Monsanto Canada Inc. v. Schmeiser

Percy Schmeiser and Schmeiser Enterprises Ltd. Appellants

v.

Monsanto Canada Inc. and Monsanto Company Respondents

and

Attorney General of Ontario, Canadian Canola Growers Association (CCGA), Ag-West Biotech Inc., BIOTECanada, Canadian Seed Trade Association, Council of Canadians, Action Group on Erosion, Technology and Concentration, Sierra Club of Canada, National Farmers Union, Research Foundation for Science, Technology and Ecology, and International Centre for Technology Assessment Interveners

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2004: January 20; 2004: May 21.

Present: McLachlin C.J. and Iacobucci, Major, Bastarache, Binnie, Arbour, LeBel, Deschamps and Fish JJ.

ON APPEAL FROM THE FEDERAL COURT OF APPEAL

Patents -- Scope and validity of patent -- Patentable subject matter -- Biotechnology -- Genes and cells -- Whether patents extent to plants -- Patent claims disclosing genetically modified genes and cells which, when inserted into plants, increased tolerance to glyphosate herbicides -- Whether patent valid.

Patent -- Infringement -- Patent disclosing genetically modified genes and cells which, when inserted into plants, increased tolerance to herbicides containing glyphosate -- Agricultural production of canola containing patented cell and gene without obtaining licence or permission -- Whether patent infringed -- Meaning of word "use" in s. 42 of Patent Act, R.S.C. 1985, c. P-4.

Patent -- Remedy -- Accounting of profits -- Whether accounting of profits may be claimed in absence of evidence of profit attributable to invention.

The respondents are the licensee and owner, respectively, of a patent that discloses the invention of chimeric genes that confer tolerance to glyphosate herbicides such as Roundup and cells containing those genes. Canola containing the patented genes and cells is marketed under the trade name "Roundup Ready Canola". The appellants grow canola commercially in Saskatchewan. The appellants never purchased Roundup Ready canola nor obtained a licence to plant it. Tests of their 1998 canola crop revealed that 95-98 per cent was Roundup Ready Canola. The respondents brought an action against the appellants for patent infringement. The trial judge found the patented gene and cell and allowed the action, concluding that the appellants knew or ought to have known that they saved and planted seed containing the patented gene and cell and that they sold the resulting crop also containing the patented gene and cell. The Federal Court of Appeal affirmed the decision but made no finding on patent validity.

Held (lacobucci, Bastarache, Arbour and LeBel JJ. dissenting in part): The appeal should be allowed in part.

Per McLachlin C.J. and Major, Fish, Binnie and Deschamps JJ.: The patent is valid. The respondents did not claim protection for the genetically modified plant itself, but rather for the genes and the modified cells that make up the plant. A purposive construction of the patent claims recognizes that the invention will be practised in plants regenerated from the patented cells, whether the plants are located inside or outside a laboratory. 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. The appellants have failed to discharge the onus to show that the Commissioner of Patents erred in allowing the patent.

To determine whether the appellants infringed s. 42 of the *Patent Act* by "using" the patented cell and gene, the word "use" in that section must be interpreted taking into account its plain meaning, the purpose of s. 42, its context, and the case law. The plain meaning of the word "use" or "*exploiter*" denotes utilization with a view to production or advantage. The purpose of s. 42 is to define the exclusive rights granted to the patent holder. The question in determining whether a defendant has "used" a patented invention is whether the defendant's activity deprived the inventor in whole or in part, directly or indirectly, of full enjoyment of the monopoly conferred by law. A contextual examination shows that if there is a commercial benefit to be derived from the invention, it belongs to the patent holder. According to the case law, 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. 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. Possession, at least in commercial circumstances, raises a rebuttable presumption of "use". 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.

In this case, the appellants' saving and planting seed, then harvesting and selling plants that contained 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. The other questions of principle relevant to "use" under s. 42 also support that preliminary conclusion. By cultivating a plant containing the patented gene and composed of the patented cells without license, the appellants deprived the respondents of the full enjoyment of the monopoly. The appellants' involvement with the disputed canola was also clearly commercial in nature.

Case law shows that infringement is established where a defendant's commercial or business activity involving a thing of which a patented part is a component necessarily involves use of the patented part. Infringement in this case therefore does not require use of the gene or cell in isolation. Infringement also does not require that the appellants have used Roundup herbicide as an aid to cultivation. First, this argument fails to account for the stand-by or insurance utility of the properties of the patented genes and cells. Second, the appellants did not provide sufficient evidence to rebut the presumption of use. While 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, in the circumstances of this case, this presumption stands unrebutted. The appellants actively cultivated Roundup Ready Canola as part of their business operations. In light of all of the relevant considerations, the appellants used the patented genes and cells, and infringement is established.

The Patent Act permits two alternative types of remedies: damages and an accounting of profits. Here damages are not available, in view of the respondents' election to seek an account of profits. The inventor is only entitled to that portion of the infringer's profit which is causally attributable to the invention. A comparison is to be made between the appellants' profit attributable to the invention and their profit had they used the best non-infringing option. The appellants' profits were precisely what they would have been had they planted and harvested ordinary 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. On this evidence, the appellants earned no profit from the invention and the respondents are entitled to nothing on their claim of account.

Per lacobucci, Bastarache, **Arbour** and LeBel JJ. (dissenting in part): The heart of the issue is whether the Federal Court of Appeal's decision can stand in light of this Court's ruling that plants as higher life forms are unpatentable. A purposive construction that limits the scope of the respondents' claims to their "essential elements" leads to the conclusion that the gene claims and the plant cell claims should not be construed to grant exclusive rights over the plant and all of its offspring. This interpretation is fair and predictable because it ties the respondents to their claims; the respondents specifically disclaim plants. Patents must be interpreted from the point of view of the person skilled in the art who must also be taken to know the law. A person skilled in the art could not reasonably have expected that patent valid because neither extends patent protection to the plant itself.

The issue at the infringement 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 the claims does not extend patent protection to plants. The meaning of "use" in s. 42 of the *Patent Act* requires a purposive interpretation of the word "use", a contextual analysis given the surrounding words in the provision, and the case law. 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 contextual analysis also links the verb "use" with the noun "invention". Accordingly, the test for determining "use" is not whether the alleged user has deprived the patentee of the invention as construed in the claims. In the context of this case, the question is whether the appellants used the respondents' genetically modified cells and genes as they existed in the laboratory prior to differentiation and propagation -- or the process of genetic alteration. Much of the case law on "use" and various analogies are unhelpful, in this context, to define the meaning of "use" because of the unique properties of biological materials, especially higher life forms that can self-replicate and spread. A knowledge element should not be incorporated in the definition of "use" since it is a settled issue in Canadian patent law that intention is irrelevant to infringement. If the person's acts interfere with the exclusive rights granted by the patent, then there is infringement, although the presumption of use may be rebutted in very rare circumstances.

In the result, the lower courts erred not only in construing the claims to extend to plants and seed, but also 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. To conclude otherwise would, in effect, confer patent protection on the plant. Since there is no claim for a "glyphosate-resistant" plant and all its offspring, saving, planting, or selling seed from glyphosate-resistant plants does not constitute an infringing use. As was done here, the respondents can still license the sale of seeds that they produce from their patented invention and can impose contractual obligations, such as prohibition on saving seeds, on the licensee.

The conclusion on the scope of the respondents' patent claims, that is determinative of both validity and infringing use, is consistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights.

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By McLachlin C.J. and Fish J.

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By Arbour J. (dissenting in part)

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Civ. 1096; Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruning, [1964] S.C.R. 49; Shell Oil Co. v. Commissioner of Patents, [1982] 2 S.C.R. 536; Schlumberger Canada Ltd. v. Commissioner of Patents (1981), 56 C.P.R. (2d) 204, Co. v. Commissioner of Patents, [1982] 2 S.C.R. 536; Schlumberger Canada Ltd. v. Commissioner of Patents (1981), 56 C.P.R. (2d) 204, aff'd [1982] 1 F.C. 845; Tennessee Eastman Co. v. Commissioner of Patents, [1974] S.C.R. 111; State Street Bank & Trust Co. v. Signature Financial Group, Inc. (1998), 149 F.3d 1368; Re Application of Boussac, CIPO, Decision No. 143, March 10, 1973; Re Application of Akzona, CIPO, Decision No. 254, July 4, 1975; Gale's Application, [1991] R.P.C. 305; Application No. 995 for a Townhouse Building Design (Re) (1979), 53 C.P.R. (2d) 211; F. Hoffmann-Laroche & Co. v. Commissioner of Patents, [1955] S.C.R. 414; Adair v. Young (1879), 12 Ch. D. 13; The King v. American Optical Co. (1950), 11 Fox. Pat. C. 62; Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada (1969), 1 Ex. C.R. 529, aff'd [1970] S.C.R. 833; Merck & Co. v. Apotex Inc. (1994), 59 C.P.R. (3d) 133, rev'd [1995] 2 F.C. 723; Saccharin Corp. v. Anglo-Continental Chemical Works, Ld. (1900), 17 R.P.C. 307; Wellcome Foundation Ltd. v. Apotex Inc., [1991] 39 C.P.R. (3d) 289; American Cyanamid Co. v. Charles E. Frosst & Co. (1965), 29 Fox Pat. C. 153; British United Shoe Machinery Co. v. Gimson Shoe Machinery Co. (1928), 45 R.P.C. 290; Computalog Ltd. v. Comtech Logging Ltd. (1992), 44 C.P.R. (3d) 77; Illinois Tool Works Inc. v. Cobra Anchors Co. (2002), 221 F.T.R. 161, 2002 FCT 829; Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co., [1996] R.P.C. 76: Pfizer Corp. v. Ministry of Health [1965] A C. 512; British United Shoe Machinery Co. v. Simon Collier Ld (1910), 27 R.P.C. 567 R.P.C. 76; Pfizer Corp. v. Ministry of Health, [1965] A.C. 512; British United Shoe Machinery Co. v. Simon Collier Ld. (1910), 27 R.P.C. 567.

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APPEAL from a judgment of the Federal Court of Appeal, [2003] 2 F.C. 165, (2002), 218 D.L.R. (4th) 31, 293 N.R. 340, 21 C.P.R. (4th) 1, [2002] F.C.J. No. 1209 (QL), 2002 FCA 309, affirming a decision of the Trial Division (2001), 202 F.T.R. 78, 12 C.P.R. (4th) 204, [2001] F.C.J. No. 436 (QL), 2001 FCT 256.

Appeal allowed in part, Iacobucci, Bastarache, Arbour and LeBel JJ. dissenting in part.

Terry J. Zakreski, for the appellants.

Roger T. Hughes, Q.C., Arthur B. Renaud and L. E. Trent Horne, for the respondents.

Sara Blake and Ryan Collier, for the intervener the Attorney General of Ontario.

Mona G. Brown and Carena Roller, for the intervener the Canadian Canola Growers Association.

Written submissions only by *Richard W. Danyliuk*, for the intervener Ag-West Biotech Inc. *Anthony G. Creber* and *Henry S. Brown*, Q.C., for the intervener BIOTECanada.

A. David Morrow and Colin B. Ingram, for the intervener the Canadian Seed Trade Association.

Steven Shrybman and Steven Barrett, for the interveners the Council of Canadians, the Action Group on Erosion, Technology and Concentration, the Sierra Club of Canada, the National Farmers Union, the Research Foundation for Science, Technology and Ecology, and the International Centre for Technology Assessment.

The judgment of McLachlin C.J. and Major, Binnie, Deschamps and Fish JJ. was delivered by

THE CHIEF JUSTICE AND FISH J. --

I. Introduction

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, R.S.C. 1985, c. P-4. We believe that it did.

In reaching this conclusion, we emphasize from the outset that we are not concerned here with the innocent discovery by farmers of 2

"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 authorized 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.

II. 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 (*Mosanto Canada Inc. v. Schmeiser* (2001), 202 F.T.R. 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.

III. Analysis

A. The Patent: Its Scope and Validity

8 Canola is a valuable crop grown in Canada and used to make edible oil and animal feed. The respondents are the licensee and owner, respectively, of Canadian Patent No. 1,313,830. This patent, titled "Glyphosate-Resistant Plants" was issued on February 23, 1993, and expires on February 23, 2010. It discloses the invention of genetically engineered genes and cells containing those genes which, when inserted into plants (in this case canola), dramatically increase their tolerance to herbicides containing glyphosate. Ordinarily, glyphosate inhibits an enzyme essential for plant survival. Most plants sprayed with a glyphosate herbicide do not survive, but a canola plant grown from seed containing the modified gene will survive.

9 Since 1996, canola seed containing the patented gene and cell has been produced in Canada under licence from the respondents; this seed has been marketed to farmers under the trade name "Roundup Ready Canola", reflecting its resistance to the glyphosate herbicide "Roundup" manufactured by the respondents. Roundup can be sprayed after the canola plants have emerged, killing all plants except the canola. This eliminates the need for tillage and other herbicides. It also avoids delaying seeding to accommodate early weed spraying.

10 In 1996, approximately 600 Canadian farmers planted this Roundup Ready Canola on 50,000 acres. By 2000, approximately 20,000 farmers planted 4.5 to 5 million acres -- nearly 40 percent of all canola grown in Canada.

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 authorized 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 authorized 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*, S.C. 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.

15 The scope of the patent is largely uncontroversial.

16 The trial judge found that "it is the <u>gene</u> and <u>the process for its insertion</u> ... and <u>the cell derived from that process</u>" that comprise the invention (para. 88 (emphasis added), see also para. 26). The Federal Court of Appeal likewise endorsed the claims as being for "genes and cells which are glyphosate-resistant" (*Mosanto Canada Inc. v. Schmeiser* [2003], 2 F.C. 165, at para. 40).

17 Everyone agrees that Monsanto did not claim protection for the genetically modified plant itself, but rather for the genes and the modified cells that make up the plant. Unlike our colleague, Arbour J., 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.

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 S.C.R. 67, 2000 SCC 67; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504. In this case, the disclosure includes the following:

Abstract of Disclosure

Plant cells transformed using such genes and plants regenerated therefrom have been shown to exhibit a substantial degree of glyphosate resistance. (AR 235)

Background of the Invention

The object of this invention is to provide a method of genetically transforming plant cells which causes the cells and plants regenerated therefrom to become resistant to glyphosate and the herbicidal salts thereof. (AR 238)

Detailed Description of the Invention

Suitable plants for the practice of the present invention include, but are not limited to, soybean, cotton, alfalfa, canola, flax, tomato, sugar beet, sunflower, potato, tobacco, corn, wheat, rice and lettuce. (AR 240-241)

19 A purposive construction therefore recognizes 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 thereform to become resistant to glyphosate" (trial judgment, para. 20 (emphasis added)).

20 More particularly, the patented claims are for:

1 A <u>chimeric gene</u>: this is a gene that does not exist in nature and is constructed from different species.

2 An <u>expression vector</u>: 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 <u>plant cells</u> into which the chimeric gene has been inserted.

5 A <u>method of regenerating a glyphosate-resistant plant</u>. 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.

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 <u>Harvard College v. Canada (Commissioner of Patents)</u>, [2002] 4 S.C.R. 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*.

Further, all members of the Court in *Harvard Mouse* noted in *obiter* that a fertilized, 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: <u>Apotex Inc. v. Wellcome Foundation Ltd.</u>, [2002] 4 S.C.R. 153, 2002 SCC 77, at paras. 42-44. 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?

The *Patent Act* confers on the patent owner "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used": s. 42. Monsanto argues that when Schmeiser planted and cultivated Roundup Ready Canola seed, he necessarily infringed their patent by making the gene or cell.

We are not inclined to the view that Schmeiser "made" the cell within the meaning of s. 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 s. 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.

29 The onus of proving infringement lies on the plaintiff, Monsanto.

30 Infringement is generally a question of fact (see *Whirlpool, supra*). In most patent infringement cases, once the claim has been construed it is clear on the facts whether infringement has taken place: one need only compare the thing made or sold by the defendant with the claims as construed. Patent infringement cases that turn on "use" are more unusual. In those rare cases where a dispute arises on this issue, as in this case, judicial interpretation of the meaning of "use" in s. 42 of the Act may be required.

Determining the meaning of "use" under s. 42 is essentially a matter of statutory construction. The starting point is the plain meaning of the word, in this case "use" or "*exploiter*". The Concise Oxford Dictionary defines "use" as "cause to act or serve for a purpose; bring into service; avail oneself of": The Concise Oxford Dictionary of Current English (9th ed.1995), at p. 1545. This denotes utilization for a purpose.

The French word "*exploiter*" is even clearer. It denotes utilization with a view to production or advantage: "*tirer parti de (une chose), en vue d'une production ou dans un but lucratif; [...] [u]tiliser d'une manière advantageuse ...": Le Nouveau Petit Robert (2003), at p. 1004.*

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 <u>purposive</u>, grounded in an understanding of the reasons for which patent protection is accorded. Second, the inquiry must be <u>contextual</u>, giving consideration to the other words of the provision. Finally, the inquiry must be attentive to the wisdom of the <u>case law</u>. We will discuss each of these aids to interpretation briefly, and then apply them to the facts of this case.

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: <u>Free World Trust v. Électro Santé Inc., [2000] 2 S.C.R. 1024</u>, 2000 SCC 66. "[P]urposive construction is capable of expanding or limiting a literal [textual claim]": *Whirlpool, supra*, at para. 49. Similarly, it is capable of influencing what amounts to "use" in a given case.

The purpose of s. 42 is to define the exclusive rights granted to the patent holder. These rights are the rights to full enjoyment of the monopoly granted by the patent. Therefore, what is prohibited is "any act that interferes with the full enjoyment of the monopoly granted to the patentee": H. G. Fox, *The Canadian Law and Practice Relating to Letters Patent for Inventions* (4th ed. 1968), at p. 349; see also *Lishman v. Erom Roche Inc.* (1996), 68 C.P.R. (3d) 72 (F.C.T.D.), at p. 77.

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: <u>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?</u>

A purposive approach is complemented by a contextual examination of s. 42 of the *Patent Act*, which shows that the patentee's monopoly generally protects its business interests. Professor D. Vaver, in *Intellectual Property Law: Copyright, Patents, Trade-marks* (1997), suggests that the common thread among "(making, constructing and using the invention and selling it to others to be used)"... is that the activity is usually for commercial purposes -- to make a profit or to further the actor's business interests ..." (p. 151). This is particularly consistent with the French version of s. 42, which uses the word "*exploiter*".

37 As a practical matter, inventors are normally deprived of the fruits of their invention and the full enjoyment of their monopoly when another person, without licence or permission, uses the invention to further a business interest. 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.

38 With respect for the contrary view of Arbour J., this does not require inventors to describe in their specifications a commercial advantage or utility for their inventions. Even in the absence of commercial exploitation, the patent holder is entitled to protection. However, a defendant's commercial activities involving the patented object will be particularly likely to constitute an infringing use. This is so because 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. The contextual analysis of the section thus complements -- and confirms -- the conclusion drawn from its purposive analysis. It is the reverse side of the same coin.

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.

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 <u>plants</u> did not amount to "using" their patented <u>genes</u> and <u>cells.</u>

41 Patent infringement actions often proceed in a manufacturing context. Case law has for that reason focussed on situations where a patented part or process plays a role in production. As Professor Vaver states, *supra*, at p. 152:

"Use" applies both to patented products and processes, and also to their output. A patent that covers a zipper-making machine or method extends to zippers made by the machine or method. Each zipper sold without authority infringes the patent, even if the zippers themselves are unpatented. This expansive doctrine applies, however, only if the patent plays an important part in production.

42 By analogy, then, the law holds that a defendant infringes a patent when the defendant manufactures, seeks to use, or uses a patented part that is contained within something that is not patented, provided the patented part is significant or important. In the case at bar, the patented genes and cells are not merely a "part" of the plant; rather, the patented genes are present throughout the genetically modified plant and the patented cells compose its entire physical structure. In that sense, the 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. If anything, the fact that the Lego structure could not exist independently of the patented blocks would strengthen the claim, underlining the significance of the patented invention to the whole product, object, or process.

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 <u>full</u> enjoyment of the monopoly conferred.

44 Thus, in Saccharin Corp. v. Anglo-Continental Chemical Works Ld. (1900), 17 R.P.C. 307 (H.C.J.), the court stated, at p. 319:

By the sale of saccharin, in the course of the production of which the patented process is used, the Patentee is deprived of some part of the whole profit and advantage of the invention, and the importer is indirectly making use of the invention.

This confirms the centrality of the question that flows from a purposive interpretation of the *Patent Act*: did the defendant by his acts or conduct, deprive the inventor, in whole or in part, directly or indirectly, of the advantage of the patented invention?

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. In *Betts v. Neilson* (1868), L.R. 3 Ch. App. 429 (aff'd by (1871) L.R. 5 H.L. 1), the object of the patent was to preserve the contents of bottles in transit. Though the bottles were merely shipped unopened through England, the defendant was held to have used the invention in England because, during its passage through that country, the

beer was protected by the invention. Lord Chelmsford said, at p. 439:

It is the employment of the machine or the article for the purpose for which it was designed which constitutes its active use; and whether the capsules were intended for ornament, or for protection of the contents of the bottles upon which they were placed, the whole time they were in *England* they may be correctly said to be in active use for the very objects for which they were placed upon the bottles by the vendors.

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. It was not relevant in *Neilson* whether the invention had actually caused bottles to be preserved during shipping, in a situation in which they would otherwise have broken. As a further example, in *Dunlop Pneumatic Tyre Co. v. British & Colonial Motor Car Co.* (1901), 18 R.P.C. 313 (H.C.J.), the defendants placed on display at a car show a car with patented tires which they had intended to remove prior to sale, substituting other tires. The exhibition of the car with the patented tires was nonetheless held to be an infringing use. The common thread is that the defendants employed the invention to their advantage, depriving the inventor of the full enjoyment of the monopoly.

47 Moreoever, as Lord Dunedin emphasized in *British United Shoe Machinery Co. v. Simon Collier Ld.* (1910), 27 R.P.C. 567 (H.L.), <u>possession as a stand-by has "insurance value</u>", as for example in the case of a fire extinguisher. The extinguisher is "used" to provide the means for extinguishment should the need arise. This is true, too, of a spare steam engine which is "intended in certain circumstances to be used for exactly the purpose for which the whole machine is being actually used" (p. 572). Exploitation of the stand-by utility of an invention uses it to advantage.

48 In *Terrell on the Law of Patents* (15th ed. 2000), at para. 8.24, the authors observe that "[t]he word `use'... would ... seem to indicate making practical use of the invention itself". In some circumstances, "practical use" may arise from the stand-by utility resulting from mere possession of the invention, or from some other practical employment with a view to advantage. Use, and thereby infringement, are then established.

49 The general rule is that the defendant's intention is irrelevant to a finding of infringement. The issue is "what the defendant does, not ... what he intends": *Stead v. Anderson* (1847), 4 C.B. 806, 136 Eng. Rep. 724 (C.P.), at p. 736; see also *Hoechst Celanese Corp. v. BP Chemicals Ltd.* (1998) 25 F.S.R. 586 (Pt. Ct.) at p. 598; *Illinois Tool Works Inc. v. Cobra Anchors Co.* (2002), 221 F.T.R. 161 (F.C.T.D.), 2002 FCT 829, at paras. 14-17; *Computalog Ltd. v. Comtech Logging Ltd.* (1992), 44 C.P.R. (3d) 77 (F.C.A.) at p. 88. 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.

Thus, possession was found to constitute "use" in *Adair v. Young* (1879), 12 Ch. D. 13 (C.A.), where a ship's master was sued for infringement in relation to the presence of patented pumps on his ship. The ship's owners had fitted the ship with the pumps but were not named in the suit. The master had no power to remove the pumps and had never used them to pump water in British waters. However, the court <u>held that the master intended to use the pumps if the need arose</u>. The court thus granted an injunction against use of the pumps to pump water.

52 Similarly, Fox states, *supra*, that "<u>[m]ere possession of a patented article may amount to infringement</u> where such possession is unlicensed and <u>where there is present the intention of user</u> to the detriment of the patentee, but not if there is no intention to use" (pp. 383-84) (emphasis added, footnotes omitted).

53 The onus of proving infringement would become impractical and unduly burdensome in cases of possession were the patent holder required to demonstrate the defendant's intention to infringe. As Professor Vaver explains, "mere possession may not be use, but a business that possesses a patented product for trade <u>may be presumed either to have used it or to intend to use it, unless it shows the contrary</u>" (*supra*, at p. 151 (emphasis added)).

The classic case of *British United Shoe, supra*, suggests that mere possession of an object containing a patented ingredient or made by a patented process may not amount to "use" if the defendant can show that the object is held without a view to advancing the defendant's interest. The defendant boot maker owned a machine containing a patented mechanism but was held not to have infringed the patent. The defendants did not use the patented part itself, as it was possible not to bring it into operation unless one wanted to do so. The court noted there was no question of the defendants' honesty (they had returned the patented part willingly when legal action commenced). In the court's view, "[t]he patented part ... was ... of no use to the Defendants and was put aside by them, and they never thought of using the patented part, nor was it appropriate to their trade" (p. 571). The court stated that there is a rebuttable presumption or "ordinary inference" that a defendant in possession of an invention had either used it or had it for the future purpose of using it in an infringing manner (p. 571).

55 Commenting on *British United Shoe* in *Pfizer Corp. v. Ministry of Health*, [1965] A.C. 512 (H.L.), Lord Wilberforce observed that "if it can positively be proved that the possession was innocent of any actual use or intention to use, the defendant will not be held to have infringed" (p. 572). Possession requires an "additional ingredient" to make up an infringement (p. 572). In *Pfizer*, according to Lord Wilberforce, use arose from the transportation of patented articles (possession) with a view to trade (the additional ingredient). Where the patent holder shows that the defendant possessed the patented invention, it is up to the defendant to show the absence of the "additional ingredient".

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. This is the natural corollary of the finding in *Neilson*, *supra*, that it was not relevant to infringement whether the beer actually was preserved by the invention, and the finding in *Adair*, *supra*, that it was irrelevant whether the ship's master had profited from the presence of the pumps on the ship. 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 utilization 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.

Mr. Schmeiser is a conventional, non-organic farmer. For years, he had a practice of saving and developing his own seed. The seed which is the subject of Monsanto's complaint can be traced to a 370-acre field, called field number 1, on which Mr. Schmeiser grew canola in 1996. In 1996 five other canola growers in Mr. Schmeiser's area planted Roundup Ready Canola.

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.

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 pickup 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.

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.

Dr. Downey testified that the high rate of post-Roundup spraying survival in the 1997 samples was "consistent only with the presence in field number 2 of canola grown from commercial Roundup tolerant seed" (trial judgment, at para. 112). According to Dr. Dixon, responsible for the testing by Monsanto US at St. Louis, the "defendants' samples contain[ed] the DNA sequences claimed in claims 1, 2, 5, and 6 of the patent and the plant cell claimed in claims 22, 23, 27, 28 and 45 of the patent" (trial judgment, at para. 113). As the trial judge noted, this opinion was uncontested.

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.

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.

The preliminary question is whether this conduct falls within the meaning of "use" or "*exploiter*". We earlier concluded that these words, taken together, connote utilization 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 "utilization" of the patented material for production and advantage, within the meaning of s. 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.

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.

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.

177 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 <u>containing the cell and</u> <u>gene</u>, 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.

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.

Although not directly at issue in this case, cultivating Roundup Ready Canola also presents future revenue opportunities to "brownbag" the product to other farmers unwilling to pay the licence fee, thus depriving Monsanto of the full enjoyment of their monopoly.

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 unrebutted.

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.

89 This is also the perspective adopted by Arbour J. In support of the proposition that infringement of gene claims occurs only in a laboratory setting, she cites *Kirin Amgen Inc. v. Hoechst Marion Roussel Ltd.*, [2002] E.W.J. No. 3792 (QL), [2002] EWCA Civ. 1096 (C.A.). That case dealt with a protein useful in the diagnosis and treatment of blood disorders. The English court construed the claims to exclude the naturally occurring form of the DNA sequence in a human cell. However, this was done to accord with the provisions of a regulatory scheme that has no parallel in Canada: Article 5 of the European Parliament's Directive 98/44/EC, which regulates patentability of biotechnological inventions. It states that the discovery of elements of the human body, including genes, is not patentable, although such

elements are patentable when isolated or otherwise produced through technical means. The legislature has not enacted a comparable statutory scheme in Canada to narrow the scope of patent construction. Thus, *Kirin Amgen* is not applicable to the case before this Court.

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.

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 C.P.R. (2d) 81 (Pat. App. Bd.), in which the inventive step consisted of acclimatizing 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 <u>sowing</u> and <u>cultivation</u>, 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

98 The trial judge granted injunctive relief and awarded Monsanto an accounting of the profits made by the respondents through growing Roundup Ready Canola, which he ultimately quantified at \$19,832. The record is not clear on precisely how this sum was arrived at; that it was awarded by the trial judge on account of profits is, however, undisputed.

99 The Court of Appeal upheld that order on the same basis and the issue is whether it erred in this regard.

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: Lubrizol Corp. v. Imperial Oil Ltd. (1996), 71 C.P.R (3d) 26 (F.C.A.) Celanese International Corp. v. BP Chemicals Ltd. (1999), 6 R.P.C. 203 (Pat. Ct.), at para. 37. This is consistent with the general law on awarding non-punitive remedies: "[I]t is essential that the losses made good are only those which, on a common sense view of causation, were caused by the breach" (<u>Canson Enterprises Ltd. v. Boughton & Co., [1991] 3 S.C.R. 534</u>, at p. 556, per McLachlin J.(as she then was) quoted with approval by Binnie J. for the Court in <u>Cadbury</u> <u>Schweppes Inc. v. FBI Foods Ltd., [1999] 1 S.C.R. 142</u>, at para. 93).

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: N. 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. 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: *Collette v. Lasnier* (1887), 13 S.C.R. 563, at p. 576, also referred to with approval in *Colonial Fastener Co., v. Lightning Fastener Co.*, [1937] S.C.R. 36.

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 <u>as a result of the invention</u>.

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.
 - IV. 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 lacobucci, Bastarache, Arbour and LeBel JJ. were delivered by

ARBOUR J. (DISSENTING IN PART) --

I. Introduction

107 This case was decided in the courts below without the benefit of this Court's decision in <u>Harvard College v. Canada (Commissioner</u> <u>of Patents), [2002] 4 S.C.R. 45</u>, 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*, *supra*, 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, supra*. 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, supra*: 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, supra*. 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 R.P.C. 465 (H.L.), at p. 481.

111 In light of *Harvard College*, *supra*, 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.

II. 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, supra*, at para. 199. Accordingly, plants do not fit within the definition of an "invention": *Patent Act*, R.S.C. 1985, c. P-4, s. 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*, *supra*, 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 C.P.R. (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 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, supra*, 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*, *supra*, 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 22-28 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 recognized 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 S.C.R. 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, supra*.

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 emphasize 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 S.C.R. 504; *Pioneer Hi-Bred Ltd. v. Canada* (*Commissioner of Patents*), [1989] 1 S.C.R. 1623; *Free World Trust v. Electro Santé Inc.*, [2000] 2 S.C.R. 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. 520-21. "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.

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 Co. v. Baldwin International Radio of Canada*, [1934] S.C.R. 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 Co., supra*, at p. 573; Lindley, L.J., in *Needham v. Johnson and Co.* (1884), 1 R.P.C. 49 (H.C.A.), at p. 58. The claims are invalid if they are broader than the disclosures: *Amfac Foods Inc. v. Irving Pulp & Paper Ltd.* (1984), 80 C.P.R. (2d) 59 (F.C.T.D.), at p. 80, citing a long list of authority; *B.V.D. Co. v. Canadian Celanese Ltd.*, [1936] S.C.R. 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 ed. 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 D.L.R. (4th) 1 (F.C.A.) at p. 18, Mahoney J.A. 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] E.W.J. No. 3792 (QL), [2002] EWCA Civ. 1096, at para. 60. In *Kirin Amgen, supra*, 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] S.C.R. 49; *Shell Oil Co. v. Commissioner of Patents*, [1982] 2 S.C.R. 536. As stated in *Farbwerke*, *supra*, 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 s. 41(1) [an exemption] of the Act, then he must comply with that section".

Subject matters that are specifically precluded by statute from patent protection are natural phenomena, laws of nature, and scientific principles: s. 27(8). Other subject matter has been excluded by judicial interpretation of s. 2 definitions of "invention" and "process" and s. 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* (1981), 56 C.P.R. (2d) 204, aff'd [1982] 1 F.C. 845 (C.A.); methods of medical treatment (*Tennessee Eastman Co. v. Commissioner of Patents* [1974] S.C.R. 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.* (1998), 149 F.3d 1368 (F.C.C.A.)); printed matter producing only an artistic intellectual or literary result (*Re Application of Boussac*, CIPO, Decision No. 143, March 10, 1973; mere human conduct or mental steps, or instructions (*Re Application of Akzona*, CIPO, Decision No. 254, July 4, 1975; Gale's Application, [1991] R.P.C. 305 at 323); and architectural plans (*Application No. 995 for a Townhouse Building Design (Re)* (1979), 53 C.P.R. (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 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.

(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] S.C.R. 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, supra*, 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 art. 27(3)(b) of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), 1869 U.N.T.S. 299 (being Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, 1867 U.N.T.S. 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 s. 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 s. 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.

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, Trade-marks* (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 (C.A.).

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 realize 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 s. 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 s. 58, now s. 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 <u>right to use</u> and sell to others the <u>specific article, machine, manufacture or composition of matter patented</u> [i.e., the invention] and so purchased, constructed or acquired without being liable to the patentee or the legal representatives of the patentee for doing so. [Emphasis added.]

149 In Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada (1969), 1 Ex. C.R. 529, at p. 553, in reasoning approved by this Court: Libbey-Owens-Ford Glass Co. v. Ford Motor Co. of Canada, [1970] S.C.R. 833, and followed in Merck & Co. v. Apotex Inc. (1994), 59 C.P.R. (3d) 133 (F.C.T.D.), the trial judge stated that "the proper approach to the interpretation of s. 58 [now s. 56] is to first read its wording, coupled with that of s. 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 F.C. 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, Ld. (1900), 17 R.P.C. 307 (H.C.J.); F. Hoffman-Laroche & Co., supra, at p. 415; Wellcome Foundation Ltd. v. Apotex Inc. (1991), 39 C.P.R. (3d) 289 (F.C.T.D.); 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 <u>product</u> (the gene or cell) extends patent protection to the unpatentable object into which it is incorporated. The respondents and the intervener, BIOTECanada, further contend that "[i]t is trite law that an un-patentable composition of matter can be an infringement by virtue of it incorporating <u>patented material</u>" (joint factum of BIOTECanada 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 ed. 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 R.P.C. 290 (C.A.), at p. 308; *Computalog Ltd. v. Contech Logging Ltd.* (1992), 44 C.P.R. (3d) 77 (F.C.A.), at p. 88; *Illinois Tool Works Inc. v. Cobra Anchors Co.* (2002), 221 F.T.R. 161 (F.C.T.D.), 2002 FCT 829. Lord Hoffmann in *Merrell Dow Pharmaceuticals Inc. v. H.N. Norton & Co.*, [1996] R.P.C. 76 (H.L.), 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] A.C. 512 (H.L.). A case such as *British United Shoe Machinery Co. v. Simon Collier Ld.* (1910), 27 R.P.C. 567 (H.L.), that may suggest the contrary is unusual and restricted to its facts: *Pfizer Corp., 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 Ld., 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 licencee. 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 art. 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 (CBAC), *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. CBAC, *supra*, at p. 12, explains the point as follows:

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 art. 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 of 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*, S.C. 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. 63), they may be all that Monsanto is entitled to. Indeed Professor Vaver, *supra*, at p. 128, recognizes that patents should not necessarily be available when other, more tailored intellectual property protection exits. 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.

III. Disposition

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

Patent Document Number 1,313,830: Glyphosate-Resistant Plants The embodiments of the invention in which an exclusive property or privilege is claimed are defined as follows:

1. A chimeric plant gene which comprises:

(a)a promoter sequence which functions in plant cells;

(b)a coding sequence which causes the production of RNA, encoding a chloroplast transit peptide/5-enolpyruvylshikimate-3-phosphate synthase (EPSPS) fusion polypeptide, which chloroplast transit peptide permits the fusion polypeptide to be imported into a chloroplast of a plant cell; and

(c)a 3' non-translated region which encodes a polyadenylation signal which functions in plant cells to cause the addition of polyadenylate nucleotides to the 3' end of the RNA;

the promoter being heterologous with respect to the coding sequence and adapted to cause sufficient expression of the fusion polypeptide to enhance the glyphosate resistance of a plant cell transformed with the gene.

2. A chimeric gene of Claim 1 in which the promoter sequence is a plant virus promoter sequence.

3. A chimeric gene of Claim 2 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).

4. A chimeric gene of Claim 3 in which the promoter sequence is the CaMV35S promoter sequence.

5. A chimeric gene of Claim 1 in which the coding sequence encodes a mutant 5-enolpyruvylshikimate-3-phosphate synthase (EPSPS).

6. A chimeric gene of Claim 1 in which the EPSPS coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

7. A chimeric gene of Claim 1 in which the chloroplast transit peptide is from a plant EPSPS gene.

8. A cloning or expression vector comprising a chimeric plant gene of Claim 1.

9. A cloning or expression vector of Claim 8 in which the chimeric plant gene encodes a chloroplast transit peptide of a plant EPSPS gene.

10. A cloning or expression vector of Claim 9 in which the chimeric plant gene comprises a promoter sequence from a plant virus.

11. A cloning or expression vector of Claim 10 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).

12. A cloning or expression vector of Claim 11 in which the promoter sequence is the CaMV35S promoter sequence.

13. A cloning or expression vector of Claim 8 in which the chimeric plant gene comprises a coding sequence encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.

14. A cloning or expression vector of Claim 8 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

15. A plant transformation vector which comprises a chimeric gene of Claim 1.

16. A plant transformation vector of Claim 15 in which the chimeric plant gene encodes a chloroplast transit peptide of a plant EPSPS gene.

17. A plant transformation vector of Claim 15 in which the chimeric plant gene comprises a promoter sequence from a plant virus.

18. A plant transformation vector of Claim 17 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).

19. A plant transformation vector of Claim 18 in which the promoter sequence is the CaMV35S promoter sequence.

20. A plant transformation vector of Claim 15 in which the chimeric plant gene comprises a coding sequence encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.

21. A plant transformation vector of Claim 15 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

22. A glyphosate-resistant plant cell comprising a chimeric plant gene of Claim 1.

23. A glyphosate-resistant plant cell of Claim 22 in which the promoter sequence is a plant virus promoter sequence.

24. A glyphosate-resistant plant cell of Claim 23 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).

25. A glyphosate-resistant plant cell of Claim 24 in which the promoter sequence is the CaMV35S promoter sequence.

26. A glyphosate-resistant plant cell of Claim 22 in which the coding sequence encodes a mutant 5-enolpyruvylshikimate-3-phosphate synthase.

27. A glyphosate-resistant plant cell of Claim 22 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

28. A glyphosate-resistant plant cell of Claim 22 in which the chloroplast transit peptide is from a plant EPSPS gene.

29. A method for producing a glyphosate-resistant dicotyledonous plant which comprises:

(a)transforming plant cells using an Agrobacterium transformation vector comprising a chimeric plant gene of Claim 1; and

(b)regenerating glyphosate-resistant plants from said transformed plant cells.

30. A method of Claim 29 in which the chimeric plant gene comprises a plant virus promoter sequence.

31. A method of Claim 30 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).

32. A method of Claim 31 in which the promoter sequence is the CaMV35S promoter sequence.

33. A method of Claim 29 in which the chimeric gene comprises a coding sequence encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.

34. A method of Claim 29 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

35. A method of Claim 29 in which the coding sequence encodes the chloroplast transit peptide from a plant EPSPS gene.

36. A method for producing a glyphosate-resistant plant cell which comprises transforming the plant cell with a plant transformation vector of Claim 15.

37. A method of Claim 36 in which the chimeric gene comprises a promoter sequence from a plant virus.

38. A method of Claim 37 in which the promoter sequence is a promoter sequence from cauliflower mosaic virus (CaMV).

39. A method of Claim 38 in which the promoter sequence is the CaMV35S promoter sequence.

40. A method of Claim 36 in which the chimeric gene comprises a coding sequence encoding a mutant 5-enolpyruvylshikimate-3-phosphate synthase.

41. A method of Claim 36 in which the coding sequence encodes an EPSPS from an organism selected from the group consisting of bacteria, fungi and plants.

42. A method of Claim 36 in which the coding sequence encodes the chloroplast transit peptide from a plant EPSPS gene.

43. A glyphosate-resistant tomato cell of Claim 22.

44. A glyphosate-resistant tobacco cell of Claim 22.

45. A glyphosate-resistant oil seed rape cell of Claim 22.

46. A glyphosate-resistant flax cell of Claim 22.

47. A glyphosate-resistant soybean cell of Claim 22.

- 48. A glyphosate-resistant sunflower cell of Claim 22.
- 49. A glyphosate-resistant sugar beet cell of Claim 22.
- 50. A glyphosate-resistant alfalfa cell of Claim 22.
- **51.** A glyphosate-resistant cotton cell of Claim 22.
- 52. Plasmid pMON546, ATCC accession number 53213.
- Appeal allowed in part, IACOBUCCI, BASTARACHE, ARBOUR and LEBEL JJ. dissenting in part.
- Solicitors for the appellants: Priel, Stevenson, Hood & Thornton, Saskatoon.
- Solicitors for the respondents: Sim, Hughes, Ashton & McKay, Toronto.
- Solicitor for the intervener the Attorney General for Ontario: Ministry of the Attorney General of Ontario, Toronto.
- Solicitors for the intervener the Canadian Canola Growers Association: cCarthy & Brown, Carman, Manitoba.
- Solicitors for the intervener Ag-West Biotech Inc.: McDougall Gauley, Saskatoon.
- Solicitors for the intervener BIOTECanada: Gowling Lafleur Henderson, Ottawa.
- Solicitors for the intervener the Canadian Seed Trade Association: Smart & Biggar, Ottawa.

Solicitors for the interveners the Council of Canadians, the Action Group on Erosion, Technology and Concentration, the Sierra Club of Canada, the National Farmers Union, the Research Foundation for Science, Technology and Ecology, and the International Centre for Technology Assessment: Sack Goldblatt Mitchell, Toronto.

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