful from a patent law point of view and lacking because it fails to take into account biosafety aspects, the question of co-existence and to consider the liability of the entity introducing the transgenic seeds into the environment.

The Schmeiser case makes it clear that the development of comprehensive liability frameworks in the field of biotechnology is a priority. This is, in fact, something which is currently being addressed in the context of the Biosafety Protocol. The ongoing negotiations for a liability and redress regime under Article 27 of the Protocol should not fail to address the issues raised by the Schmeiser decision to ensure that the international liability and redress regime which will hopefully be adopted in the next few years is comprehensive, coherent and solid.