

# Monsanto v. Schmeiser: Patent Protection for Genetically Modified Genes and Cells in Canada

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On May 21, 2004, the Supreme Court of Canada rendered its decision to uphold Monsanto's claim of patent infringement against Percy Schmeiser<sup>1</sup>. McLachlin C.J. and Fish J. wrote for the majority, with Major, Binnie and Deschamps JJ. concurring. The minority judgment was written by Arbour J., with Iacobucci, Bastarache and LeBel JJ. concurring. Many members of the biotechnology industry welcomed the decision. However, the decision still leaves some issues unresolved with respect to the scope of protection afforded to biotechnology-related inventions.

By way of background, glyphosate is an herbicide which ordinarily kills plants. A glyphosate resistance gene, which is the subject of Monsanto's Canadian Patent No. 1,313,830 entitled "Glyphosate-Resistant Plants.", confers resistance to the glyphosate-containing herbicide Roundup<sup>TM</sup>. Therefore, plants containing the patented gene will survive spraying with Roundup. Such a trait is useful to farmers, as it allows them to spray their crops for weeds even after canola plants have emerged. Canola seeds containing the patented gene are sold under the trademark "Roundup Ready Canola<sup>TM</sup>," and Monsanto charges a \$15 per acre license fee to farmers to grow the seeds.

In 1997, Percy Schmeiser, a canola farmer, planted seeds saved from one of his fields, as was his usual practice. He sprayed a three-acre patch of this crop with Roundup, and found that 60% of the plants survived the spraying. The origin of these Roundup-resistant plants is unclear, but it is possible that seed blew onto the Schmeiser property from neighbouring farms, where Roundup Ready Canola was being cultivated. Mr. Schmeiser harvested the Roundup-

resistant canola from the patch he had sprayed and kept it separate from the rest of his crop. In 1998, Mr. Schmeiser had this harvest treated for use as seed, and used it to plant approximately 1,000 acres. Testing of samples of canola plants taken from Mr. Schmeiser's fields sown in 1998 confirmed that 95 to 98% of the canola was Roundup resistant. Mr. Schmeiser did not obtain a licence from Monsanto to grow the canola.

In August 1998, Monsanto sued Mr. Schmeiser for patent infringement. At the Federal Court Trial Division, the trial judge found that Monsanto's patent was valid and infringed by Mr. Schmeiser<sup>2</sup>. This finding was upheld by the Federal Court of Appeal<sup>3</sup>. The case was further appealed to the Supreme Court of Canada. By a narrow 5 to 4 majority, the Supreme Court of Canada also found that the patent was valid and that Mr. Schmeiser had infringed it.

Both the majority and minority agreed that the claims in Monsanto's patent are valid. The claims are directed to a modified glyphosate resistance gene, cloning vectors containing the gene, various plant cells containing the gene, and a process for inserting the gene into cells. However, the claims are not directed to modified plants containing the gene. The patent is therefore not directed to a higher life form, which the Supreme Court of Canada had previously decided did not constitute patentable subject matter in the case of *Harvard College v. Canada (Commissioner of Patents)*.<sup>4</sup>

Where the majority and minority opinions diverge is on the scope of protection afforded by the claims in Monsanto's



patent, and whether Mr. Schmeiser's activities infringed Monsanto's patent, contrary to s. 42 of the *Patent Act*<sup>5</sup>. According to s. 42, a patent grants to the patentee the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used. The main issue at the Supreme Court of Canada was the definition of the word "using," and whether or not Mr. Schmeiser's activities could be construed as "use" of Monsanto's invention.

According to the majority view, a defendant has "used" a patented invention when the defendant has deprived the inventor, either directly or indirectly, of the full enjoyment of the monopoly conferred by the patent.<sup>6</sup> It was argued that Mr. Schmeiser had not "used" the invention by growing plants because plants are not covered by the claims in Monsanto's patent, and only plant cells containing the modified gene were covered. The counter argument was that the plants were composed of modified plant cells containing the modified genes and therefore, growing the modified plants constitutes use of the invention. The majority interpreted existing case law relating to mechanical inventions as supporting the proposition that even if a product as a whole is not covered by a patent, if an important part or component of the product is patented, exploitation of the product may still result in infringement.<sup>7</sup> Patented components are not usually intended to be used in isolation. Moreover, under a purposive interpretation of the claims, the majority found that the purpose of the patent was to sell plants or seeds containing the modified genes. Further, even if the modified plants were not sprayed with Roundup, mere possession of a patented object may constitute "use" of the object's stand-by or insurance utility, which amounts to infringement. Therefore, even if resistance genes were not in use, the mere possession of plants containing the genes provides insurance in case the plants are eventually sprayed with Roundup herbicide. The majority also held that possession of an item containing a patented part, at least in commercial circumstances, raises a reputable presumption of use, although the absence of intention to employ or gain any advantage from the invention may be relevant to rebutting this presumption.<sup>8</sup>

On the facts of this case, the majority found that Mr. Schmeiser had been in possession of Roundup Ready Canola in a commercial setting, and that he had knowingly selected and planted Roundup Ready Canola in his fields.<sup>9</sup> Mr. Schmeiser used the patented material, contrary to the *Patent Act* by planting and saving seeds, thereby depriving Monsanto of the full enjoyment of its monopoly. Mr.

Schmeiser failed to rebut the presumption of use by failing to present credible evidence that he neither used nor intended to use the invention. Although Mr. Schmeiser testified that he had not used Roundup to reduce weeds, and therefore did not gain any agricultural advantage from the patented crop, the majority found he could have profited from the invention in the future by using Roundup or by selling the seed. However, since Mr. Schmeiser had not actually gained any profits from his use of the invention, Monsanto was not entitled to an accounting of profits, despite the finding of infringement.<sup>10</sup>

The minority, in contrast, held that "use" of an invention under s. 42 of the *Patent Act* should be constrained by the subject-matter of the claims.<sup>11</sup> The minority argued that existing case law on "use" and analogies to mechanical inventions are not helpful in this context because of the unique ability of biological organisms to self-replicate. Thus, the test for infringement should be whether or not the defendant has deprived the patentee of his monopoly over the use of the invention *as construed by the claims*. The minority emphasized the importance of fairness and predictability to the public, so that others may know what activities will infringe a patent.<sup>12</sup> The minority argued that, given the previous holding of the Supreme Court of Canada in the *Harvard Mouse* case, a person skilled in the art would not expect the scope of Monsanto's patent to include non-patentable subject matter.<sup>13</sup> Therefore, a person skilled in the art would not expect modified plants to infringe claims directed to modified plant genes and cells containing the modified plant genes. Because the claims of Monsanto's patent do not encompass modified plants, the minority held that cultivation of plants containing the patented gene and cell cannot constitute "use" of the invention.<sup>14</sup> Thus, the scope of the claims was limited to manipulations of the modified cells and genes in a laboratory environment, and no infringement was found by the minority. The minority argued that a patent on the cells and genes of a plant cannot be used to indirectly confer patent protection on the entire plant, when the plant itself as a higher life form is not patentable according to *Harvard Mouse*.<sup>15</sup>

The minority decision in *Monsanto* does not view biotechnological inventions as being equivalent to other, more "traditional" inventions. The minority decision suggests that there is one definition of "use" for mechanical inventions, and that a second definition of "use" must be formulated for biological materials.<sup>16</sup> However, the cultivation of crops containing a patented gene is arguably indistinguishable from the production of a mechanical invention containing a



patented component. In both cases, the patented component confers some benefit on the production process or the ultimate product. Knowingly growing a patented plant to gain such benefit is no different from knowingly copying a patented component to gain a benefit, yet the minority definition of “use” would encompass only the latter activity.

As indicated above, the minority judgment holds that the use of the patented gene, vectors, and cells should be limited to their use in creating cloning vectors and transgenic plant cells in a laboratory setting. However, Monsanto’s patent describes the use of such genes, vectors, and cells in plants, not merely as laboratory vectors and cells. As discussed in the majority decision, which cites the trial judgment, “it is difficult to imagine a more likely or more evident purpose for patenting ‘a method of genetically transforming plants cells which causes the cells and plants regenerated there from to become resistant to glyphosate’.”<sup>17</sup>

The minority also argued that even if a patentee cannot obtain patent protection for modified plants or seeds, a patentee can still impose contractual obligations on a licensee to limit the licensee’s ability to use and sell plants and seeds. However, this argument fails to take into account the fact that without the force of a valid patent behind a license, there may be little economic incentive for licensees to adhere to a license agreement, let alone contractually bind themselves to begin with. Moreover, plants may easily escape from a licensee’s field through no fault of the licensee. A neighbouring farmer could then cultivate the genetically modified plant, and the inventor would have no recourse against the farmer as there would be no privity between the patentee and the neighbouring farmer.

The decision of the majority provides support to the Canadian biotechnology industry in a number of ways. First, by acknowledging that patents on modified genes, vectors, and cells containing modified genes have effect beyond the genes, vectors, and cells themselves, patents held by biotechnology researchers have greater scope and therefore greater value. Second, the effective scope of patent protection in Canada is now arguably similar to the scope of protection available to patentees in other industrially developed countries and regions, such as the United States and Europe. Therefore, the Canadian biotechnology industry can compete on a global level. Third, the majority acknowledged that the purpose of the patent obtained by Monsanto was to maintain a monopoly over the production and sale of glyphosate resistant plants. Arguably, if no protection were afforded to biotechnology inventions involving plants (or

other higher life forms), there would be significantly less incentive to conduct research and invest in this area of technology. If an inventor has no recourse against unauthorized use of his invention, there is little reason to invest in such technology.

Many perceive the majority decision in *Monsanto* to be inconsistent with the Supreme Court of Canada’s holding in *Harvard Mouse*. However, the majority in *Monsanto* argue that their decision is, in fact, consistent with *Harvard Mouse*, noting that the gene and cell claims in Monsanto’s glyphosate-resistant plant patent are analogous to the plasmid and somatic cell culture claims which had been allowed by the Commissioner of Patents in *Harvard’s* patent for a genetically modified “oncomouse”.<sup>18</sup> It was only the claim for the “oncomouse” itself, as a higher life form, which was denied, and Monsanto did not claim modified plants in its patent. Notably, both the majority and minority in *Monsanto* agree that the claims in Monsanto’s patent are valid.<sup>19</sup>

The minority also argued that the majority decision in *Monsanto* has indirectly allowed patent protection for the entire plant, while the plant itself is considered unpatentable subject matter.<sup>20</sup> This is not the first time inconsistencies have appeared in Canadian patent law. For example, methods of medical treatment are not considered patentable subject matter in Canada in light of the Supreme Court of Canada’s decision in *Tennessee Eastman Co. v. Canada (Commissioner of Patents)*.<sup>21</sup> However, in the case of *Apotex Inc. v. Wellcome Foundation Ltd.*<sup>22</sup> the Supreme Court of Canada affirmed that claims directed to the use of a pharmaceutical product to treat a disease are patentable. Therefore, in some cases, use claims can in effect extend to methods of medical treatment depending on the language of the claims.

The minority decision attempts to reconcile the Supreme Court of Canada’s majority holding in the *Harvard Mouse* case with the situation in *Monsanto*. The majority in the *Harvard House* case indicated that although a genetically modified mouse cell may constitute patentable subject matter, the cell then grows into an adult mouse without human intervention and therefore, the adult mouse does not constitute patentable subject matter. The minority in *Monsanto* held that:

The plant cell claim ends at the point where the isolated plant cell containing the chimeric gene is placed into the growth medium for regenera-



tion. 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.<sup>23</sup>

Although the minority decision in *Monsanto* appears to be consistent with the holding of the majority in *Harvard Mouse*, the majority decision in the *Harvard Mouse* case has received some criticism.<sup>24</sup>

From scientific and legal points of view, it seems illogical that a modified cell is patentable immediately after it is modified, yet somehow the resulting organism loses its patentability through a genetically pre-programmed biological process.

The majority in *Monsanto* recognizes that many biotechnology inventions will only receive the full benefit of patent protection if the scope of the patent extends to genetically modified organism as a whole. The majority asserts that it has only interpreted the *Patent Act* as it perceives it, and any amendments will be open to Parliament to pursue:

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.

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.<sup>25</sup>

Until Parliament enacts amendments to the *Patent Act* that clarify what can and cannot constitute patentable subject matter in Canada, the biotechnology community may need to rely on the distinctions outlined by the majority judgment in *Monsanto* in support of patent infringement claims involving higher life forms.

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1. *Monsanto Canada Inc. v. Schmeiser*, [2004] 1 S.C.R. 902, 2004 SCC 34 [*Monsanto* cited to S.C.R.].
2. *Monsanto Canada Inc. v. Schmeiser*, (2001) 202 F.T.R. 78, 12 C.P.R. (4th) 204, [2001] F.C.J. No. 436 (QL), 2001 FCT 256.
3. *Schmeiser v. Monsanto Canada Inc.*, [2003] 2 F.C. 165, 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.
4. [2002] 4 S.C.R. 45, 2002 SCC 76 [*Harvard Mouse* cited to S.C.R.].
5. *R.S.C. 1985, c. P-4*.
6. *Monsanto*, *supra* note 1 at para. 58.
7. *Ibid.* at paras. 41, 42 and 46.
8. *Ibid.* at para. 56.
9. *Ibid.* at para. 68.
10. *Ibid.* at para. 105.
11. *Ibid.* at para. 145.
12. *Ibid.* at para. 127.
13. *Ibid.* at para. 128.
14. *Ibid.* at para. 160.
15. *Ibid.*
16. *Ibid.* at para. 156.
17. *Ibid.* at para. 19.
18. *Ibid.* at para. 22.
19. *Ibid.* at paras. 24 and 138.
20. *Ibid.* at para. 160.
21. [1974] S.C.R. 111.
22. [2002] 4 S.C.R. 153, (2002) SCC 77.
23. *Monsanto*, *supra* note 1 at para. 130.
24. See for example: Richard Owens “Harvard mouse-trap” *National Post* (7 December 2002) FP11; Daniel Gervais “Eeek! The mouse confounds the House!” *The Ottawa Citizen* (14 December 2002) B7; BIOTECanada, News Release, “BIOTECanada responds to Supreme Court Decision on Harvard Mouse Case” (5 December 2002) online: <<http://www.newswire.ca>>.
25. *Monsanto*, *supra* note 1 at paras. 93 and 94.

